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Completed

Efficacy, Safety, and Pharmacokinetics of APT-1011 in Subjects With Eosinophilic Esophagitis (EoE) (FLUTE)

ClinicalTrials.gov ID NCT03191864

Sponsor Adare Pharmaceuticals, Inc.

Information provided by Adare Pharmaceuticals, Inc. (Responsible Party)

Last Update Posted 2023-04-26

Results Posted Tab

Results Overview

Conditions

Eosinophilic Esophagitis

Intervention/Treatment

Feedback

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- Drug: APT-1011
- Drug: Placebo

Other Study ID Numbers

- 2016-004749-10 (EudraCT Number)

Study Design

Allocation: Randomized

Interventional Model: Parallel Assignment

Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor)

Masking Description: Double Blind

Primary Purpose: Treatment

Results Point of Contact

Name/Title: Senior Director Clinical Operations and Medical Affairs
Organization: Ellodi Pharmaceuticals (Formerly Adare Pharmaceuticals)
Phone: (609) 450-1312
Email: karol.knoop@ellodipharma.com

Enrollment (Actual)

106

Study Type

Interventional

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Study Record Dates

These dates track the progress of study record and summary results submissions to ClinicalTrials.gov. Study records and reported results are reviewed by the National Library of Medicine (NLM) to make sure they meet specific quality control standards before being posted on the public website.

Study Registration Dates

First Submitted

2017-06-15

First Posted

2017-06-19

Results Reporting Dates

Results First Submitted

2022-10-03

Results First Posted with QC Comments

2022-11-02

Results First Posted

2023-04-26

Certification/Extension Dates

Certification/Extension First Submitted

2021-01-27

Certification/Extension First Posted

2023-04-26

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Study Record Updates

Last Update Posted

2023-04-26

Last Verified

2023-04

Participant Flow

Recruitment Details

Recruitment in 6 countries (United States, Canada, Belgium, Germany, Spain, and Switzerland) took place between 22-Jun-2017 (First Subject Enrolled) until 23-Aug-2018 (Last Subject Enrolled).

Pre-assignment Details

The Screening Period was 4 weeks (28 days) and utilized a single-blind placebo run-in period. Along with the reports confirming the subject's primary diagnosis of EoE, the Investigator assessed eligibility criteria of the subject based on screening results. The Global EoE Symptom Score had to be >3 for the subject to continue in the study.

Patients who were screened (308) are presented under Baseline Symptom Assessment, those enrolled (106) are presented in Part 1 - Induction.

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien

Expand

Period Title: **Baseline Symptom Assessment**

Started [1]	0	0	0
Completed	0	0	0
Not Completed	0	0	0

Reason Not Completed

Lost to Follow-up	0	0	0
Patient Diary Unavailable at Site	0	0	0
Adverse Event	0	0	0
Withdrawal by Subject	0	0	0

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Violation of inclusion/exclusion criteria	0	0	0

[1] Due to the high placebo response rates, the study utilized a 4-week single-blind placebo run-in period to not only establish the baseline symptoms for the study, but also to ensure that all subjects enrolled had sufficient severity of EoE to warrant inclusion in the study.

Period Title: **Part 1 - Induction**

Started	21	22	22
Completed	18	19	20
Not Completed	3	3	2

Reason Not Completed

Violation of inclusion/exclusion criteria	0	0	1
Adverse Event	0	2	0
Randomized but never dosed	0	0	1
Withdrawal by Subject	3	1	0

Period Title: **Part 2 - Maintenance**

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Started [1]	10	19	14
Completed	5	17	11
Not Completed	5	2	3
Reason Not Completed			
Refused EGD at Week 26	0	0	1
Subject Could Not Transfer Site to Complete the Study	1	0	0
Physician Decision	1	0	0
Lack of Efficacy	1	2	2
Adverse Event	0	0	0
Withdrawal by Subject	2	0	0
Unresponsive - Patient missed multiple appointments	0	0	0

[1] Note that those subjects that were non-responders at Week 12 were switched from another arm to the Single-blind APT-1011 3 mg BID arm. This arm was a single-blinded arm for the subjects only.

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Baseline Characteristics

Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Baseline Participants	21	22	22
Baseline Analysis Population Description	[Not Specified]		

Expand all / Collapse all

Age, Categorical

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	21 participants	22 participants	22 participants
<=18 years	0 0.0%	0 0.0%	0 0.0%
Between 18 and 65 years	21 100.0%	21 95.5%	21 95.5%

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>=65 years	0 0.0%	1 4.5%	1 4.5%

Age, Continuous

Mean (Standard Deviation) | Unit of measure: years

Number Analyzed	21 participants	22 participants	22 participants
	36.8 (11.65)	41.3 (12.24)	41.9 (12.09)

Sex: Female, Male

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	21 participants	22 participants	22 participants
Female	7 33.3%	7 31.8%	10 45.5%
Male	14 66.7%	15 68.2%	12 54.5%

Ethnicity (NIH/OMB)

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	21 participants	22 participants	22 participants
Hispanic or Latino	4 19.0%	5 22.7%	2 9.1%
Not Hispanic or Latino	17 81.0%	17 77.3%	20 90.9%
Unknown or Not Reported	0 0.0%	0 0.0%	0 0.0%

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Race (NIH/OMB)

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	21 participants	22 participants	22 participants
American Indian or Alaska Native	0 0.0%	0 0.0%	0 0.0%
Asian	0 0.0%	0 0.0%	0 0.0%
Native Hawaiian or Other Pacific Islander	0 0.0%	0 0.0%	0 0.0%
Black or African American	0 0.0%	0 0.0%	1 4.5%
White	21 100.0%	22 100.0%	21 95.5%
More than one race	0 0.0%	0 0.0%	0 0.0%
Unknown or Not Reported	0 0.0%	0 0.0%	0 0.0%

Region of Enrollment

Measure Type: Number | Unit of measure: participants

Number Analyzed	21 participants	22 participants	22 participants
North America	15	16	18
Europe	6	6	4

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Smoking Status

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	21 participants		22 participants		22 participants	
Never	18	85.7%	17	77.3%	19	86.4%
Former	2	9.5%	3	13.6%	3	13.6%
Current	1	4.8%	2	9.1%	0	0.0%
Missing	0	0.0%	0	0.0%	0	0.0%

History of esophageal stricture(s)

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	21 participants		22 participants		22 participants	
Yes	11	52.4%	10	45.5%	8	36.4%
No	10	47.6%	12	54.5%	14	63.6%
Missing	0	0.0%	0	0.0%	0	0.0%

Current esophageal stricture(s) based on the study EGD

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	21 participants		22 participants		22 participants	
Yes	4	19.0%	5	22.7%	5	22.7%

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No	17 81.0%	17 77.3%	17 77.3%
Missing	0 0.0%	0 0.0%	0 0.0%

History of positive steroid response to EOE

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	21 participants	22 participants	22 participants
Yes	3 14.3%	5 22.7%	5 22.7%
No	18 85.7%	17 77.3%	17 77.3%
Missing	0 0.0%	0 0.0%	0 0.0%

Proton pump inhibitor status

Measure Type: Count of Participants | Unit of measure: Participants

Number Analyzed	21 participants	22 participants	22 participants
Continuing into study	12 57.1%	16 72.7%	13 59.1%
Not continuing into study	9 42.9%	6 27.3%	9 40.9%
Missing	0 0.0%	0 0.0%	0 0.0%

Height

Mean (Standard Deviation) | Unit of measure: cm

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Number Analyzed	21 participants	22 participants	22 participants
	175.4 (8.55)	173.0 (8.56)	171.0 (9.62)

Weight

Mean (Standard Deviation) | Unit of measure: kg

Number Analyzed	21 participants	22 participants	22 participants
	87.45 (17.69)	83.72 (14.72)	83.47 (18.45)

BMI

Mean (Standard Deviation) | Unit of measure: kg/m^2

Number Analyzed	21 participants	22 participants	22 participants
	28.27 (5.19)	27.39 (4.34)	28.68 (6.74)

Global EOE Symptom Score prior to randomization [1]

Mean (Standard Deviation) | Unit of measure: units on a scale

Number Analyzed	21 participants	22 participants	22 participants
	5.14 (1.62)	4.50 (2.13)	5.00 (1.95)

[1] Measure Description: Global Eosinophilic Esophagitis Symptom Score: On a scale from 0 (no symptoms) to 10 (most severe symptoms), how severe were your EoE symptoms over the past 7 days? Patients were asked to think of all their symptoms due to EoE and make an overall statement by selecting a number.

