IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: Alexis HOWERTON ; Hal GERBER Serial No.: 17/081,694 Filing Date: 27-Oct-2020 Patent No.: 11,304,950 Issue Date: 19-Apr-2022 Title: **METHODS FOR TREATING TESTICULAR AND OVARIAN ADRENAL REST TUMORS**	Confirmation No.: 4191

REQUEST FOR CERTIFICATE OF CORRECTION OF THE ISSUED PATENT FOR PATENT OFFICE AND APPLICANT MISTAKES (37 C.F.R. §1.322 and 37 C.F.R. §1.323)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
ATTN: Certificate of Correction Branch

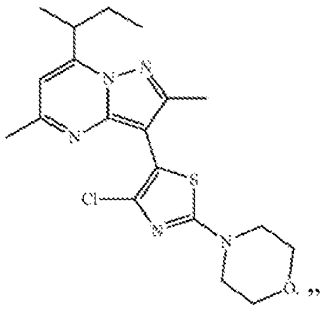
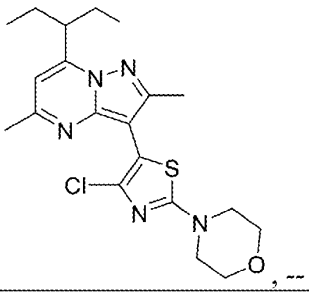
Commissioner:

It is noted that an error of a minor nature or character appears in this patent due to a mistake on the part of the Office, as more fully described below. The Patentee believes that correction thereof does not involve such changes in the patent as would constitute new matter or would require re-examination of the patent. A certificate of correction is therefore requested.

Attached hereto is Form PTO/SB/44 which is suitable for printing.

MISTAKES ON THE PART OF THE OFFICE:

In reviewing the issued Patent, Applicant noted the following errors, which Applicant believes is attributable to the Patent Office. The changes requested are located in the issued Patent at:

Requested Corrections	**Support for Corrections found at the Prosecution File History, for instance, at**
Column 6, lines 4-18 Please delete  “ and insert  --	Paragraph [0020] of the specification as filed on October 27, 2020
Column 92, lines 63-65 Please delete “Diagnosis of TART via testicular ultrasound and/or magnetic resonance imaging (MRI) at screening with 21 lesion(s) measuring ≥ 2 cm in diameter” and insert --Diagnosis of TART via testicular ultrasound and/or magnetic resonance imaging (MRI) at screening with ≥ 1 lesion(s) measuring ≥ 2 cm in diameter--	Paragraph [0301] of the specification as filed on October 27, 2020

Column 94, lines 6-9 Please delete "This includes a screening period of 54 weeks, a treatment period of 12 weeks, and a safety follow-up period of 4 weeks." and insert --This includes a screening period of ≤4 weeks, a treatment period of 12 weeks, and a safety follow-up period of 4 weeks.--	Paragraph [0302] of the specification as filed on October 27, 2020

MISTAKES ON THE PART OF THE APPLICANT:

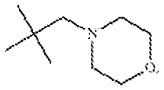
In reviewing the issued Patent, Applicant noted the following errors, which Applicant believes is not attributable to the Patent Office. The changes requested are located in the issued Patent at:

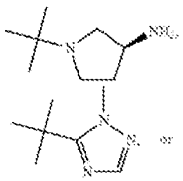
Requested Corrections	**Support for Corrections found at the Prosecution File History, for instance, at**
Column 10, lines 19-20 Please delete "[Subject 003001 (A); Subject 007002 (B)]." and insert --[Patient 10 (A); Patient 8 (B)].--	FIG. 5A and FIG. 5B of the drawings as filed October 27, 2020
Column 10, lines 26-27 Please delete "[Subject 003001 (A); Subject 007002 (B)]." and insert --[Patient 10 (A); Patient 8 (B)].--	FIG. 7A and FIG. 7B of the drawings as filed October 27, 2020
Column 10, lines 33-34 Please delete "[Subject 003001 (A); Subject 007002 (B)]." and insert --[Patient 10 (A); Patient 8 (B)].--	FIG. 9A and FIG. 9B of the drawings as filed October 27, 2020
Column 10, lines 46-48 Please delete "FIG. 12A-12B. Graphic representation of ACTH levels (A) and 17-OHP levels (B) after treatment with a CRF_1 antagonist (Compound 1)." and insert --FIG. 12A-12B. Graphic representation of ACTH levels (A) and 17-OHP levels (B) after treatment with a CRF_1 antagonist.--	FIG. 12A-12B of the drawings as filed October 27, 2020; paragraph [0326] of the specification as filed October 27, 2020

