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

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Notice of References Cited	Application/Control No. 14/409,493	Applicant(s)/Patent Under Reexamination JENSEN ET AL.	
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U.S. PATENT DOCUMENTS

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	CPC Classification	US Classification
	A	US-				
	B	US-				
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*		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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	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	
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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

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