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Outcome Measures

Expand all / Collapse all

1. Percentage of Subjects With ≤6 Peak Eosinophils/High-power Field (HPF)

Type: Primary | Time Frame: Week 12

Description	Histology (eosinophils per high power field [HPF]): percentage of subjects with ≤6 PEAK eosinophils/HPF after assessing at least 5-6 biopsies from the proximal and distal esophagus (~3 each) where the HPF area is 235 square microns (40 magnification lens with a 22 mm ocular).
Time Frame	Week 12
Analysis Population Description	Full Analysis Set Population

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	21	22	21
Responder *Measure Type: Count of Participants | Unit of Measure: Participants	10 47.6%	19 86.4%	14 66.7%
Non-Responder *	11 52.4%	3 13.6%	7 33.3%

* Measure Type: Count of Participants | Unit of Measure: Participants

Expand all / Collapse all

Statistical Analysis 1 : APT-1011 1.5 mg HS, Placebo BID | Superiority | Cochran-Mantel-Haenszel

Statistical Analysis 2 : APT-1011 1.5 mg BID, Placebo BID | Superiority | Cochran-Mantel-Haenszel

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Statistical Analysis 3 : APT-1011 3 mg HS, Placebo BID | Superiority | Cochran-Mantel-Haenszel

Statistical Analysis 4 : APT-1011 3 mg BID, Placebo BID | Superiority | Cochran-Mantel-Haenszel

2. Percentage of Subjects Who Met the Primary Endpoint at Week 12 and Maintained the Primary Endpoint at Weeks 26 and 52

Type: Secondary | Time Frame: Week 26, and Week 52

Description	Percentage of subjects who entered Part 2 - Maintenance and met the primary endpoint (histology) at Week 12 and maintained the primary endpoint at Week 26 and Week 52. Note: Following Week 14, all patients in the placebo group were given APT-1011 3mg BID and results reflect percentage of subjects who met the primary endpoint following 12 or 38 weeks of treatment.
Time Frame	Week 26, and Week 52
Analysis Population Description	Full Analysis Set Population

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Arm/Group Title	Responder APT-1011 1.5 mg HS	Responder APT-1011 1.5 mg BID	Responder APT-1011 3 mg H
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	10	19	14
Week 26 Responders ∗Measure Type: Count of Participants | Unit of Measure: Participants	7 70.0%	17 89.5%	11 78.6%
Week 52 Responders *	3 30.0%	16 84.2%	9 64.3%

* Measure Type: Count of Participants | Unit of Measure: Participants

3. Change From Baseline Eosinophilic Esophagitis Endoscopic Reference Score (EREFs) at Week 12, 26, and 52

Type: Secondary | Time Frame: Week 12, Week 26, and Week 52

Description	Endoscopic changes will be assessed as per the EREFs evaluation based on the following endoscopic features: edema [Grade {Gr} 0 (absent) or Gr 1 (present)], strictures [Gr 0 (absent) or Gr 1 (present)], rings [Gr 0 (none), Gr 1 (mild), Gr 2 (moderate), Gr 3 (severe)], exudates [Gr 0 (none), Gr 1 (mild), Gr (severe)], furrows [Gr 0 (none), Gr 1

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	(mild), Gr 2 (severe)], crepe paper esophagus [Gr 0 (absent) or Gr 1 (present)], narrow caliber esophagus [Gr 0 (absent) or Gr 1 (present)], and esophageal erosions [Normal (0), Gr A (1), Gr B (2), Gr C (3), or Gr D (4)]. EREFs: 0 (best) to 15 (worst) based on the sum of the subscores listed above. Population used are those who entered Part 1 - Induction. The number of participants analyzed for each timepoint reflect the actual number of participants with data at that timepoint. Note: Following Week 14, all patients in the placebo group were given APT-1011 3 mg BID and results reflect EREF evaluation following 12 or 38 weeks of treatment.
Time Frame	Week 12, Week 26, and Week 52
Analysis Population Description	Full Analysis Set Population receiving double-blind study medication

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	18	20	20

Week 12 Change From Baseline

Number Analyzed	18 participants	20 participants	20 participants
∗Mean (Standard Deviation) | Unit of Measure: units on a scale	-2.4 (2.04)	-2.7 (2.66)	-3.3 (2.36)

Week 26 Change From Baseline

Number Analyzed	8 participants	19 participants	13 participants
∗	-3.1 (1.25)	-3.2 (2.77)	-4.2 (2.61)

Week 52 Change From Baseline

Number Analyzed	5 participants	17 participants	11 participants

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*	-3.4 (1.82)	-3.5 (3.08)	-3.8 (3.19)

cts With a Peak Eosinophils/HPF Number <1 and <15

Frame: Week 12, Week 26, and Week 52

* Mean (Standard Deviation) | Unit of Measure: units on a scale

Description	Percentage of subjects with a peak eosinophils/HPF <1 and <15 at Week 12, 26 and 52. Population used are those who entered Part 1 - Induction. The number of participants analyzed for each timepoint reflect the actual number of participants with data at that timepoint. Note: Following Week 14, all patients in the placebo group were given APT-1011 3mg BID and results reflect peak eosinophils/HPF following 12 or 38 weeks of treatment.
Time Frame	Week 12, Week 26, and Week 52
Analysis Population Description	Full Analysis Set Population receiving double-blind study medication

Expand all / Collapse all

Statistical Analysis 1 : APT-1011 1.5 mg HS, Placebo BID | Other | ANCOVA

Statistical Analysis 2 : APT-1011 1.5 mg BID, Placebo BID | Other | ANCOVA

Statistical Analysis 3 : APT-1011 3 mg HS, Placebo BID | Other | ANCOVA

Statistical Analysis 4 : APT-1011 3 mg BID, Placebo BID | Other | ANCOVA

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	18	20	20

Week 12 : <1/HPF

Number Analyzed	18 participants	20 participants	20 participants
∗Measure Type: Count of Participants | Unit of Measure: Participants	7 38.9%	14 70.0%	12 60.0%

Week 12 : <15/HPF

Number Analyzed	18 participants	20 participants	20 participants
∗	12 66.7%	19 95.0%	15 75.0%

Week 26 : <1/HPF

Number Analyzed	8 participants	19 participants	13 participants
∗	4 50.0%	15 78.9%	9 69.2%

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Week 26 : <15/HPF

Number Analyzed	8 participants	19 participants	13 participants
*	8 100.0%	18 94.7%	12 92.3%

Week 52 : <1/HPF

Number Analyzed	5 participants	17 participants	11 participants
*	1 20.0%	12 70.6%	7 63.6%

Week 52 : <15/HPF

Number Analyzed	5 participants	17 participants	11 participants
*	3 60.0%	17 100.0%	10 90.9%

* Measure Type: Count of Participants | Unit of Measure: Participants

Time Frame	Week 4, 8, 12, 14, 18, 22, 26, 28, 36, 44, and 52
Analysis Population Description	Full Analysis Set Population receiving double-blind study medication

ıe Global EoE Symptom Score

Frame: Week 4, 8, 12, 14, 18, 22, 26, 28, 36, 44, and 52

Change from baseline global EOE symptom score assessed prior to randomization to scores for 7-day recall at Week 4, 8, 12, 14, 18, 22, 26, 28, 36, 44, and 52 visits.

Global Eosinophilic Esophagitis Symptom Score: On a scale from 0 (no symptoms) to 10 (most severe symptoms), how severe were your EoE symptoms over the past 7 days? Patients were asked to think of all their symptoms due to EoE and make an overall statement by selecting a number.

Population used are those who entered Part 1 - Induction. The number of participants analyzed for each timepoint reflect the actual number of participants with data at that timepoint. Note: Following Week 14, all patients in the placebo group were given APT-1011 3mg BID and results reflect change from baseline global EOE symptom score following 4, 8, 12, 14, 22, 30 or 38 weeks of treatment.

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	21	21	20

Week 4 Change from Baseline

Number Analyzed	21 participants	20 participants	20 participants
∗Mean (Standard Deviation) | Unit of Measure: units on a scale	-1.8 (2.64)	-1.3 (2.15)	-2.5 (3.12)

Week 8 Change from Baseline

Number Analyzed	18 participants	21 participants	19 participants
∗	-2.6 (2.12)	-1.7 (1.94)	-3.1 (2.64)

Week 12 Change from Baseline

Number Analyzed	18 participants	21 participants	20 participants

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*	-3.1 (2.17)	-1.5 (2.20)	-3.1 (2.74)

Week 14 Change from Baseline

Number Analyzed	10 participants	18 participants	13 participants
*	-2.7 (2.26)	-2.3 (2.45)	-3.9 (2.81)

Week 18 Change from Baseline

Number Analyzed	9 participants	19 participants	14 participants
*	-4.1 (1.36)	-2.7 (2.58)	-4.1 (2.92)

Week 22 Change from Baseline

Number Analyzed	8 participants	19 participants	14 participants
*	-4.0 (1.41)	-3.2 (2.46)	-3.8 (2.97)

Week 26 Change from Baseline

Number Analyzed	8 participants	18 participants	13 participants
*	-3.8 (1.39)	-3.1 (2.52)	-4.0 (2.68)

Week 28 Change from Baseline

Number Analyzed	7 participants	18 participants	10 participants
*	-4.3 (1.38)	-3.3 (2.42)	-4.8 (2.44)

Week 36 Change from Baseline

Number Analyzed	6 participants	16 participants	11 participants

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*	-4.2 (1.47)	-3.9 (2.25)	-4.8 (2.09)

Week 44 Change from Baseline

Number Analyzed	5 participants	15 participants	11 participants
*	-4.8 (2.39)	-3.7 (2.41)	-4.4 (3.20)

Week 52 Change from Baseline

Number Analyzed	4 participants	14 participants	10 participants
*	-3.3 (1.71)	-3.1 (2.40)	-4.2 (2.66)

* Mean (Standard Deviation) | Unit of Measure: units on a scale

Expand all / Collapse all

Statistical Analysis 1 : APT-1011 1.5 mg HS, Placebo BID | Other | ANCOVA

Statistical Analysis 2 : APT-1011 1.5 mg BID, Placebo BID | Other | ANCOVA

Statistical Analysis 3 : APT-1011 3 mg HS, Placebo BID | Other | ANCOVA

Statistical Analysis 4 : APT-1011 3 mg BID, Placebo BID | Other | ANCOVA

3. Change in Number of Dysphagia Episodes

Type: Secondary | Time Frame: Week 12, Week 26 and Week 52

Description	Change in the number of dysphagia episodes at baseline (14-day period prior to randomization) compared with the 14-day period prior to the time point of interest.
	Population used are those who entered Part 1 - Induction. The number of participants analyzed for each timepoint reflect the actual number of participants with data at that timepoint. Note: Following Week 14, all

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	patients in the placebo group were given APT-1011 3mg BID and results reflect the change in the number of dysphagia episodes following 12 or 38 weeks of treatment.
Time Frame	Week 12, Week 26 and Week 52
Analysis Population Description	Full Analysis Set Population receiving double-blind study medication

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	18	21	20

Week 12 Change from Baseline

ıe 7-Day Eosinophilic Esophagitis Activity Index (EEsAI) Total Score

Frame: Weeks 12, 26 and 52

Number Analyzed	18 participants	21 participants	20 participants
∗Mean (Standard Deviation) | Unit of Measure: change in episodes per 14-day period	-8.2 (5.47)	-4.4 (9.41)	-9.3 (7.85)

Change from Baseline 7-Day EEsAI total score assessed at randomization and those assessed at Weeks 12, 26 and 52 (Total score 100).

