UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO SECTION 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

Date of Report: March 5, 2015

Commission File Number: 001-36815

Ascendis Pharma A/S

(Exact Name of Registrant as Specified in Its Charter)

Tuborg Boulevard 12 DK-2900 Hellerup Denmark (Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F 🗵	Form 40-F	
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Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1):

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7):

Representatives of Ascendis Pharma A/S (the "Company") plan to present the information in the posters attached hereto as Exhibit 99.1 at the ENDO 2015 conference being held at the San Diego Convention Center on Thursday, March 5, 2015 during the Pediatric Endocrinology—Clinical/Translational Session that is being held from 1:00 pm-3:00 pm Pacific time.

The furnishing of the attached presentation is not an admission as to the materiality of any information therein. The information contained in the posters is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the Securities and Exchange Commission (the "SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing or furnishing of other reports or documents with the SEC, through press releases or through other public disclosures.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Ascendis Pharma A/S

Date: March 5, 2015

By: /s/ Thomas P. Soloway

Thomas P. Soloway Senior Vice President, Chief Financial Officer

EXHIBIT INDEX

Exhibit No.	Description
99.1	Company posters dated March 5, 2015.

LBT-078 Six-Month Interim Safety and Efficacy of Different Dose Levels of TransCon hGH Administered Once-weekly Versus Standard Daily Human Growth Hormone Replacement Therapy in Pre-Pubertal Children with Growth Hormone Deficiency (GHD)

Pierre Chatelain¹, MD, Oleg Malievsky², MD, Klaudziya Radziuk³, MD, Heba Hassan Elsedfy⁴, MD,

Evgenia Mikhailova⁵, MD, Michael Beckert⁶, MD

¹University Claude Bernard, Lyon, France, ²Bashkir State Medical University, Ufa, Russia, ³ 2nd Children City Clinic, Minsk, Belarus, ⁴Ain Shams University Hospital, Cairo, Egypt, ⁵Samara State Medical University, Samara, Russia, ⁶Ascendis Pharma A/S, on behalf of the TransCon hGH study group

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Background

TransCon hGH is a long-acting prodrug of recombinant human Growth Hormone (hGH) that releases fully active unmodified hGH into the blood compartment. TransCon hGH was shown in two Phase 1 studies in Healthy Volunteers and a Phase 2 study in adults with GH Deficiency (AGHD) to:

- 1) Be safe and well tolerated,
- 2) Produce dose dependent, predictable levels of growth hormone,
- 3) Be suitable for a once-weekly dosing regimen,
- 4) Provide a pharmacokinetic (PK) hGH and IGF-I pharmacodynamic (PD) response comparable to daily hGH throughout the dosing period.

This interim analysis consists of 25 patients (approximately 50 % of the total enrollment in the study) completing all six months of treatment, and demonstrates that TransCon hGH has a safety and efficacy profile comparable to daily hGH.



Figure 1: The TransCon hGH prodrug consists of hGH transiently bound to a polyethylene glycol carrier molecule *via* a TransCon linker. The released hGH is unmodifed, and designed to maintain the same mode of action and distribution in the body as daily hGH.

Objectives

The objective of this study is to investigate

- 1) Safety and Tolerability,
- 2) Pharmacokinetics and Pharmacodynamics, and
- 3) Efficacy of TransCon hGH

in children with Growth Hormone Deficiency.

Design & Methods

Pre-pubertal, treatment naïve GHD children received s.c. injections of one of three once-weekly TransCon hGH doses (0.14, 0.21 and 0.30 mg hGH/kg/week) or daily hGH (Genotropin[®]; 0.03 mg hGH/kg/day = 0.21 mg/kg/week) over a six-month treatment period, in a randomized, comparator-controlled dose response Phase 2 study. Patient GHD diagnoses were established in accordance with international consensus guidelines, based on auxology (height & height velocity), GH stimulation tests & IGF-I. Children Small for Gestational Age (SGA) were excluded.