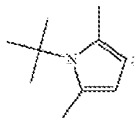
Column 10, lines 51-52 Please delete "FIG. 14 depicts the proof of concept and escalating QD dosing at 10 pm." and insert --FIG. 14 depicts the proof of concept and escalating QD dosing at 10 pm for Cohort A and the single dose level and BID dosing at 10 am and 10 pm for Cohort B.--	FIG. 14 of the drawings as filed October 27, 2020
Column 90, lines 56-61 Please delete "This mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-hydroxyprogesterone (17-OHP) in subjects with CAH." and insert --This mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-hydroxyprogesterone (17-OHP) in subjects with CAH (FIG. 12A-12B).--	FIG. 12A-12B of the drawings as filed October 27, 2020; paragraph [0326] of the specification as filed October 27, 2020
Column 94, lines 50-54 Please delete "In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH." and insert --In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH (FIG. 12A-12B).--	FIG. 12A-12B of the drawings as filed October 27, 2020; paragraph [0326] of the specification as filed October 27, 2020

Column 96, lines 14-18 Please delete "In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH." and insert --In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH (FIG. 12A-12B).--	FIG. 12A-12B of the drawings as filed October 27, 2020; paragraph [0326] of the specification as filed October 27, 2020
Column 97, lines 27-28 Please delete "FIGS. 12A-12B demonstrate single pill of CRF_1 receptor antagonist improves ACTH and 17-OHP in CAH patients." and insert --FIGS. 12A-12B demonstrate single pill of CRF_1 receptor antagonist (i.e., as described in US 2017/0020877 A1) improves ACTH and 17-OHP in CAH patients.--	US 2017/0020877 A1 cited in information disclosure statement filed February 22, 2021; paragraph [0317] of the specification as filed October 27, 2020
Column 99, Table 2 Please delete "200 mg BID (Weed 2)" and insert --200 mg BID (Week 2)--	FIG. 15B, FIG. 16B, and FIG. 17B of the drawings as filed October 27, 2020

Column 2, lines 39-62
Please delete







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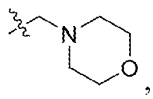
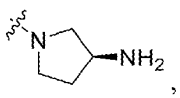
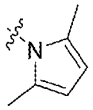
--  ,  , , or  ;--

Column 3, lines 6-11
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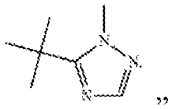

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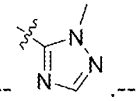

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Column 4, lines 19-24
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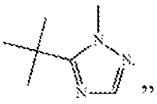

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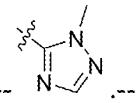

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Column 5, lines 19-24

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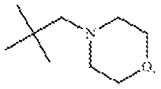

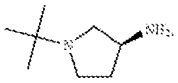

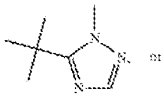

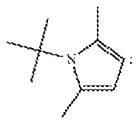

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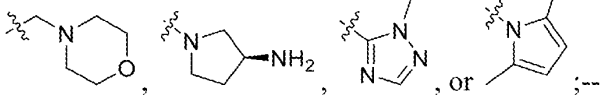

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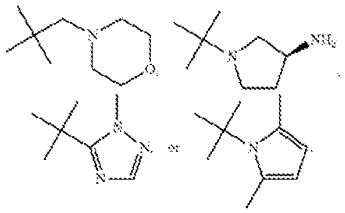
Column 42, lines 26-36