Eosinophilic Esophagitis Activity Index Total Score: 0 (best) to 100 (worst) based on the sum of the categorized subscores for frequency of trouble swallowing [never (0), 1-3x (15) or 4-6x (27) per week]; duration of trouble swallowing [≤5 min (0), >5 min (6)]; pain when swallowing [no (0), yes (15)]; Visual Dysphagia Question score [0 (best),12,19, 21, or 23 (worst)]; avoidance modification and slow eating score [0 (best), 9, or 25 (worst)].

A higher score means a worse outcome.

Week 26 Change from Baseline

Number Analyzed	8 participants	19 participants	13 participants
∗	-12.8 (5.65)	-10.0 (10.97)	-9.8 (7.82)

Population used are those who entered Part 1 - Induction. The number of participants analyzed for each timepoint reflect the actual number of participants with data at that timepoint. Note: Following Week 14, all patients in the placebo group were given APT-1011 3mg BID and results reflect the change from baseline 7-day EEs

Week 52 Change from Baseline

Number Analyzed	6 participants	16 participants	10 participants

Weeks 12, 26 and 52

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*	Full Analysis Set Population	-11.2 (5.26)	-13.0 (10.79)	-9.5 (9.66)

* Mean (Standard Deviation) | Unit of Measure: change in episodes per 14-day period

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	18	20	20

EEsAI Total Score Week 12 Change from Baseline

Number Analyzed	18 participants	20 participants	20 participants
∗Mean (Standard Deviation) | Unit of Measure: units on a scale	-20.4 (15.90)	-15.6 (21.02)	-22.7 (16.60)

EEsAI Total Score Week 26 Change from Baseline

e 7-Day Eosinophilic Esophagitis Activity Index (EEsAI) Subscores

Number Analyzed	8 participants	19 participants	13 participants
*	-25.6 (21.11)	-29.6 (25.48)	-28.8 (21.10)

Frame: Weeks 12, 26 and 52

The Avoidance, Modification and Slow Eating (AMS) Score and Visual Dysphagia Question (VDQ) Score are components of the EEsAI.

AMS: Answers to three items determining the pattern of behavioral adaptation were scored for each food consistency consumed by the subject (avoidance, modification, and eating slowly). The AMS score ranges from 0 (best) to 25 (worst).

EEsAI Total Score Week 52 Change from Baseline

Number Analyzed	5 participants	17 participants	11 participants

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*	-39.8 (28.42)	-37.4 (27.02)	-37.0 (23.72)

* Mean (Standard Deviation) | Unit of Measure: units on a scale

VDG: The degree of perceived difficulty when eating 8 different food consistencies was assessed. The VDQ score ranges from 0 (best) to 23 (worst).

A higher score for either subscore means a worse outcome. Negative change from baseline represents a worsening in quality of life for the total score or subscore.

Population used are those who entered Part 1 - Induction. The number of participants analyzed for each timepoint reflect the actual number of participants with data at that timepoint. Note: Following Week 14, all patients in the placebo group were given APT-1011 3mg BID and results reflect change from baseline.

Expand all / Collapse all

Statistical Analysis 1 : APT-1011 1.5 mg HS, Placebo BID | Superiority | ANCOVA

Time Frame	Weeks 12, 26 and 52
Analysis Population Description	Full Analysis Set Population

Statistical Analysis 2 : APT-1011 1.5 mg BID, Placebo BID | Superiority | ANCOVA

Statistical Analysis 3 : APT-1011 3 mg HS, Placebo BID | Superiority | ANCOVA

Statistical Analysis 4 : APT-1011 3 mg BID, Placebo BID | Superiority | ANCOVA

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	18	20	20

VDQ Score Week 12 Change from Baseline

Number Analyzed	18 participants	19 participants	20 participants
∗Mean (Standard Deviation) | Unit of Measure: units on a scale	-3.9 (6.53)	-2.5 (3.24)	-5.0 (6.00)

VDQ Score Week 26 Change from Baseline

Number Analyzed	8 participants	18 participants	13 participants
∗	-3.1 (4.36)	-6.8 (7.03)	-6.8 (6.46)

VDQ Score Week 52 Change from Baseline

Number Analyzed	5 participants	16 participants	11 participants

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*	-9.4 (9.50)	-9.4 (8.25)	-12.6 (9.67)

AMS Score Week 12 Change from Baseline

Number Analyzed	18 participants	20 participants	20 participants
*	0.0 (0.00)	-3.0 (7.80)	-1.4 (3.30)

AMS Score Week 26 Change from Baseline

Number Analyzed	8 participants	19 participants	13 participants
*	0.0 (0.00)	-2.2 (8.31)	-0.7 (4.44)

AMS Score Week 52 Change from Baseline

Number Analyzed	5 participants	17 participants	11 participants
*	0.0 (0.00)	-3.5 (8.39)	-0.8 (2.71)

* Mean (Standard Deviation) | Unit of Measure: units on a scale

Expand all / Collapse all

Statistical Analysis 1 : APT-1011 1.5 mg HS, Placebo BID | Superiority | ANCOVA

Statistical Analysis 2 : APT-1011 1.5 mg BID, Placebo BID | Superiority | ANCOVA

Statistical Analysis 3 : APT-1011 3 mg HS, Placebo BID | Superiority | ANCOVA

9. Percentage of Subjects With Mean 7-day EEsAI Total Score <20

Type: Secondary | Time Frame: Weeks 12, 26, and 52

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Description	Percentage of subjects with mean 7-day EEsAI total score <20 to those assessed at Weeks 12, 26 and 52.
	Eosinophilic Esophagitis Activity Index Total Score: 0 (best) to 100 (worst) based on the sum of the categorized subscores for frequency of trouble swallowing [never (0), 1-3x (15) or 4-6x (27) per week]; duration of trouble swallowing [<= 5 min (0), >5 min (6)]; pain when swallowing [no (0), yes (15)]; Visual Dysphagia Question score [0 (best),12,19,21, or 23 (worst)]; avoidance modification and slow eating score [0 (best), 9, or 25 (worst)].
	Population used are those who entered Part 1 - Induction. The number of participants analyzed for each timepoint reflect the actual number of participants with data at that timepoint. Note: Following Week 14, all patients in the placebo group were given APT-1011 3mg BID and results reflect change from baseline global EOE symptom score following 12 or 38 weeks of treatment
Time Frame	Weeks 12, 26, and 52
Analysis Population Description	Full Analysis Set population

Statistical Analysis 4 : APT-1011 3 mg BID, Placebo BID | Superiority | ANCOVA

Statistical Analysis 5 : APT-1011 1.5 mg BID, Placebo BID | Superiority | ANCOVA

Statistical Analysis 6 : APT-1011 1.5 mg BID, Placebo BID | Superiority | ANCOVA

Statistical Analysis 7 : APT-1011 3 mg HS, Placebo BID | Superiority | ANCOVA

Statistical Analysis 8 : APT-1011 3 mg BID, Placebo BID | Superiority | ANCOVA

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	18	20	20

Week 12 EEsAI Total Score <20

Number Analyzed	18 participants	20 participants	20 participants
∗Measure Type: Count of Participants | Unit of Measure: Participants	4 22.2%	1 5.0%	6 30.0%

Week 26 EEsAI Total Score <20

Number Analyzed	8 participants	19 participants	13 participants
∗	3 37.5%	5 26.3%	7 53.8%

Week 52 EEsAI Total Score <20

Number Analyzed	5 participants	17 participants	11 participants
∗	3 60.0%	7 41.2%	7 63.6%

ine Patient Global Impression of Severity (PGIS) for EoE Symptoms as Assessed Prior to Randomization

Frame: Weeks 4, 8, 12, 14, 18, 22, 26, 28, 36, 44, and 52

Change From Baseline PGIS for EoE Symptoms as Assessed Prior to Randomization at Weeks 4, 8, 12, 14, 18, 22, 26, 28, 36, 44, and 52.