Demographics

Mean + SD	All subjects	0.14 mg/ kg/week ACP-001	0.21 mg/ kg/week ACP-001	0.30 mg/ kg/week ACP-001	0.03 mg/ kg/day Genotropin
# Subjects	25	6	6	7	6
Age (Screening;	7.39	7.62	7.29	7.08	7.61
years)	(2.25)	(2.51)	(2.29)	(2.68)	(1.94)
Height SDS	-3.22	-3.23	-2.85	-3.12	-3.71
	(1.02)	(1.48)	(0.47)	(0.72)	(1.22)
GH Stimulation					
Test [ng/mL]	4.50	4.38	5.54	3.34	4.95
(Screening)	(2.91)	(3.03)	(2.62)	(2.57)	(3.62)
IGF-I SDS	-2.43	-2.27	-2.29	-2.41	-2.77
	(0.78)	(0.69)	(0.72)	(0.78)	(1.00)

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Results: Growth

At 6 months (Figure 2B), mean annualized height velocities among the three dosing levels administered weekly ranged from 11.9 cm for the 0.14 mg/kg/week dose to 14.5 cm for the 0.30 mg/kg/week dose, which were comparable to 11.5 cm for the active comparator, daily injections of Genotropin[®] at a 0.21 mg/kg/week dose.

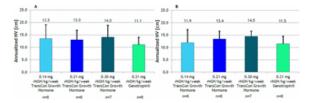


Figure 2: Mean annualized Height Velocity at 3 months (A) and 6 months (B)

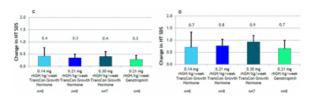


Figure 3: Mean change in HT SDS from baseline to 3 months (C) and 6 months (D)

Results: PK/PD

Maximum hGH blood concentration is comparable between equivalent weekly doses of TransCon Growth Hormone and daily hGH (Figure 4); and a dose-proportional increase in IGF-I levels (SDS) into the normal range (Figure 5) was observed following dosing of the three TransCon Growth Hormone dose levels.

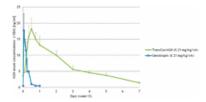


Figure 4: hGH levels for TransCon hGH (0.21 mg rhGH/kg/week) and daily hGH (0.21 mg rhGH/kg/week)

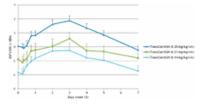


Figure 5: Dose proportional IGF-I SDS elevation into the normal range following dosing of the three TransCon Growth Hormone dose levels

Conclusion

To date, TransCon hGH has demonstrated efficacy and safety comparable to that observed with daily hGH. Injection site reactions have generally been mild and similar to what is expected with daily hGH injections, with no nodule formation or lipoatrophy noted. This TransCon hGH Phase 2 study conducted in a pediatric population confirms the excellent safety and efficacy profile observed in previous clinical trials.

TransCon Human Growth Hormone – a Once-Weekly Prodrug of Recombinant Human Growth Hormone: Design, Characterization and PK/PD in Growth Hormone Deficient (GHD) Adults <u>Kennett Sprogoe, PhD1</u>, Michael Beckert, MD2, David Gilfoyle, DPhil³, Thomas Kurpiers, PhD4, Thomas Wegge, PhD4 and Harald Rau, PhD4 ¹Ascendis Pharma, Inc., ²Ascendis Pharma A/S, on behalf of the TransCon hGH study group, ³Ascendis Pharma A/S, ⁴Ascendis Pharma GmbH

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Background

TransCon hGH is a once-weekly prodrug of recombinant human growth hormone (hGH) intended to improve compliance and treatment outcome of patients requiring growth hormone therapy. TransCon hGH is designed to maintain the same mode of action and distribution within the body as daily administered hGH. TransCon hGH liberates unmodified hGH into the bloodstream *via* a non-enzymatic self-cleaving process relying only on physiological pH and temperature conditions, which ensures predictable release of unmodified hGH. The hGH released from TransCon hGH has been demonstrated to be identical to hGH for daily administration, for which safety and efficacy has been established through decades of therapy. In clinical studies, TransCon hGH has demonstrated an efficacy, safety, tolerability and immunogenic profile that is comparable to that of daily hGH.



Figure 1: The TransCon hGH prodrug consists of hGH transiently bound to a polyethylene glycol carrier molecule *via* a TransCon linker. The released hGH is unmodifed, and designed to maintain the same mode of action and distribution in the body as daily hGH.

Objectives and Methods

To compare the structure and *in vitro* biopotency of growth hormone (GH) released from TransCon hGH with hGH for daily administration, and compare the exposure of hGH released from TransCon hGH with daily administered hGH, together with the resulting IGF-I levels in (Growth Hormone Deficient) GHD adults.

hGH released from TransCon hGH was characterized by high resolution mass spectrometry, circular dichroism, N-terminal amino acid sequencing, peptide mapping and cell based biopotency assays. Pharmacokinetic and pharmacodynamic data of TransCon hGH and daily hGH was obtained in a Phase 2 study in GHD adults.