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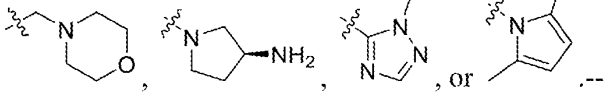

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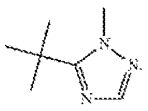
Column 42, lines 49-54
Please delete

“  ”

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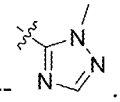
--  --

Column 51, lines 35-58
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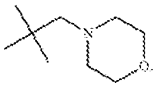

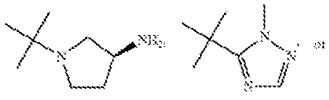

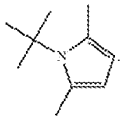

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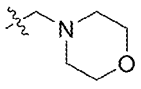
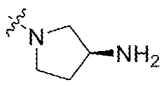
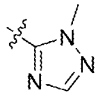
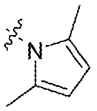
--  ,  ,  , or  --

Column 54, lines 29-34
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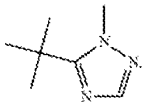
“  ”

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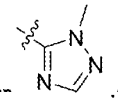
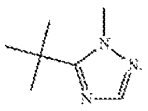
--  --

Column 54, lines 39-44
Please delete



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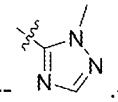
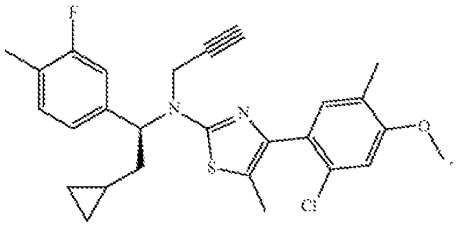


Column 82, lines 57-67
Please delete



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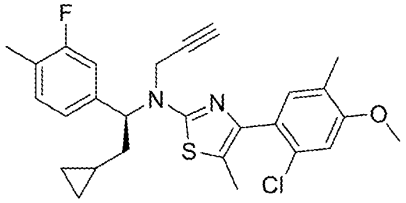
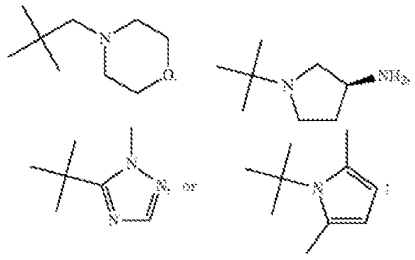


Column 97, line 6
Please delete
"andreogen production"
and insert
--androgen production--

Column 100, lines 37-47, claim 1
Please delete



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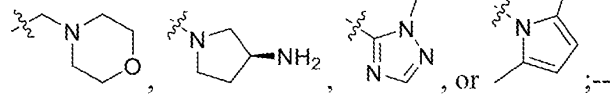
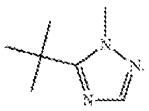
--  ;--

Column 100, lines 61-64, claim 8
Please delete



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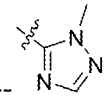
--  .--

Column 101, lines 5-9, claim 9
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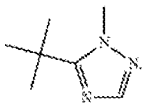

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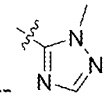
--  .--

FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees, or credit any overpayment to Deposit Account No. 23-2415 (Docket No. 50535-710.301).