Population used are those who entered Part 1 - Induction. The number of participants analyzed for each timepoint reflect the actual number of participants with data at that timepoint. Note: Following Week 14, all

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* Measure Type: Count of Participants	Unit of Measure: Participants
	of Participants placebo group were given APT-1011 3mg BID and results reflect change from baseline global EOE symptoms following 4, 8, 12, 14, 22, 30 or 38 weeks of treatment.
Time Frame	Weeks 4, 8, 12, 14, 18, 22, 26, 28, 36, 44, and 52
Analysis Population Description	Full Analysis Set

Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	20	21	20

Week 4

Number Analyzed	20 participants	19 participants	20 participants
Mild to None ∗Measure Type: Count of Participants | Unit of Measure: Participants	1 5.0%	0 0.0%	0 0.0%
Mild to Mild *	0 0.0%	0 0.0%	1 5.0%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	1 5.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	0 0.0%	0 0.0%	4 20.0%

Moderate to Mild *	8 40.0%	7 36.8%	5 25.0%
Moderate to Moderate *	5 25.0%	5 26.3%	4 20.0%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	0 0.0%	1 5.0%
Severe to Mild *	3 15.0%	1 5.3%	1 5.0%
Severe to Moderate *	1 5.0%	3 15.8%	3 15.0%
Severe to Severe *	0 0.0%	3 15.8%	1 5.0%
Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	1 5.0%	0 0.0%	0 0.0%

Week 8

Number Analyzed	17 participants		21 participants		19 participants	
Mild to None *	0	0.0%	0	0.0%	0	0.0%
Mild to Mild *	0	0.0%	0	0.0%	1	5.3%
Mild to Moderate *	1	5.9%	0	0.0%	0	0.0%
Mild to Severe *	0	0.0%	0	0.0%	0	0.0%
Mild to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Moderate to None *	1	5.9%	1	4.8%	4	21.1%
Moderate to Mild *	8	47.1%	6	28.6%	5	26.3%
Moderate to Moderate *	3	17.6%	6	28.6%	3	15.8%
Moderate to Severe *	0	0.0%	0	0.0%	0	0.0%
Moderate to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Severe to None *	1	5.9%	0	0.0%	1	5.3%
Severe to Mild *	1	5.9%	1	4.8%	2	10.5%
Severe to Moderate *	1	5.9%	6	28.6%	1	5.3%
Severe to Severe *	0	0.0%	1	4.8%	2	10.5%

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Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Severe *	1 5.9%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 12

Number Analyzed	18 participants	20 participants	20 participants
Mild to None *	0 0.0%	0 0.0%	0 0.0%
Mild to Mild *	1 5.6%	0 0.0%	1 5.0%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	1 5.6%	0 0.0%	5 25.0%
Moderate to Mild *	10 55.6%	7 35.0%	5 25.0%

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Moderate to Moderate *	2 11.1%	5 25.0%	3 15.0%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	2 11.1%	0 0.0%	1 5.0%
Severe to Mild *	1 5.6%	3 15.0%	0 0.0%
Severe to Moderate *	0 0.0%	4 20.0%	4 20.0%
Severe to Severe *	0 0.0%	1 5.0%	1 5.0%
Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	1 5.6%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 14

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Number Analyzed	10 participants		18 participants		13 participants	
Mild to None *	0	0.0%	0	0.0%	0	0.0%
Mild to Mild *	1	10.0%	0	0.0%	1	7.7%
Mild to Moderate *	0	0.0%	0	0.0%	0	0.0%
Mild to Severe *	0	0.0%	0	0.0%	0	0.0%
Mild to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Moderate to None *	0	0.0%	1	5.6%	5	38.5%
Moderate to Mild *	7	70.0%	8	44.4%	1	7.7%
Moderate to Moderate *	0	0.0%	2	11.1%	1	7.7%
Moderate to Severe *	0	0.0%	0	0.0%	0	0.0%
Moderate to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Severe to None *	0	0.0%	1	5.6%	0	0.0%
Severe to Mild *	1	10.0%	1	5.6%	3	23.1%
Severe to Moderate *	0	0.0%	5	27.8%	1	7.7%
Severe to Severe *	0	0.0%	0	0.0%	1	7.7%
Severe to Very Severe *	0	0.0%	0	0.0%	0	0.0%

Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	1 10.0%	0 0.0%	0 0.0%

Week 18

Number Analyzed	9 participants	18 participants	14 participants
Mild to None *	0 0.0%	0 0.0%	0 0.0%
Mild to Mild *	0 0.0%	0 0.0%	1 7.1%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	0 0.0%	1 5.6%	5 35.7%
Moderate to Mild *	6 66.7%	9 50.0%	2 14.3%
Moderate to Moderate *	1 11.1%	1 5.6%	1 7.1%

Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	2 11.1%	1 7.1%
Severe to Mild *	1 11.1%	2 11.1%	2 14.3%
Severe to Moderate *	0 0.0%	3 16.7%	1 7.1%
Severe to Severe *	0 0.0%	0 0.0%	1 7.1%
Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	1 11.1%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 22

Number Analyzed	8 participants	18 participants	13 participants
Mild to None *	0 0.0%	0 0.0%	0 0.0%

Mild to Mild *	0 0.0%	0 0.0%	1 7.7%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	1 12.5%	2 11.1%	3 23.1%
Moderate to Mild *	6 75.0%	8 44.4%	2 15.4%
Moderate to Moderate *	0 0.0%	1 5.6%	2 15.4%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	1 5.6%	1 7.7%
Severe to Mild *	1 12.5%	3 16.7%	1 7.7%
Severe to Moderate *	0 0.0%	2 11.1%	2 15.4%
Severe to Severe *	0 0.0%	1 5.6%	0 0.0%
Severe to Very Severe *	0 0.0%	0 0.0%	1 7.7%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%

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Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 26

Number Analyzed	8 participants	17 participants	13 participants
Mild to None *	0 0.0%	0 0.0%	0 0.0%
Mild to Mild *	0 0.0%	0 0.0%	1 7.7%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	2 25.0%	1 5.9%	4 30.8%
Moderate to Mild *	2 25.0%	8 47.1%	2 15.4%
Moderate to Moderate *	2 25.0%	2 11.8%	1 7.7%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Severe to None *	0 0.0%	2 11.8%	2 15.4%
Severe to Mild *	1 12.5%	2 11.8%	2 15.4%
Severe to Moderate *	0 0.0%	2 11.8%	0 0.0%
Severe to Severe *	0 0.0%	0 0.0%	1 7.7%
Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	1 12.5%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 28

Number Analyzed	7 participants	16 participants	10 participants
Mild to None *	0 0.0%	0 0.0%	0 0.0%
Mild to Mild *	0 0.0%	0 0.0%	1 10.0%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%

Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	2 28.6%	1 6.3%	4 40.0%
Moderate to Mild *	3 42.9%	7 43.8%	1 10.0%
Moderate to Moderate *	0 0.0%	2 12.5%	0 0.0%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	2 12.5%	2 20.0%
Severe to Mild *	1 14.3%	2 12.5%	0 0.0%
Severe to Moderate *	0 0.0%	2 12.5%	1 10.0%
Severe to Severe *	0 0.0%	0 0.0%	1 10.0%
Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	1 14.3%	0 0.0%	0 0.0%
Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%

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Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 36

Number Analyzed	6 participants	15 participants	11 participants
Mild to None *	0 0.0%	0 0.0%	0 0.0%
Mild to Mild *	0 0.0%	0 0.0%	1 9.1%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	0 0.0%	2 13.3%	5 45.5%
Moderate to Mild *	4 66.7%	7 46.7%	1 9.1%
Moderate to Moderate *	0 0.0%	1 6.7%	0 0.0%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	3 20.0%	2 18.2%

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Severe to Mild *	1 16.7%	2 13.3%	1 9.1%
Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to Very Severe *	0 0.0%	0 0.0%	1 9.1%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	1 16.7%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 44

Number Analyzed	5 participants	15 participants	10 participants
Mild to None *	0 0.0%	0 0.0%	0 0.0%
Mild to Mild *	0 0.0%	0 0.0%	1 10.0%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%

Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	1 20.0%	1 6.7%	3 30.0%
Moderate to Mild *	2 40.0%	8 53.3%	1 10.0%
Moderate to Moderate *	0 0.0%	1 6.7%	1 10.0%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	3 20.0%	2 20.0%
Severe to Mild *	1 20.0%	2 13.3%	1 10.0%
Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to Very Severe *	0 0.0%	0 0.0%	1 10.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	1 20.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%

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Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 52

Number Analyzed	4 participants	14 participants	10 participants
Mild to None *	0 0.0%	0 0.0%	1 10.0%
Mild to Mild *	0 0.0%	0 0.0%	0 0.0%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	0 0.0%	3 21.4%	5 50.0%
Moderate to Mild *	3 75.0%	3 21.4%	1 10.0%
Moderate to Moderate *	0 0.0%	4 28.6%	0 0.0%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	3 21.4%	1 10.0%
Severe to Mild *	0 0.0%	1 7.1%	1 10.0%
Severe to Moderate *	1 25.0%	0 0.0%	0 0.0%

ine PGIS for Difficulty With Food or Pills Going Down as Assessed Prior to Randomization Post-Baseline

Frame: Weeks 4, 8, 12, 14, 18, 22, 26, 28, 36, 44, and 52

Change From Baseline PGIS for Difficulty with Food or Pills Going Down as Assessed Prior to Randomization at Weeks 4, 8, 12, 14, 18, 22, 26, 28, 36, 44, and 52.

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Severe to Severe *	0	0.0%	0	0.0%	0	0.0%
Severe to Very Severe *	0	0.0%	0	0.0%	1	10.0%
Very Severe to None *	0	0.0%	0	0.0%	0	0.0%
Very Severe to Mild *	0	0.0%	0	0.0%	0	0.0%
Very Severe to Moderate *	0	0.0%	0	0.0%	0	0.0%
Very Severe to Severe *	0	0.0%	0	0.0%	0	0.0%
Very Severe to Very Severe *	0	0.0%	0	0.0%	0	0.0%

Population used are those who entered Part 1 - Induction. The number of participants analyzed for each timepoint reflect the actual number of participants with data at that timepoint. Note: Following Week 14, all patients in the placebo group were given APT-1011 3mg BID and results reflect change from baseline PGIS for difficulty with food or pills going down following 4, 8, 12, 14, 22, 30 or 38 weeks of treatment.

