PRESS RELEASE

DEBIOPHARM APPLIES EXTENDED-RELEASE FORMULATION EXPERTISE TO REDUCE TREATMENT FREQUENCY BURDEN FOR ACROMEGALY & GEP-NET PATIENTS

- *Acromegaly and gastroenteropancreatic neuroendocrine tumors (GEP-NETs) are rare diseases that require life-long chronic treatment. Monthly somatostatin analog (SSA) injections are the standard of care as first-line medical treatment.*
- *Debiopharm is developing Debio 4126, a novel 3-month extended-release octreotide formulation, to optimize acromegaly and GEP-NET patient care by reducing injection frequency, which translates into an improved quality of life and less time spent with medical visits.*
- *Debio 4126 is currently being investigated in two clinical studies. One of them (study Debio 4126-102) is a phase 1b study in patients with acromegaly or GEP-NETs. This study was designed to characterize the pharmacokinetic, pharmacodynamic, efficacy, safety, and tolerability profiles of Debio 4126 administered intramuscularly (IM) every 3 months over an extended period.*

Lausanne, Switzerland – January 12th, 2023 – Debiopharm (www.debiopharm.com), a Swiss-based, global biopharmaceutical company, today announced that the first patient was dosed with Debio 4126, a 3-month extended-release formulation of octreotide, in their open-label, non-randomized, single-arm, multicenter phase 1b study (Debio 4126-102). The study is composed of two patient cohorts – 1 group of patients with acromegaly and 1 group with functioning GEP-NETs Patients will receive 4 injections of Debio 4126 for a total treatment duration of 48 weeks.

Debio 4126 is currently the only 3-month SSA in clinical development. The development of Debio 4126 arises from Debiopharm's wish to leverage their modified-release Debiosphere™ technology to alleviate the treatment burden of patients with rare diseases, such as acromegaly and GEP-NETs, by reducing the injection frequency to 4 injections per year.

In healthy volunteers, Debio 4126, an extended-release formulation of octreotide, exhibited good bioavailability and sustained release for up to 3 months.[1] It has the potential to offer efficacy and safety similar to those of marketed 1-month SSAs. If successful, Debio 4126 will equip healthcare professionals with a new, more convenient option for treating acromegalic and GEP/NET patients.

"Going into this 2-year long phase 1b trial, we look forward to ascertaining the benefits of this extended-release formulation. We believe that patient quality of life can be improved through the substantially reduced number of injections, from 12 to 4/year," **explained Dr Simona Ispas Jouron, Senior Medical Director, Endocrinology & Rare Diseases at Debiopharm**.

Prior to this compound, Debiopharm's extended-release formulation expertise extends over more than 35 years with the development of multiple formulations of agonist analogue triptorelin, benefiting patients affected by prostate cancer, breast cancer, endometriosis, central precocious puberty (CPP), and uterine myomas.

"The success of triptorelin is linked to our modified-release Debiosphere™ technology that has contributed to the improvement of the quality of life of patients treated long-term, particularly with our 1, 3 and 6-month formulations of triptorelin and now with Debio 4126. This formulation adds significant value to an efficacious and safe standard of care." **expressed Bertrand Ducrey, CEO of Debiopharm**.

About Acromegaly

Acromegaly is a rare chronic disorder caused by excessive GH secretion by pituitary adenomas, with more than 95% of cases being benign.[2] The condition most commonly affects middle-aged adults, with a slight predominance of female patients (52-60%)[3] and equal distribution among ethnicities. The disease is clinically diagnosed based on characteristic symptoms, including progressive skeletal and soft tissue overgrowth, mainly at the extremities (hands and feet) and head. Diagnosis is confirmed biochemically via increased serum concentrations of GH and IGF-1. Acromegaly is associated with a twofold increase in mortality relative to that expected in the general population, mostly due to cardiovascular events. Associated risk factors include hypertension, glucose metabolism abnormalities, dyslipidemia, abdominal adiposity, and peripheral insulin resistance (metabolic syndrome). Untreated acromegaly is associated with a reduced quality of life and life expectancy shortened by approximately 10 years.[2]

About Gastro-entero-pancreatic neuroendocrine tumors (GEP-NET)
GEP-NETs are rare and complex malignant solid tumors, derived from neuroendocrine cells, occurring in various sites along the gastrointestinal tract. Although these tumors have been considered rare, the most recent data from the US Surveillance Epidemiology and End Results show an increase of more than 400% in the incidence of these diseases over the period from 1973 to 2004.[4] Age at diagnosis is generally younger than 50 years, and these tumors may arise sporadically or because of hereditary predisposition. Survival of patients with GEP-NETs depends on the stage and histology. Patients with well and moderately differentiated metastases have a 5-year survival probability of 35%, while poorly differentiated metastases lead to a 5-year survival probability of 4%[4]

About Debio 4126
Octreotide is a synthetic octapeptide that mimics the pharmacology of endogenous somatostatin (SST). Currently, octreotide is available as immediate-release (Sandostatin®) and 4-week long-release formulations (Sandostatin LAR®). Debio 4126 is a novel, 3-month extended-release formulation of octreotide being developed by Debiopharm.

Debiopharm's commitment to patients
Debiopharm aims to develop innovative therapies that target high unmet medical needs in oncology and bacterial infections. We identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy, and then select pharmaceutical commercialization partners to maximize patient access globally.

For more information, please visit www.debiopharm.com

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