Respectfully submitted,
WILSON SONSINI GOODRICH & ROSATI
A Professional Corporation

Date: March 12, 2025

By: /Kaia R. Parenti/
Kaia R. Parenti
Registration No. 81,050

650 Page Mill Road
Palo Alto, CA 94304
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Customer No. 21971

PTO/SB/44 (09-07)
Approved for use through 03/31/2023. OMB 0651-0033
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(Also Form PTO-1050)

UNITED STATES PATENT AND TRADEMARK OFFICE
CERTIFICATE OF CORRECTION

PATENT NO. : 11,304,950

Page 1 of 8

APPLICATION NO. : 17/081,694

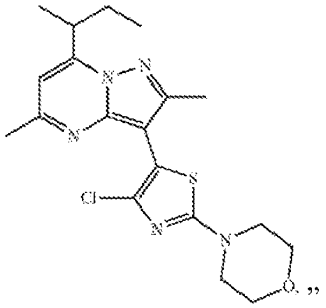
ISSUE DATE : April 19, 2022

INVENTOR(S) : Alexis HOWERTON ; Hal GERBER

It is certified that an error appears, or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below.

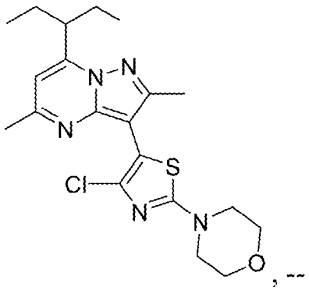
Column 6, lines 4-18

Please delete



“ ”

and insert



-- --

Column 92, lines 63-65

Please delete

“Diagnosis of TART via testicular ultrasound and/or magnetic resonance imaging (MRI) at screening with 21 lesion(s) measuring ≥ 2 cm in diameter”

and insert

--Diagnosis of TART via testicular ultrasound and/or magnetic resonance imaging (MRI) at screening with ≥ 1 lesion(s) measuring ≥ 2 cm in diameter--

Column 94, lines 6-9
Please delete
"This includes a screening period of 54 weeks, a treatment period of 12 weeks, and a safety follow-up period of 4 weeks."
and insert
--This includes a screening period of ≤4 weeks, a treatment period of 12 weeks, and a safety follow-up period of 4 weeks.--

Column 10, lines 19-20
Please delete
"[Subject 003001 (A); Subject 007002 (B)]."
and insert
--[Patient 10 (A); Patient 8 (B)].--

Column 10, lines 26-27
Please delete
"[Subject 003001 (A); Subject 007002 (B)]."
and insert
--[Patient 10 (A); Patient 8 (B)]. --

Column 10, lines 33-34
Please delete
"[Subject 003001 (A); Subject 007002 (B)]."
and insert
--[Patient 10 (A); Patient 8 (B)].--

Column 10, lines 46-48
Please delete
"FIG. 12A-12B. Graphic representation of ACTH levels (A) and 17-OHP levels (B) after treatment with a CRF_1 antagonist (Compound 1)."
and insert
--FIG. 12A-12B. Graphic representation of ACTH levels (A) and 17-OHP levels (B) after treatment with a CRF_1 antagonist.--

Column 10, lines 51-52
Please delete
"FIG. 14 depicts the proof of concept and escalating QD dosing at 10 pm."
and insert
--FIG. 14 depicts the proof of concept and escalating QD dosing at 10 pm for Cohort A and the single dose level and BID dosing at 10 am and 10 pm for Cohort B.--

Column 90, lines 56-61
Please delete
"This mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-hydroxyprogesterone (17-OHP) in subjects with CAH."
and insert

--This mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-hydroxyprogesterone (17-OHP) in subjects with CAH (FIG. 12A-12B).--

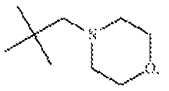
Column 94, lines 50-54
Please delete
"In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH."
and insert
--In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH (FIG. 12A-12B).--

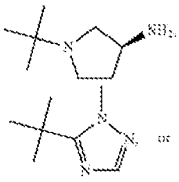
Column 96, lines 14-18
Please delete
"In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH."
and insert
--In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH (FIG. 12A-12B).--

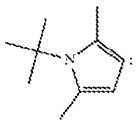
Column 97, lines 27-28
Please delete
"FIGS. 12A-12B demonstrate single pill of CRF_1 receptor antagonist improves ACTH and 17-OHP in CAH patients."
and insert
--FIGS. 12A-12B demonstrate single pill of CRF_1 receptor antagonist (i.e., as described in US 2017/0020877 A1) improves ACTH and 17-OHP in CAH patients.--