Weeks 4, 8, 12, 14, 18, 22, 26, 28, 36, 44, and 52

Full Analysis Set

* Measure Type: Count of Participants | Unit of Measure: Participants

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	20	21	20

Week 4

Number Analyzed	20 participants	19 participants	20 participants
Mild to None ∗Measure Type: Count of Participants | Unit of Measure: Participants	2 10.0%	0 0.0%	0 0.0%
Mild to Mild *	1 5.0%	1 5.3%	1 5.0%
Mild to Moderate *	0 0.0%	0 0.0%	1 5.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	0 0.0%	0 0.0%	6 30.0%

Moderate to Mild *	6 30.0%	6 31.6%	4 20.0%
Moderate to Moderate *	5 25.0%	4 21.1%	4 20.0%
Moderate to Severe *	1 5.0%	1 5.3%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	0 0.0%	1 5.0%
Severe to Mild *	1 5.0%	1 5.3%	0 0.0%
Severe to Moderate *	2 10.0%	2 10.5%	2 10.0%
Severe to Severe *	1 5.0%	4 21.1%	0 0.0%
Severe to Very Severe *	0 0.0%	0 0.0%	1 5.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	1 5.0%	0 0.0%	0 0.0%

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Week 8

Number Analyzed	17 participants		21 participants		19 participants	
Mild to None *	0	0.0%	0	0.0%	0	0.0%
Mild to Mild *	2	11.8%	1	4.8%	2	10.5%
Mild to Moderate *	1	5.9%	0	0.0%	0	0.0%
Mild to Severe *	0	0.0%	0	0.0%	0	0.0%
Mild to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Moderate to None *	1	5.9%	1	4.8%	4	21.1%
Moderate to Mild *	8	47.1%	5	23.8%	5	26.3%
Moderate to Moderate *	1	5.9%	6	28.6%	4	21.1%
Moderate to Severe *	0	0.0%	0	0.0%	0	0.0%
Moderate to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Severe to None *	1	5.9%	0	0.0%	1	5.3%
Severe to Mild *	2	11.8%	1	4.8%	1	5.3%
Severe to Moderate *	0	0.0%	7	33.3%	0	0.0%
Severe to Severe *	0	0.0%	0	0.0%	1	5.3%

Severe to Very Severe *	0 0.0%	0 0.0%	1 5.3%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	1 5.9%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 12

Number Analyzed	18 participants	20 participants	20 participants
Mild to None *	1 5.6%	0 0.0%	0 0.0%
Mild to Mild *	2 11.1%	1 5.0%	2 10.0%
Mild to Moderate *	1 5.6%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	3 16.7%	0 0.0%	5 25.0%
Moderate to Mild *	4 22.2%	5 25.0%	6 30.0%

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Moderate to Moderate *	3 16.7%	6 30.0%	3 15.0%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	3 16.7%	0 0.0%	1 5.0%
Severe to Mild *	0 0.0%	4 20.0%	0 0.0%
Severe to Moderate *	0 0.0%	3 15.0%	2 10.0%
Severe to Severe *	0 0.0%	1 5.0%	1 5.0%
Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	1 5.6%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 14

Number Analyzed	10 participants		18 participants		13 participants	
Mild to None *	0	0.0%	0	0.0%	1	7.7%
Mild to Mild *	1	10.0%	1	5.6%	0	0.0%
Mild to Moderate *	0	0.0%	0	0.0%	0	0.0%
Mild to Severe *	0	0.0%	0	0.0%	0	0.0%
Mild to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Moderate to None *	1	10.0%	0	0.0%	4	30.8%
Moderate to Mild *	7	70.0%	7	38.9%	3	23.1%
Moderate to Moderate *	0	0.0%	2	11.1%	1	7.7%
Moderate to Severe *	0	0.0%	1	5.6%	0	0.0%
Moderate to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Severe to None *	0	0.0%	1	5.6%	0	0.0%
Severe to Mild *	0	0.0%	2	11.1%	2	15.4%
Severe to Moderate *	0	0.0%	4	22.2%	1	7.7%
Severe to Severe *	0	0.0%	0	0.0%	1	7.7%
Severe to Very Severe *	0	0.0%	0	0.0%	0	0.0%

Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	1 10.0%	0 0.0%	0 0.0%

Week 18

Number Analyzed	9 participants	18 participants	14 participants
Mild to None *	0 0.0%	0 0.0%	1 7.1%
Mild to Mild *	0 0.0%	1 5.6%	0 0.0%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	0 0.0%	1 5.6%	5 35.7%
Moderate to Mild *	8 88.9%	7 38.9%	3 21.4%
Moderate to Moderate *	0 0.0%	2 11.1%	1 7.1%

Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	2 11.1%	1 7.1%
Severe to Mild *	0 0.0%	2 11.1%	1 7.1%
Severe to Moderate *	0 0.0%	3 16.7%	1 7.1%
Severe to Severe *	0 0.0%	0 0.0%	1 7.1%
Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	1 11.1%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 22

Number Analyzed	8 participants	18 participants	13 participants
Mild to None *	0 0.0%	0 0.0%	0 0.0%

Mild to Mild *	0	0.0%	1	5.6%	1	7.7%
Mild to Moderate *	0	0.0%	0	0.0%	0	0.0%
Mild to Severe *	0	0.0%	0	0.0%	0	0.0%
Mild to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Moderate to None *	2	25.0%	1	5.6%	3	23.1%
Moderate to Mild *	6	75.0%	7	38.9%	3	23.1%
Moderate to Moderate *	0	0.0%	2	11.1%	2	15.4%
Moderate to Severe *	0	0.0%	0	0.0%	0	0.0%
Moderate to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Severe to None *	0	0.0%	2	11.1%	1	7.7%
Severe to Mild *	0	0.0%	2	11.1%	1	7.7%
Severe to Moderate *	0	0.0%	3	16.7%	1	7.7%
Severe to Severe *	0	0.0%	0	0.0%	0	0.0%
Severe to Very Severe *	0	0.0%	0	0.0%	1	7.7%
Very Severe to None *	0	0.0%	0	0.0%	0	0.0%
Very Severe to Mild *	0	0.0%	0	0.0%	0	0.0%

Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 26

Number Analyzed	8 participants	17 participants	13 participants
Mild to None *	0 0.0%	0 0.0%	0 0.0%
Mild to Mild *	0 0.0%	1 5.9%	1 7.7%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	3 37.5%	0 0.0%	4 30.8%
Moderate to Mild *	3 37.5%	7 41.2%	3 23.1%
Moderate to Moderate *	1 12.5%	2 11.8%	1 7.7%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Severe to None *	0 0.0%	3 17.6%	2 15.4%
Severe to Mild *	0 0.0%	3 17.6%	1 7.7%
Severe to Moderate *	0 0.0%	1 5.9%	0 0.0%
Severe to Severe *	0 0.0%	0 0.0%	1 7.7%
Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	1 12.5%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 28

Number Analyzed	7 participants	16 participants	10 participants
Mild to None *	0 0.0%	0 0.0%	1 10.0%
Mild to Mild *	0 0.0%	1 6.3%	0 0.0%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%

Mild to Severe *	0	0.0%	0	0.0%	0	0.0%
Mild to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Moderate to None *	4	57.1%	0	0.0%	4	40.0%
Moderate to Mild *	2	28.6%	7	43.8%	1	10.0%
Moderate to Moderate *	0	0.0%	1	6.3%	0	0.0%
Moderate to Severe *	0	0.0%	0	0.0%	0	0.0%
Moderate to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Severe to None *	0	0.0%	3	18.8%	2	20.0%
Severe to Mild *	0	0.0%	2	12.5%	0	0.0%
Severe to Moderate *	0	0.0%	2	12.5%	1	10.0%
Severe to Severe *	0	0.0%	0	0.0%	1	10.0%
Severe to Very Severe *	0	0.0%	0	0.0%	0	0.0%
Very Severe to None *	0	0.0%	0	0.0%	0	0.0%
Very Severe to Mild *	1	14.3%	0	0.0%	0	0.0%
Very Severe to Moderate *	0	0.0%	0	0.0%	0	0.0%

Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 36

Number Analyzed	6 participants	15 participants	11 participants
Mild to None *	0 0.0%	0 0.0%	0 0.0%
Mild to Mild *	0 0.0%	1 6.7%	1 9.1%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	2 33.3%	2 13.3%	5 45.5%
Moderate to Mild *	3 50.0%	5 33.3%	1 9.1%
Moderate to Moderate *	0 0.0%	1 6.7%	0 0.0%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	4 26.7%	2 18.2%

Severe to Mild *	0 0.0%	1 6.7%	1 9.1%
Severe to Moderate *	0 0.0%	1 6.7%	0 0.0%
Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to Very Severe *	0 0.0%	0 0.0%	1 9.1%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Severe *	1 16.7%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 44

Number Analyzed	5 participants	15 participants	10 participants
Mild to None *	0 0.0%	0 0.0%	0 0.0%
Mild to Mild *	0 0.0%	1 6.7%	1 10.0%
Mild to Moderate *	0 0.0%	0 0.0%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%

Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	2 40.0%	1 6.7%	3 30.0%
Moderate to Mild *	2 40.0%	6 40.0%	1 10.0%
Moderate to Moderate *	0 0.0%	0 0.0%	1 10.0%
Moderate to Severe *	0 0.0%	1 6.7%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	3 20.0%	2 20.0%
Severe to Mild *	0 0.0%	3 20.0%	1 10.0%
Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to Very Severe *	0 0.0%	0 0.0%	1 10.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	1 20.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%

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Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Week 52

Number Analyzed	4 participants	14 participants	10 participants
Mild to None *	0 0.0%	0 0.0%	1 10.0%
Mild to Mild *	0 0.0%	0 0.0%	0 0.0%
Mild to Moderate *	0 0.0%	1 7.1%	0 0.0%
Mild to Severe *	0 0.0%	0 0.0%	0 0.0%
Mild to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to None *	2 50.0%	2 14.3%	5 50.0%
Moderate to Mild *	2 50.0%	4 28.6%	1 10.0%
Moderate to Moderate *	0 0.0%	3 21.4%	0 0.0%
Moderate to Severe *	0 0.0%	0 0.0%	0 0.0%
Moderate to Very Severe *	0 0.0%	0 0.0%	0 0.0%
Severe to None *	0 0.0%	3 21.4%	1 10.0%
Severe to Mild *	0 0.0%	1 7.1%	1 10.0%
Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%

ine Patient Global Impression of Change (PGIC) for EoE Symptoms as Assessed Prior to Randomization

Frame: Weeks 4, 8, 12, 14, 18, 22, 26, 36, 44, and 52

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Severe to Severe *	0 0.0%	0 0.0%	1 10.0%
Severe to Very Severe *	0 0.0%	0 0.0%	1 10.0%
Very Severe to None *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Mild *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Moderate *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Severe *	0 0.0%	0 0.0%	0 0.0%
Very Severe to Very Severe *	0 0.0%	0 0.0%	0 0.0%

Change From Baseline PGIC for EoE Symptoms as Assessed Prior to Randomization at Weeks 4, 8, 12, 14, 18, 22, 26, 28, 36, 44, and 52.