Results: In vitro

Characterization of hGH released from TransCon hGH (pH 9.0 and 22° C for 48 hours and separated from residual TransCon hGH by size exclusion HPLC) confirmed that it is unmodified and structurally identical to hGH for daily administration. Cell based biopotency assays confirm that full activity of the GH is restored when it is released from the prodrug.

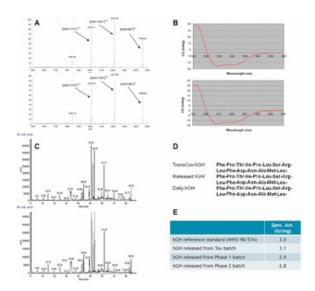


Figure 2: *In vitro* characterization demonstrates that hGH released from TransCon hGH (top figures in A, B and C above) is unmodified and identical to hGH for daily injection (bottom figures in A, B and C above). A) High resolution ESI mass spectra. The molecular weight of hGH based on the [hGH+11H+]¹¹⁺ peak is 22,124.32 Da and 22,124.21 Da for the released hGH and daily hGH, respectively. B) Far UV circular dichroism of hGH following buffer exchange into 100 mM borate, pH 9.0 indicates the expected, mainly α -helical structure. C) Tryptic peptide mapping of hGH by reversed-phase HPLC demonstrates 96 % sequence coverage. D) Nterminal amino acid sequence analysis indicates the expected primary sequence with no detectable microheterogeneity. E) Biopotency (Nb2-11 cell line) of the WHO hGH reference standard and hGH liberated from TransCon hGH from sequential batches.

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Results: PK/PD

PK/PD data (week 4) obtained from GHD adults (n=37) show that maximum levels of both hGH and IGF-I are comparable between weekly administered TransCon hGH and daily administered hGH at the same cumulative weekly dose, and that there is no supraphysiological exposure to either hGH or IGF-I.

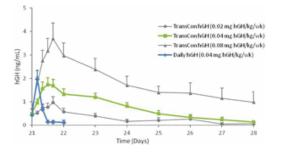


Figure 3: Dose proportional increase in serum levels of free hGH with increasing TransCon hGH dose in a Phase 2 study in GHD adults. The Cmax of free hGH is comparable between same weekly dose of TransCon hGH and daily hGH; Error bars +SEM.

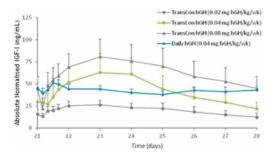


Figure 4: hGH released from TransCon hGH elicited an IGF-I response that was similar to the IGF-I response of the same cumulative dose of hGH administered as seven daily injections. The IGF-I response was dose proportional across the dose range. Reported as absolute baseline correction relative to Week 1 pre-dose IGF-I concentrations; Error bars +SEM.

Discussion

Due to its small size (22 kDa), hGH distributes throughout the body, where it acts directly on organs and tissues. Through interaction with the GH receptors, present in virtually every tissue, hGH acts directly and via IGF-I on tissues to increase growth and improve metabolic and cardiovascular health.¹ Both pathological excess and deficiency of GH are associated with cardiovascular mortality.² As the myocardium and vessels express IGF-I and functional receptors for both GH and IGF-I, an intact GH/IGF-I system with neither deficiency nor excess appears to be optimal for normal cardiovascular function.3 To ensure safe and efficacious hGH and IGF-I levels in the cardiovascular compartment and target tissues, TransCon hGH has been designed to provide comparable maximum blood concentration (Cmax), exposure (AUC) and tissue distribution of released unmodified hGH compared to daily administered hGH. The IGF-I response to TransCon hGH is similar to the IGF-I response of the same cumulative dose of hGH administered as seven daily injections and is dose proportional, enabling robust titration of patients to desired IGF-I level.

1: JCEM 2007, 92(12):4529–35; 2: JACC 2014, 64(14) 1452–60; 3: Endocrine 2015, 48(1):25-35

Conclusion

Whether released from the pituitary gland or administered as daily injections, GH distributes throughout the body to exert important effects in GH responsive tissue, including bone, muscle, liver and fat tissue. These include anabolic and metabolic effects. Growth hormone released from TransCon hGH has been shown to be identical to hGH in daily administered products. Clinical studies in patients with GHD demonstrate that TransCon hGH has comparable efficacy to daily hGH when administered at the same cumulative weekly dose. Importantly, TransCon hGH does not cause supraphysiological exposure to hGH or IGF-I.

Designed to maintain the same mode of action and distribution to GH responsive tissues as daily hGH, TransCon hGH has the potential to offer patients requiring GH replacement therapy a long-acting alternative to daily injections.