Column 99, Table 2
Please delete
"200 mg BID
(Weed 2)"
and insert
--200 mg BID
(Week 2)--

Column 2, lines 39-62
Please delete

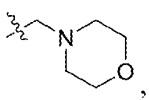
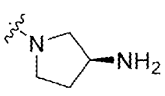
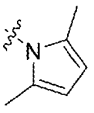






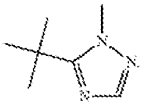
“ ”

and insert

--  ,  , , or  ;--

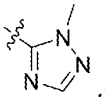
Column 3, lines 6-11

Please delete



“ ”

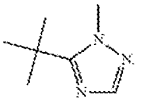
and insert



-- .--

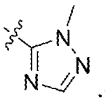
Column 4, lines 19-24

Please delete



“ ”

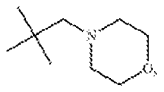
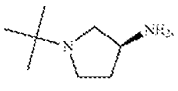
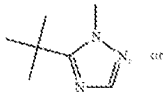
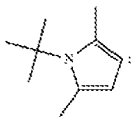
and insert



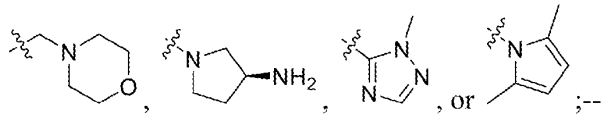
-- .--

Column 5, lines 19-24

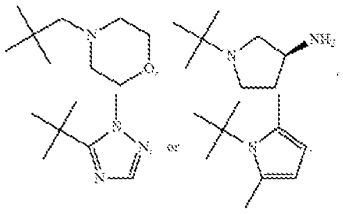
Please delete





“ ”

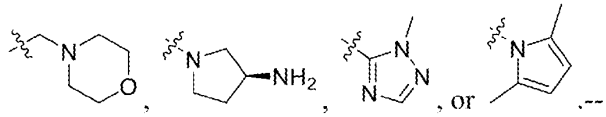
and insert


--, , , or ;--

Column 42, lines 26-36

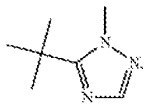

Please delete “ ”

and insert

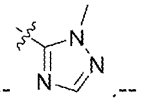

--, , , or .--

Column 42, lines 49-54

Please delete

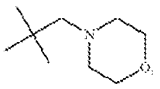

“ ”

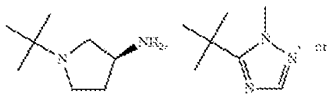
and insert

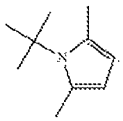

--.--

Column 51, lines 35-58

Please delete

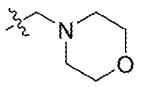
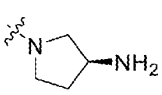
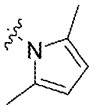






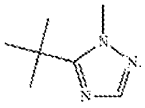
“ ”

and insert

--  ,  , , or  .--

Column 54, lines 29-34

Please delete

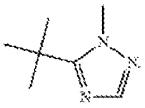
“  ”

and insert

-- .--

Column 54, lines 39-44

Please delete

“  ”

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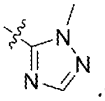
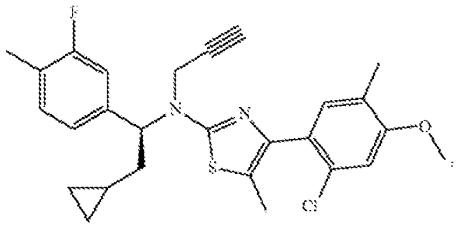
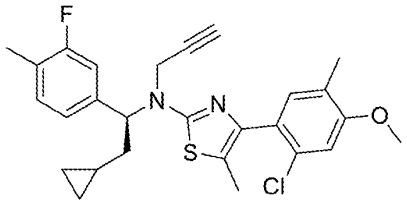
--  .--