Population used are those who entered Part 1 - Induction. The number of participants analyzed for each timepoint reflect the actual number of participants with data at that timepoint. Note: Following Week 14, all patients in the placebo group were given APT-1011 3mg BID and results reflect change from baseline PGIC for EoE symptoms following 4, 8, 12, 14, 22, 30 or 38 weeks of treatment.

Weeks 4, 8, 12, 14, 18, 22, 26, 36, 44, and 52

Full Analysis Set

* Measure Type: Count of Participants | Unit of Measure: Participants

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	21	22	20

Week 4

Number Analyzed	21 participants	20 participants	20 participants
Much Worse *Measure Type: Count of Participants | Unit of Measure: Participants	0 0.0%	0 0.0%	0 0.0%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	1 4.8%	0 0.0%	1 5.0%
Stayed the Same *	4 19.0%	4 20.0%	4 20.0%
A Little Improved *	9 42.9%	9 45.0%	4 20.0%

Moderately Improved *	4 19.0%	3 15.0%	6 30.0%
Much Improved *	3 14.3%	4 20.0%	5 25.0%

Week 8

Number Analyzed	17 participants	22 participants	19 participants
Much Worse *	0 0.0%	0 0.0%	0 0.0%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	1 5.9%	0 0.0%	1 5.3%
Stayed the Same *	2 11.8%	3 13.6%	3 15.8%
A Little Improved *	4 23.5%	9 40.9%	5 26.3%
Moderately Improved *	7 41.2%	4 18.2%	4 21.1%
Much Improved *	3 17.6%	6 27.3%	6 31.6%

Week 12

Number Analyzed	18 participants	22 participants	20 participants
Much Worse *	0 0.0%	0 0.0%	0 0.0%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	0 0.0%	0 0.0%	1 5.0%

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Stayed the Same *	1 5.6%	4 18.2%	4 20.0%
A Little Improved *	6 33.3%	5 22.7%	2 10.0%
Moderately Improved *	5 27.8%	5 22.7%	4 20.0%
Much Improved *	6 33.3%	8 36.4%	9 45.0%

Week 14

Number Analyzed	10 participants	18 participants	13 participants
Much Worse *	0 0.0%	0 0.0%	0 0.0%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	0 0.0%	0 0.0%	1 7.7%
Stayed the Same *	0 0.0%	3 16.7%	1 7.7%
A Little Improved *	3 30.0%	4 22.2%	1 7.7%
Moderately Improved *	5 50.0%	3 16.7%	3 23.1%
Much Improved *	2 20.0%	8 44.4%	7 53.8%

Week 18

Number Analyzed	9 participants	18 participants	14 participants
Much Worse *	0 0.0%	0 0.0%	0 0.0%

Moderately Worse *	0	0.0%	0	0.0%	1	7.1%
A Little Worse *	0	0.0%	1	5.6%	1	7.1%
Stayed the Same *	0	0.0%	3	16.7%	0	0.0%
A Little Improved *	2	22.2%	1	5.6%	1	7.1%
Moderately Improved *	6	66.7%	2	11.1%	1	7.1%
Much Improved *	1	11.1%	11	61.1%	10	71.4%

Week 22

Number Analyzed	8 participants		18 participants		14 participants	
Much Worse *	0	0.0%	0	0.0%	1	7.1%
Moderately Worse *	0	0.0%	0	0.0%	1	7.1%
A Little Worse *	0	0.0%	0	0.0%	0	0.0%
Stayed the Same *	0	0.0%	3	16.7%	0	0.0%
A Little Improved *	2	25.0%	1	5.6%	2	14.3%
Moderately Improved *	2	25.0%	3	16.7%	3	21.4%
Much Improved *	4	50.0%	11	61.1%	7	50.0%

Week 26

Number Analyzed	8 participants		18 participants		13 participants	
Much Worse *	0	0.0%	0	0.0%	0	0.0%
Moderately Worse *	0	0.0%	0	0.0%	2	15.4%
A Little Worse *	0	0.0%	0	0.0%	0	0.0%
Stayed the Same *	0	0.0%	2	11.1%	0	0.0%
A Little Improved *	3	37.5%	1	5.6%	0	0.0%
Moderately Improved *	1	12.5%	2	11.1%	2	15.4%
Much Improved *	4	50.0%	13	72.2%	9	69.2%

Week 28

Number Analyzed	7 participants		17 participants		10 participants	
Much Worse *	0	0.0%	0	0.0%	0	0.0%
Moderately Worse *	0	0.0%	0	0.0%	1	10.0%
A Little Worse *	0	0.0%	0	0.0%	0	0.0%
Stayed the Same *	0	0.0%	3	17.6%	0	0.0%
A Little Improved *	1	14.3%	0	0.0%	1	10.0%
Moderately Improved *	2	28.6%	3	17.6%	0	0.0%

Much Improved *	4 57.1%	11 64.7%	8 80.0%

Week 36

Number Analyzed	6 participants	16 participants	11 participants
Much Worse *	0 0.0%	0 0.0%	0 0.0%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	0 0.0%	0 0.0%	0 0.0%
Stayed the Same *	1 16.7%	0 0.0%	1 9.1%
A Little Improved *	1 16.7%	1 6.3%	0 0.0%
Moderately Improved *	1 16.7%	1 6.3%	0 0.0%
Much Improved *	3 50.0%	14 87.5%	10 90.9%

Week 44

Number Analyzed	5 participants	15 participants	11 participants
Much Worse *	0 0.0%	0 0.0%	1 9.1%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	0 0.0%	0 0.0%	0 0.0%
Stayed the Same *	0 0.0%	0 0.0%	0 0.0%
A Little Improved *	1 20.0%	2 13.3%	0 0.0%

Moderately Improved *	1 20.0%	1 6.7%	2 18.2%
Much Improved *	3 60.0%	12 80.0%	8 72.7%

ine PGIC of Difficulty With Food or Pills as Assessed Prior to Randomization Post-Baseline Visit

Frame: Weeks 4, 8, 12, 14, 18, 22, 26, 36, 44, and 52

Week 52

Change From Baseline PGIC of Difficulty with Food or Pills as Assessed Prior to Randomization at Weeks 4, 8, 12, 14, 18, 22, 26, 28, 36, 44, and 52.

Population used are those who entered Part 1 - Induction. The number of participants analyzed for each timepoint reflect the actual number of participants with data at that timepoint. Note: Following Week 14, all patients in the placebo group were given APT-1011 3mg BID and results reflect change from baseline PGIC of difficulty with food or pills following 4, 8, 12, 14, 22, 30 or 38 weeks of treatment.

Weeks 4, 8, 12, 14, 18, 22, 26, 36, 44, and 52

Full Analysis Set

	4 participants	14 participants	10 participants
Number Analyzed			
Much Worse *	0 0.0%	0 0.0%	0 0.0%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	0 0.0%	0 0.0%	1 10.0%
Stayed the Same *	0 0.0%	1 7.1%	0 0.0%
A Little Improved *	1 25.0%	0 0.0%	0 0.0%
Moderately Improved *	2 50.0%	3 21.4%	1 10.0%
Much Improved *	1 25.0%	10 71.4%	8 80.0%

* Measure Type: Count of Participants | Unit of Measure: Participants

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	21	22	20

Week 4

Number Analyzed	21 participants	20 participants	20 participants
Much Worse *Measure Type: Count of Participants | Unit of Measure: Participants	0 0.0%	0 0.0%	0 0.0%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	1 4.8%	0 0.0%	2 10.0%
Stayed the Same *	4 19.0%	3 15.0%	4 20.0%
A Little Improved *	8 38.1%	10 50.0%	4 20.0%

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Moderately Improved *	6 28.6%	5 25.0%	4 20.0%
Much Improved *	2 9.5%	2 10.0%	6 30.0%

Week 8

Number Analyzed	17 participants	22 participants	19 participants
Much Worse *	0 0.0%	0 0.0%	1 5.3%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	2 11.8%	0 0.0%	1 5.3%
Stayed the Same *	2 11.8%	5 22.7%	1 5.3%
A Little Improved *	3 17.6%	5 22.7%	5 26.3%
Moderately Improved *	6 35.3%	4 18.2%	3 15.8%
Much Improved *	4 23.5%	8 36.4%	8 42.1%

Week 12

Number Analyzed	18 participants	22 participants	20 participants
Much Worse *	0 0.0%	0 0.0%	0 0.0%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	0 0.0%	0 0.0%	2 10.0%

Stayed the Same *	1 5.6%	4 18.2%	2 10.0%
A Little Improved *	5 27.8%	5 22.7%	5 25.0%
Moderately Improved *	6 33.3%	4 18.2%	2 10.0%
Much Improved *	6 33.3%	9 40.9%	9 45.0%

