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**APPLICATION NUMBER: 14/409,493
FILING DATE: *December 19, 2014*
PATENT NUMBER: 9764003
ISSUE DATE: *September 19, 2017***



Certified by

Kathi

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Under Secretary of Commerce
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Notice of References Cited	Application/Control No. 14/409,493		Applicant(s)/Patent Under Reexamination JENSEN ET AL.	
	Examiner KRISTINA M. HELLMAN		Art Unit 1675	Page 1 of 2

U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
	A	US-				
	B	US-				
	C	US-				
	D	US-				
	E	US-				
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FOREIGN PATENT DOCUMENTS

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NON-PATENT DOCUMENTS

*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)				
	U	Kim et al., "Effects of once-weekly dosing of a long-acting release formulation of exenatide on glucose control and body weight in subjects with type 2 diabetes," Diabetes Care 30:1487-1493 (2007)				
	V	Bydureon NDA 022200/S-008 package information, pp. 1-179 (Feb. 2014)				
	W	Clinical Trial NCT00696657, entitled "A Randomised Controlled Clinical Trial in Type 2 Diabetes Comparing Semaglutide to Placebo and Liraglutide," pp. 1-5 (3/11/2015) - accessed 9/24/15 at URL clinicaltrials.gov/archive/NCT00696657/2011_03_25				
	X	Lau et al., "Discovery of the once-weekly glucagon-like peptide-1 (GLP-1) analogue semaglutide," J. Med. Chem. 58:7370-7380 (2015)				

*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).)
Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

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*		Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages)
	U	Eperzan assessment report, Euro. Med. Agency, pp. 1-124 (2014)- accessed 9/24/2015 at URL: ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/002735/WC500165119.pdf
	V	Trulicity assessment report, Euro. Med. Agency, pp. 1-172 (2014)- accessed 9/24/2015 at URL: ema.europa.eu/docs/en_GB/document_library/EPAR_-_Public_assessment_report/human/002825/WC500179473.pdf)
	W	
	X	

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← History of this study ↑ Current version of this study

View of NCT00696657 on 2011_03_25

ClinicalTrials Identifier: NCT00696657

Updated: 2011_03_25

Descriptive Information

Brief title A Randomised Controlled Clinical Trial in Type 2 Diabetes Comparing Semaglutide to Placebo and Liraglutide

Official title Investigation of Safety and Efficacy of Five Doses of Semaglutide Versus Placebo and Open-label Liraglutide, as Add on Therapy, in Subjects Diagnosed With Type 2 Diabetes Currently Treated With Metformin or Controlled With Diet and Exercise A 12 Week Multi-centre, Multi National, Double-blind, Placebo-controlled, Randomised, Nine Armed Parallel Group, Dose Finding Trial

Brief summary

This trial was conducted in Europe,Asia and Africa.
Study participants were randomised evenly to treatment with semaglutide (0.1 mg QW - 1.6 mg QW, 6 treatment arms, placebo or liraglutide (1.2 mg QD, or 1.8 mg QD).Treatment allocation to semaglutide or placebo was double-blind, whereas liraglutide treatment was administered open-label.Primary efficacy parameter was HbA1c and the treatment duration was 12 weeks.

Detailed description

Phase Phase 2

Study type Interventional

Study design Treatment

Study design Randomized

Study design Double Blind (Subject, Investigator)

Study design Placebo Control

Study design Parallel Assignment

Study design Safety/Efficacy Study

Primary outcome Measure: HbA1c
Time Frame: after 12 weeks of treatment
Safety Issue? No

Secondary outcome Measure: Percentage of subjects with an adverse events
Time Frame: after 12 weeks of treatment
Safety Issue? No

Secondary outcome Measure: Percentage of subjects with hypoglycaemic episode
Time Frame: after 12 weeks of treatment
Safety Issue? No

Secondary outcome Measure: Change from baseline in ECG

	Time Frame: week 0, week 12
	Safety Issue? No
Secondary outcome	Measure: Change from baseline in vital signs (Pulse)
	Time Frame: week 0, week 12
	Safety Issue? No
Secondary outcome	Measure: Change from baseline in vital signs (blood pressure)
	Time Frame: week 0, week 12
	Safety Issue? No
Secondary outcome	Measure: Change from baseline in standard safety laboratory parameters (haematology)
	Time Frame: week 0, week 12
	Safety Issue? No
Secondary outcome	Measure: Change from baseline in standard safety laboratory parameters (biochemistry)
	Time Frame: week 0, week 12
	Safety Issue? No
Secondary outcome	Measure: Change from baseline in standard safety laboratory parameters (urinalysis)
	Time Frame: week 0, week 12
	Safety Issue? No
Secondary outcome	Measure: Change from baseline in calcitonin
	Time Frame: week 0, week 12
	Safety Issue? No
Secondary outcome	Measure: Percentage of subjects developing anti-semaglutide antibodies
	Time Frame: after 12 weeks of treatment
	Safety Issue? No
Enrollment	415 (Actual)
Condition	Diabetes Mellitus, Type 2
Arm/Group	Arm Label: A Experimental
Arm/Group	Arm Label: B Experimental
Arm/Group	Arm Label: C Experimental
Arm/Group	Arm Label: D Experimental
Arm/Group	Arm Label: E Experimental
Arm/Group	Arm Label: F Experimental
Arm/Group	Arm Label: G1 Placebo Comparator
Arm/Group	Arm Label: G2 Placebo Comparator
Arm/Group	Arm Label: G3 Placebo Comparator
Arm/Group	Arm Label: G4 Placebo Comparator