Column 82, lines 57-67

Please delete

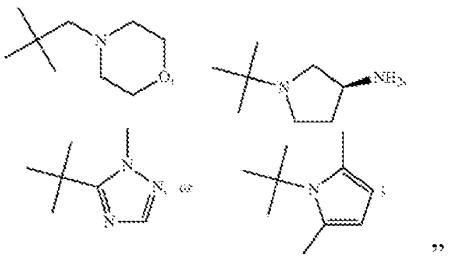
“  ”

and insert

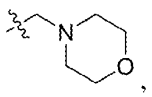
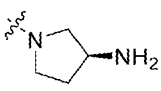
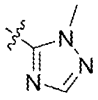
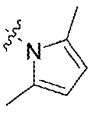
--  , --

Column 97, line 6
Please delete
“andreogen production”
and insert
--androgen production--

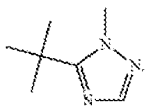
Column 100, lines 37-47, claim 1
Please delete

“  ”

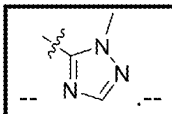
and insert

--  ,  ,  , or  ;--

Column 100, lines 61-64, claim 8
Please delete

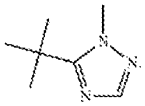
“  ”

and insert



Column 101, lines 5-9, claim 9

Please delete



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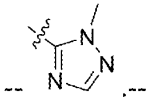

MAILING ADDRESS OF SENDER: (Please do not use customer number below)
Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto, CA 94304

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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ELECTRONIC ACKNOWLEDGEMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/081,694	**03/12/2025 06:39:22 PM Z ET**	**50535-710.301**

Title of Invention

METHODS FOR TREATING TESTICULAR AND OVARIAN ADRENAL REST TUMORS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	11304950
CONFIRMATION #	4191	FILED BY	Colleen Mensching
PATENT CENTER #	69556979	FILING DATE	10/27/2020
CUSTOMER #	21971	FIRST NAMED INVENTOR	Alexis HOWERTON
CORRESPONDENCE ADDRESS	-	AUTHORIZED BY	Kaia Parenti

Documents

TOTAL DOCUMENTS: 1

DOCUMENT	PAGES	DESCRIPTION	SIZE (KB)
Spruce 50535-710.301 - Request for Certificate of Correction of Patent.pdf	19	Request for Certificate of Correction	8501 KB

Digest

DOCUMENT	MESSAGE DIGEST(SHA-512)
Spruce 50535-710.301 - Request for Certificate of Correction of Patent.pdf	850CB891755A087115814E27ADC34579CC5BE4515CE3CA9B0C9AB25D1277E9D3CDF608B95374416445D8B785DB058F768940754B6CE1FA81B84B31BB485F1C71

This Acknowledgement Receipt evidences receipt on the noted date by the USPTO of the indicated documents, characterized by the applicant, and including page counts, where applicable. It serves as evidence of receipt similar to a Post Card, as described in MPEP 503.

New Applications Under 35 U.S.C. 111

If a new application is being filed and the application includes the necessary components for filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application

National Stage of an International Application under 35 U.S.C. 371

If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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ELECTRONIC PAYMENT RECEIPT

APPLICATION #	RECEIPT DATE / TIME	ATTORNEY DOCKET #
17/081,694	**03/12/2025 06:39:22 PM Z ET**	**50535-710.301**

Title of Invention

METHODS FOR TREATING TESTICULAR AND OVARIAN ADRENAL REST TUMORS

Application Information

APPLICATION TYPE	Utility - Nonprovisional Application under 35 USC 111(a)	PATENT #	11304950
CONFIRMATION #	4191	FILED BY	Colleen Mensching
PATENT CENTER #	69556979	AUTHORIZED BY	Kaia Parenti
CUSTOMER #	21971	FILING DATE	10/27/2020
CORRESPONDENCE ADDRESS	-	FIRST NAMED INVENTOR	Alexis HOWERTON

Payment Information

PAYMENT METHOD	PAYMENT TRANSACTION ID	PAYMENT AUTHORIZED BY
DA / 232415	**E20253BI40267900**	**Colleen Mensching**

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If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage

submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.