Week 14

Number Analyzed	10 participants	18 participants	13 participants
Much Worse *	0 0.0%	0 0.0%	0 0.0%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	0 0.0%	0 0.0%	2 15.4%
Stayed the Same *	0 0.0%	4 22.2%	0 0.0%
A Little Improved *	3 30.0%	3 16.7%	1 7.7%
Moderately Improved *	4 40.0%	3 16.7%	2 15.4%
Much Improved *	3 30.0%	8 44.4%	8 61.5%

Week 18

Number Analyzed	9 participants	18 participants	14 participants
Much Worse *	0 0.0%	0 0.0%	0 0.0%

Moderately Worse *	0 0.0%	0 0.0%	1 7.1%
A Little Worse *	0 0.0%	1 5.6%	1 7.1%
Stayed the Same *	0 0.0%	3 16.7%	0 0.0%
A Little Improved *	1 11.1%	1 5.6%	1 7.1%
Moderately Improved *	6 66.7%	4 22.2%	2 14.3%
Much Improved *	2 22.2%	9 50.0%	9 64.3%

Week 22

Number Analyzed	8 participants	18 participants	14 participants
Much Worse *	0 0.0%	0 0.0%	1 7.1%
Moderately Worse *	0 0.0%	0 0.0%	1 7.1%
A Little Worse *	0 0.0%	0 0.0%	0 0.0%
Stayed the Same *	0 0.0%	2 11.1%	0 0.0%
A Little Improved *	2 25.0%	2 11.1%	2 14.3%
Moderately Improved *	2 25.0%	5 27.8%	3 21.4%
Much Improved *	4 50.0%	9 50.0%	7 50.0%

Week 26

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Number Analyzed	8 participants		18 participants		13 participants	
Much Worse *	0	0.0%	0	0.0%	0	0.0%
Moderately Worse *	0	0.0%	0	0.0%	2	15.4%
A Little Worse *	0	0.0%	1	5.6%	0	0.0%
Stayed the Same *	0	0.0%	2	11.1%	0	0.0%
A Little Improved *	2	25.0%	0	0.0%	0	0.0%
Moderately Improved *	4	50.0%	3	16.7%	2	15.4%
Much Improved *	2	25.0%	12	66.7%	9	69.2%

Week 28

Number Analyzed	7 participants		17 participants		10 participants	
Much Worse *	0	0.0%	0	0.0%	0	0.0%
Moderately Worse *	0	0.0%	0	0.0%	1	10.0%
A Little Worse *	0	0.0%	0	0.0%	0	0.0%
Stayed the Same *	0	0.0%	2	11.8%	0	0.0%
A Little Improved *	1	14.3%	1	5.9%	1	10.0%
Moderately Improved *	2	28.6%	3	17.6%	0	0.0%

Much Improved *	4 57.1%	11 64.7%	8 80.0%

Week 36

Number Analyzed	6 participants	16 participants	11 participants
Much Worse *	0 0.0%	0 0.0%	0 0.0%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	0 0.0%	0 0.0%	0 0.0%
Stayed the Same *	0 0.0%	1 6.3%	1 9.1%
A Little Improved *	1 16.7%	0 0.0%	0 0.0%
Moderately Improved *	3 50.0%	3 18.8%	0 0.0%
Much Improved *	2 33.3%	12 75.0%	10 90.9%

Week 44

Number Analyzed	5 participants	15 participants	11 participants
Much Worse *	0 0.0%	0 0.0%	1 9.1%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	0 0.0%	0 0.0%	0 0.0%
Stayed the Same *	0 0.0%	1 6.7%	0 0.0%
A Little Improved *	1 20.0%	0 0.0%	0 0.0%

Moderately Improved *	1 20.0%	1 6.7%	2 18.2%
Much Improved *	3 60.0%	13 86.7%	8 72.7%

Week 52

Number Analyzed	4 participants	14 participants	10 participants
Much Worse *	0 0.0%	0 0.0%	0 0.0%
Moderately Worse *	0 0.0%	0 0.0%	0 0.0%
A Little Worse *	0 0.0%	1 7.1%	1 10.0%
Stayed the Same *	1 25.0%	0 0.0%	0 0.0%
A Little Improved *	0 0.0%	0 0.0%	0 0.0%
Moderately Improved *	1 25.0%	5 35.7%	1 10.0%
Much Improved *	2 50.0%	8 57.1%	8 80.0%

* Measure Type: Count of Participants | Unit of Measure: Participants

logic Non-responders by Dose at Weeks 12, 26, and 52

Frame: Weeks 12, 26 and 52

Percentage of histologic non-responders by dose at Weeks 12, 26, and 52.

Note: Following Week 14, all patients in the placebo group were given APT-1011 3mg BID and results reflect non-response following 12 or 38 weeks of treatment.

Weeks 12, 26 and 52

Full Analysis Set Population

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	21	22	21
Week 12 *Measure Type: Count of Participants | Unit of Measure: Participants	11 52.4%	2 9.1%	7 33.3%
Week 26 *	11 52.4%	5 22.7%	7 33.3%
Week 52 *	16 76.2%	6 27.3%	10 47.6%

* Measure Type: Count of Participants | Unit of Measure: Participants

15. Percentage of Subjects Requiring Emergency Endoscopic Food Dis-impaction

Type: Secondary | Time Frame: before Week 14, between Week 14 and Week 28, between Week 28 and Week 52

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Description	Percentage of subjects requiring emergency endoscopic food dis-impaction by dose before Week 14, between Week 14 and Week 28, and between Week 28 and Week 52. Note: There were no patients in the placebo group after Week 14.
Time Frame	before Week 14, between Week 14 and Week 28, between Week 28 and Week 52
Analysis Population Description	Full Analysis Set Population

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Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	21	22	21
Before Week 14 *Measure Type: Count of Participants | Unit of Measure: Participants	0 0.0%	0 0.0%	0 0.0%
Between Week 14 and Week 28 *	0 0.0%	0 0.0%	0 0.0%
Between Week 28 and Week 52 *	0 0.0%	0 0.0%	0 0.0%

* Measure Type: Count of Participants | Unit of Measure: Participants

16. Percentage of Subjects Requiring Esophageal Dilation

Type: Secondary | Time Frame: baseline to Week 52

Description	Percentage of subjects requiring esophageal dilation by dosing group and part of the study.

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	Note: There were no patients in the placebo group after Week 14.		
Time Frame	baseline to Week 52		
Analysis Population Description	Full Analysis Set Population		
Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	21	22	21
Measure Type: Count of Participants | Unit of Measure: Participants	0 0.0%	0 0.0%	0 0.0%

17. Number of Subjects Discontinuing Due to HPA Axis Suppression

Type: Other Pre-specified | Time Frame: baseline to Week 52

Description	Number of subjects discontinuing due to HPA axis suppression. Note: There were no patients in the placebo group after Week 14.

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Time Frame	baseline to Week 52		
Analysis Population Description	Safety Analysis Population		
Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	21	23	21
Measure Type: Count of Participants | Unit of Measure: Participants	0 0.0%	0 0.0%	0 0.0%

18. Number of Subjects With Oral and Esophageal Candidiasis

Type: Other Pre-specified | Time Frame: baseline to Week 52

Description	Frequency of oral and esophageal candidiasis. Note: There were no patients in the placebo group after Week 14.
Time Frame	baseline to Week 52

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Analysis Population Description	Safety Analysis Population		
Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	21	23	21
Oesophageal candidiasis *Measure Type: Count of Participants | Unit of Measure: Participants	0 0.0%	2 8.7%	0 0.0%
Oral candidiasis *	0 0.0%	3 13.0%	1 4.8%

* Measure Type: Count of Participants | Unit of Measure: Participants

19. Number of Subjects With Treatment-Emergent Adverse Events Leading to Study Discontinuation in Part 1

Type: Other Pre-specified | Time Frame: baseline to Week 12

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Description	Number of Subjects With Treatment-Emergent Adverse Events (TEAEs) Leading to Study Discontinuation in Part 1.		
Time Frame	baseline to Week 12		
Analysis Population Description	Safety Analysis Population		
Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	21	23	21
Measure Type: Count of Participants | Unit of Measure: Participants	0 0.0%	2 8.7%	0 0.0%

20. Number of Subjects With Treatment-Emergent Adverse Events Leading to Study Discontinuation in Part 2

Type: Other Pre-specified | Time Frame: Week 12 to 52

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Description	Number of Subjects With Treatment-Emergent Adverse Events (TEAEs) Leading to Study Discontinuation in Part 2.		
Time Frame	Week 12 to 52		
Analysis Population Description	Safety Analysis Population		
Arm/Group Title	APT-1011 1.5 mg HS	APT-1011 1.5 mg BID	APT-1011 3 mg HS
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien
Overall Number of Participants Analyzed	10	19	14
Measure Type: Count of Participants | Unit of Measure: Participants	1 10.0%	0 0.0%	0 0.0%

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Adverse Events

Time Frame
to Week 14 (Part 1) to Week 52 (Part 2)

Adverse Event Reporting Description

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Adverse events were collected and reported from the time of signature on the ICF to the last study visit. All SAEs were collected and reported from the ICF signature to 30 days after the last study procedure or study drug administration.

One subject randomized to placebo was erroneously dispensed APT-1011 1.5 mg BID therefore this subject is included in the APT-1011 1.5mg BID arm for safety reporting (FAS). This subject is included in the placebo arm for efficacy reporting (ITT).