Arm/Group	Arm Label: G5	Placebo Comparator
Arm/Group	Arm Label: G6	Placebo Comparator
Arm/Group	Arm Label: H	Experimental
Arm/Group	Arm Label: I	Experimental
Intervention	Drug: semaglutide	Arm Label: A
	0.1 mg, once weekly, s.c. injection	
Intervention	Drug: semaglutide	Arm Label: B
	0.2 mg, once weekly, s.c. injection	
Intervention	Drug: semaglutide	Arm Label: C
	0.4 mg, once weekly, s.c. injection	
Intervention	Drug: semaglutide	Arm Label: D
	0.8 mg, once weekly, s.c. injection	
Intervention	Drug: semaglutide	Arm Label: E
	0.8 mg with titration, once weekly, s.c. injection	
Intervention	Drug: semaglutide	Arm Label: F
	1.6 mg with titration, once weekly, s.c. injection	
Intervention	Drug: placebo	Arm Label: G1
	0.1 mg, once weekly, s.c. injection	
Intervention	Drug: placebo	Arm Label: G2
	0.2 mg, once weekly, s.c. injection	
Intervention	Drug: placebo	Arm Label: G3
	0.4 mg, once weekly, s.c. injection	
Intervention	Drug: placebo	Arm Label: G4
	0.8 mg with titration, once weekly, s.c. injection	
Intervention	Drug: placebo	Arm Label: G5
	0.8 mg with titration, once weekly, s.c. injection	
Intervention	Drug: placebo	Arm Label: G6
	1.6 mg, once weekly, s.c. injection	
Intervention	Drug: liraglutide	Arm Label: H
	1.2 mg with titration, once daily, s.c. injection	
Intervention	Drug: liraglutide	Arm Label: I
	1.8 mg with titration, once daily, s.c. injection	

URL <http://novonordisk-trials.com>
See also Clinical Trials at Novo Nordisk

Recruitment Information

Status Completed
Start date 2008-06
Last follow-up date 2009-02 (Actual)
Primary completion date 2009-02 (Actual)
Criteria

Inclusion Criteria:

- Men and women-not-of-childbearing potential diagnosed with type 2 diabetes for at least three months
- Stable treatment regimen with either metformin (at least 1500 mg) or diet and exercise alone for at least three months
- HbA1c: 7.0-10.0 % (both inclusive)
- Body weight between 60 kg and 110 kg

Exclusion Criteria:

- Treatment with insulin, GLP-1 receptor agonists (including liraglutide), dipeptidyl peptidase-4 inhibitors, sulphonylurea, thiazolidinediones, Alpha-GIs, or any investigational drug, within the last three months
- Impaired liver or kidney function
- Proliferative retinopathy or maculopathy requiring acute treatment
- Clinically significant active cardiovascular disease and uncontrolled treated/untreated hypertension
- Recurrent major hypoglycaemia or hypoglycaemic unawareness
- Present or planned use of any drug which could interfere with the glucose levels (e.g. systemic corticosteroids)

Gender Both
Minimum age 18 Years
Healthy volunteers No

Administrative Data

Organization name Novo Nordisk
Organization study ID NN9535-1821
Secondary ID 2007-003956-12 (EudraCT Number)
Sponsor Novo Nordisk
Health Authority Austria: Federal Ministry for Health and Women
Health Authority Bulgaria: Bulgarian Drug Agency
Health Authority Finland: Finnish Medicines Agency
Health Authority France: Afssaps - French Health Products Safety Agency
Health Authority Germany: Federal Institute for Drugs and Medical Devices
Health Authority Hungary: National Institute of Pharmacy
Health Authority India: Ministry of Health
Health Authority Italy: National Monitoring Centre for Clinical Trials - Ministry of Health

Health Authority	Serbia: Medicines and Medical Devices Agency of Serbia
Health Authority	South Africa: Medicines Control Council
Health Authority	Spain: Spanish Agency of Medicines
Health Authority	Switzerland: Laws and standards
Health Authority	Turkey: Ministry of Health
Health Authority	United Kingdom: Medicines and Healthcare Products Regulatory Agency