New International Application Filed with the USPTO as a Receiving Office

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
17/081,694	10/27/2020	Alexis HOWERTON	50535-710.301	4191

21971 7590 06/17/2025

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650 PAGE MILL ROAD
PALO ALTO, CA 94304-1050

EXAMINER	
PIHONAK, SARAH	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
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APPLICATION NO.	ISSUE DATE	PATENT NO.
17/081,694	17-Jun-2025	11304950

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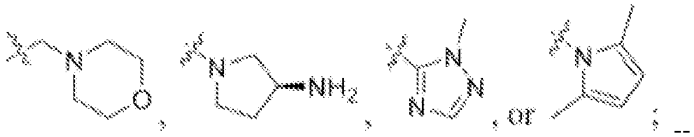
CERTIFICATE OF CORRECTION

PATENT NO. : 11,304,950 B2
APPLICATION NO. : 17/081694
DATED : April 19, 2022
INVENTOR(S) : Alexis Howerton and Hal Gerber

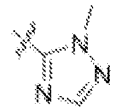
It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In the Specification

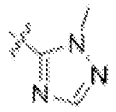
Column 2, Lines 39-62 should read:

--  --

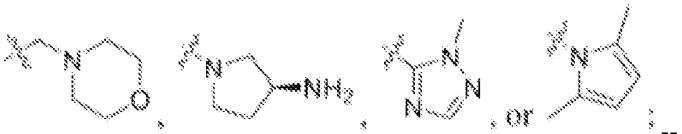
Column 3, Lines 6-11 should read:

--  --

Column 4, Lines 19-24 should read:

--  --

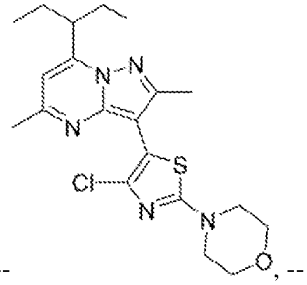
Column 5, Lines 19-24 should read:

--  --

Signed and Sealed this
Seventeenth Day of June, 2025

Coke Morgan Stewart
Acting Director of the United States Patent and Trademark Office

Column 6, Lines 4-18 should read:



--, --

Column 10, Lines 19-20 Please delete:
"[Subject 003001 (A); Subject 007002 (B)]."
And insert:
--[Patient 10 (A); Patient 8 (B)].--

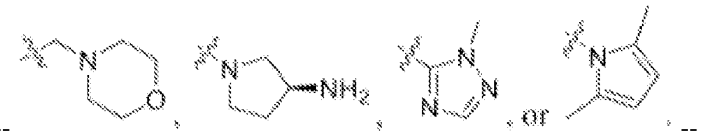
Column 10, Lines 26-27 Please delete:
"[Subject 003001 (A); Subject 007002 (B)]."
And insert:
--[Patient 10 (A); Patient 8 (B)].--

Column 10, Lines 33-34 Please delete:
"[Subject 003001 (A); Subject 007002 (B)]."
And insert:
--[Patient 10 (A); Patient 8 (B)].--

Column 10, Lines 46-48 Please delete:
"FIG. 12A-12B. Graphic representation of ACTH levels (A) and 17-OHP levels (B) after treatment with a CRF_1 antagonist (Compound 1)."
And insert:
--FIG. 12A-12B. Graphic representation of ACTH levels (A) and 17-OHP levels (B) after treatment with a CRF_1 antagonist.--

Column 10, Lines 51-52 Please delete:
"FIG. 14 depicts the proof of concept and escalating QD dosing at 10 pm."
And insert:
--FIG. 14 depicts the proof of concept and escalating QD dosing at 10 pm for Cohort A and the single dose level and BID dosing at 10 am and 10 pm for Cohort B.--