Arm/Group Title	APT-1011 1.5 mg HS Part 1	APT-1011 1.5 mg BID Part 1	APT-1011 3 mg HS Part 1
Arm/Group Description	Placebo after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate Placebo: Placebo tablets are identical in composition to APT-1011 except they exclude the active ingredient.	APT-1011 1.5 mg after breakfast, APT-1011 1.5 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation of fluticasone propionate	Placebo after breakfast, APT-101 mg HS APT-1011: APT-1011 is an orally disintegrating tablet formulation fluticasone propionate Placebo: Placebo tablets are ider in composition to APT-1011 exce they exclude the active ingredien

Expand

All-Cause Mortality

Arm/Group Title	APT-1011 1.5 mg HS Part 1	APT-1011 1.5 mg BID Part 1	APT-1011 3 mg HS Part 1
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)

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Serious Adverse Events

Arm/Group Title	APT-1011 1.5 mg HS Part 1	APT-1011 1.5 mg BID Part 1	APT-1011 3 mg HS Part 1
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hodgkin's disease †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Nervous system disorders			
Status epilepticus †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Renal and urinary disorders			
Ureterolithiasis †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)

† Indicates events were collected by systematic assessment

1 Term from vocabulary, MedDRA 22.0

Other (Not Including Serious) Adverse Events

Frequency Threshold for Reporting Other Adverse Events	0%

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Arm/Group Title	APT-1011 1.5 mg HS Part 1	APT-1011 1.5 mg BID Part 1	APT-1011 3 mg HS Part 1
	Affected / at Risk (%)	Affected / at Risk (%)	Affected / at Risk (%)
Total	13/21 (61.90%)	17/23 (73.91%)	16/21 (76.19%)
Blood and lymphatic system disorders			
Leukopenia †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Neutropenia †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Cardiac disorders			
Atrioventricular block first degree †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Bundle branch block right †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Palpitations †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Congenital, familial and genetic disorders			
Gilbert's syndrome †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Ear and labyrinth disorders			
Deafness bilateral †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Ear pain †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)

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Middle ear effusion †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Endocrine disorders			
Adrenal suppression †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Hypothyroidism †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Gastrointestinal disorders			
Dyspepsia †1	1/21 (4.76%)	1/23 (4.35%)	2/21 (9.52%)
Diarrhoea †1	0/21 (0.00%)	0/23 (0.00%)	2/21 (9.52%)
Nausea †1	0/21 (0.00%)	1/23 (4.35%)	1/21 (4.76%)
Flatulence †1	1/21 (4.76%)	1/23 (4.35%)	0/21 (0.00%)
Erosive oesophagitis †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Vomiting †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Abdominal pain †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Gastrooesophageal reflux disease †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)
Oesophagitis †1	0/21 (0.00%)	0/23 (0.00%)	2/21 (9.52%)
Toothache †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)

Abdominal pain upper †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Dysphagia †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Gastritis erosive †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Hiatus hernia †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Odynophagia †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Abdominal discomfort †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Abdominal distension †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Abdominal pain lower †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Angular cheilitis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Constipation †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Diarrhoea haemorrhagic †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Faeces pale †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Faeces soft †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)

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Gastric mucosa erythema †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Gastric polyps †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Gastritis haemorrhagic †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Glossodynia †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)
Haemorrhoids thrombosed †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Oesophageal food impaction †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)
Oesophageal ulcer †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Oral pain †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Paraesthesia oral †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)
Stomatitis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
General disorders			
Fatigue †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Chills †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Early satiety †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)

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Face oedema †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Gait disturbance †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Generalized oedema †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Influenza like illness †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Non-cardiac chest pain †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Oedema peripheral †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Pain †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Peripheral swelling †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Pyrexia †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Temperature regulation disorder †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Hepatobiliary disorders			
Hepatic steatosis †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Immune system disorders			
Seasonal allergy †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Infections and infestations			

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Nasopharyngitis †1	3/21 (14.29%)	3/23 (13.04%)	2/21 (9.52%)
Oeseophageal candidiasis †1	0/21 (0.00%)	2/23 (8.70%)	0/21 (0.00%)
Oral candidiasis †1	0/21 (0.00%)	2/23 (8.70%)	1/21 (4.76%)
Upper respiratory tract infection †1	0/21 (0.00%)	1/23 (4.35%)	1/21 (4.76%)
Gastroenteritis †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Urinary tract infection †1	0/21 (0.00%)	1/23 (4.35%)	1/21 (4.76%)
Viral upper respiratory tract infection †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Influenza †1	0/21 (0.00%)	1/23 (4.35%)	1/21 (4.76%)
Pharyngitis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Sinusitis †1	1/21 (4.76%)	0/23 (0.00%)	1/21 (4.76%)
Vulvovaginal mycotic infection †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Gastroenteritis viral †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Oropharyngeal candidiasis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)

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Acute sinusitis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Bacterial vaginosis †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Bronchitis †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)
Cellulitis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Conjunctivitis viral †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Ear infection †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Epididymitis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Fungal infection †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Gastrointestinal viral infection †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Genital infection fungal †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Helicobacter infection †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Impetigo †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Infectious mononucleosis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Kidney infection †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)

Oral infection †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Otitis media †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Respiratory tract infection †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Tinea infection †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Tooth abscess †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Viral infection †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Injury, poisoning and procedural complications			
Skin laceration †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Muscle strain †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Arthropod bite †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Back injury †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Concussion †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Contusion †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)
Corneal abrasion †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Eye injury †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)

Hand fracture †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Limb injury †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Muscle rupture †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Road traffic accident †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Tooth fracture †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Wound †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Investigations			
Cortisol decreased †1	0/21 (0.00%)	2/23 (8.70%)	1/21 (4.76%)
Aspartate aminotransferase increased †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Alanine aminotransferase increased †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Blood glucose increased †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Protein urine present †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)

ACTH stimulation test abnormal †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Blood bilirubin increased †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Blood creatinine increased †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Blood pressure increased †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Electrocardiogram QRS complex prolonged †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Electrocardiogram QT prolonged †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Heart rate increased †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Lymphocyte count increased †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Neutrophil count decreased †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Neutrophil percentage decreased †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)

Weight increased †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Metabolism and nutrition disorders			
Appetite disorder †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Dehydration †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Glucose tolerance impaired †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Hypercholesterolaemia †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Hypovitaminosis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Type 2 diabetes mellitus †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Musculoskeletal and connective tissue disorders			
Back pain †1	2/21 (9.52%)	0/23 (0.00%)	1/21 (4.76%)
Arthralgia †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Pain in extremity †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Muscle spasms †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Myalgia †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Arthritis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)

Flank pain †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Joint effusion †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Joint swelling †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)
Musculoskeletal chest pain †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Neck pain †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)
Rotator cuff syndrome †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Tendonitis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Tenosynovitis stenosans †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cartilage neoplasm †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Nervous system disorders			
Headache †1	1/21 (4.76%)	1/23 (4.35%)	1/21 (4.76%)
Migraine †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Carpal tunnel syndrome †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)

Cervical radiculopathy †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Dizziness †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Somnolence †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Syncope †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Taste disorder †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Psychiatric disorders			
Anxiety †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Depression †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Insomnia †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Depressed mood †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Libido decreased †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Post-traumatic stress disorder †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)
Stress †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Renal and urinary disorders			
Hypertonic bladder †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)

Nephrolithiasis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Proteinuria †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Reproductive system and breast disorders			
Prostatitis †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Benign prostatic hyperplasia †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Epididymal cyst †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Erectile dysfunction †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Genital rash †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Gynaecomastia †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Menstruation irregular †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Pelvic discomfort †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Peyronie's disease †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain †1	2/21 (9.52%)	0/23 (0.00%)	0/21 (0.00%)
Nasal congestion †1	2/21 (9.52%)	0/23 (0.00%)	0/21 (0.00%)

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Cough †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Aspiration †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Asthma †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Dyspnoea †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Hyperventilation †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Laryngeal inflammation †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Oropharyngeal spasm †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Pulmonary congestion †1	1/21 (4.76%)	0/23 (0.00%)	0/21 (0.00%)
Sinus congestion †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Tonsillolith †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Skin and subcutaneous tissue disorders			
Ingrowing nail †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Rash †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Acne †1	0/21 (0.00%)	0/23 (0.00%)	1/21 (4.76%)

Cutaneous calcification †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Dermatitis contact †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Pityriasis rosea †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)
Pruritus allergic †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Rash vesicular †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Rosacea †1	0/21 (0.00%)	0/23 (0.00%)	0/21 (0.00%)
Vascular disorders			
Hypertension †1	0/21 (0.00%)	1/23 (4.35%)	0/21 (0.00%)

† Indicates events were collected by systematic assessment

1 Term from vocabulary, MedDRA 22.0

Limitations and Caveats

[Not Specified]

Collaborators and Investigators

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This is where you will find people and organizations involved with this study.

Sponsor

Adare Pharmaceuticals, Inc.

Investigators

- Study Director: Peter C Richardson, Adare Pharmaceuticals, Inc.

Publications

From PubMed

These publications come from PubMed, a public database of scientific and medical articles. This list is automatically created by ClinicalTrials.gov Identifier (NCT Number), and these articles may or may not be about the study.

- Dellon ES, Lucendo AJ, Schlag C, Schoepfer AM, Falk GW, Eagle G, Nezamis J, Comer GM, Knoop K, Hirano I. Fluticasone Propionate Orally Disintegrating Tablet (APT-1011) for Eosinophilic Esophagitis: Randomized Controlled Trial. Clin Gastroenterol Hepatol. 2022 Nov;20(11):2485-2494.e15. doi: 10.1016/j.cgh.2022.02.013. Epub 2022 Feb 16. (https://pubmed.ncbi.nlm.nih.gov/35181572)

More Information

Record History

Certain Agreements

Principal Investigators are NOT employed by the organization sponsoring the study.

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There IS an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed

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