Column 42, Lines 26-36 should read:



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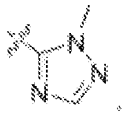
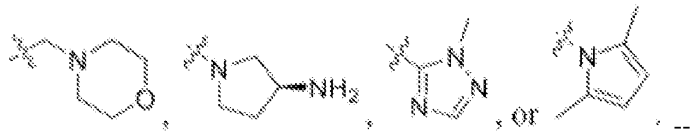
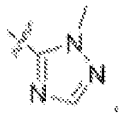
Column 42, Lines 49-54 should read:

--  --

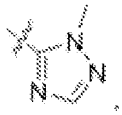
Column 51, Lines 35-58 should read:

--  --

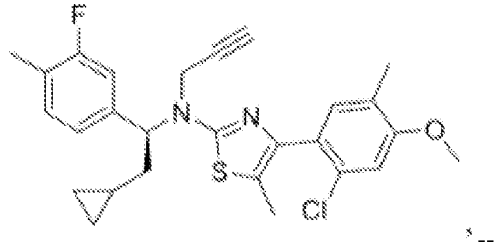
Column 54, Lines 29-34 should read:

--  --

Column 54, Lines 39-44 should read:

--  --

Column 82, Lines 57-67 should read:

--  --

Column 90, Lines 56-61 Please delete:
"This mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-hydroxyprogesterone (17-OHP) in subjects with CAH."
And insert:
--This mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-hydroxyprogesterone (17-OHP) in subjects with CAH (FIG. 12A-12B).--

Column 92, Lines 63-65 Please delete:
"Diagnosis of TART via testicular ultrasound and/or magnetic resonance imaging (MRI) at screening with 21 lesion(s) measuring $\geq$ 2 cm in diameter"

And insert:
--Diagnosis of TART via testicular ultrasound and/or magnetic resonance imaging (MRI) at screening with ≥ 1 lesion(s) measuring ≥ 2 cm in diameter--

Column 94, Lines 6-9 Please delete:
"This includes a screening period of 54 weeks, a treatment period of 12 weeks, and a safety follow-up period of 4 weeks."
And insert:
--This includes a screening period of ≤4 weeks, a treatment period of 12 weeks, and a safety follow-up period of 4 weeks.--

Column 94, Lines 50-54 Please delete:
"In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH."
And insert:
--In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH (FIG. 12A-12B).--

Column 96, Lines 14-18 Please delete:
"In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH."
And insert:
--In CAH, this mechanism of action has been validated in a previous proof-of-concept study using a similar small-molecule CRF_1 receptor antagonist, which produced dose-dependent reductions in ACTH and 17-OHP in subjects with CAH (FIG. 12A-12B).--

Column 97, Line 6 Please delete:
"andreogen production"
And insert:
--androgen production--

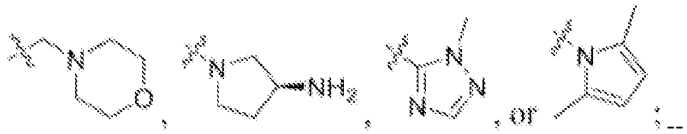
Column 97, Lines 27-28 Please delete:
"FIGS. 12A-12B demonstrate single pill of CRF_1 receptor antagonist improves ACTH and 17-OHP in CAH patients."
And insert:
--FIGS. 12A-12B demonstrate single pill of CRF_1 receptor antagonist (i.e., as described in US 2017/0020877 A1) improves ACTH and 17-OHP in CAH patients.--

Column 99, Table 2 Please delete:
"200 mg BID
(Weed 2)"

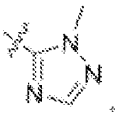
And insert:
--200 mg BID
(Week 2)--

In the Claims

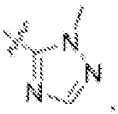
Column 100, Lines 34-47, Claim 1 should read:

--  --

Column 100, Lines 61-64, Claim 8 should read:

--  --

Column 101, Lines 5-9, Claim 9 should read:

--  --