PRESS RELEASE

REDEFINING ACROMEGALY CARE: FIRST PATIENT RANDOMIZED IN DEBIOPHARM'S PHASE III OXTEND-03™ TRIAL OF 3-MONTH DEBIO 4126 TREATMENT

OXTEND-03™ (NCT06930625) is a Phase III, multi-center, randomized trial assessing the efficacy and safety of Debio 4126, the first and only octreotide formulation designed for quarterly (3-month) dosing

Lausanne, Switzerland – December 4th, 2025 – Debiopharm (www.debiopharm.com), a privately-owned, Swiss-based biopharmaceutical company committed to establishing tomorrow's standards of care in oncology and rare diseases, today announced that the first patient has been randomized in the **OXTEND-03™** clinical trial.

This pivotal Phase III trial is designed to evaluate the efficacy and safety of **Debio 4126**, a novel long-acting octreotide formulation and the first potential **3-month somatostatin analogue (SSA)**, in adults with acromegaly who are currently maintained on somatostatin analogs.

OXTEND-03™ is a global trial spanning approximately 75 sites across 21 countries, aiming to enroll around 120 patients. The primary goal of the trial is to confirm Debio 4126's ability to maintain biochemical control of the disease while significantly **reducing the patient's annual treatment burden from 12 injections to just 4**. This shift is expected to enhance patient convenience, improve long-term adherence, and potentially decrease healthcare resource utilization.

"The dosing of the first patient in **OXTEND-03™** is a monumental achievement for our team and confirms our commitment to addressing high unmet needs in rare diseases," said **Yanina Negievich, Medical Director for the Debio 4126 Program at Debiopharm**. "Our goal with Debio 4126 is to empower patients by reducing the complexity of their treatment. Moving from monthly to quarterly injections could make a real difference, helping patients focus on living rather than managing their condition."

"Acromegaly management can be highly demanding due to the required monthly injections in many patients, which impose a significant physical and emotional burden. A quarterly treatment regimen could be a game-changer for both patients and healthcare professionals. The OXTEND-03™ trial is essential for validating Debio 4126 as a new, less burdensome option that maintains control, potentially leading to better patient adherence and overall well-being." said **Maria Fleseriu, MD, FACE, professor and director of pituitary center, global principal investigator**

About Acromegaly and the Need for Innovation
Acromegaly is a rare, chronic endocrine disorder characterized by the pituitary gland's excessive production of growth hormone. The estimated prevalence is between **28 and 137 cases per million** people [1]. While current medical treatment typically involves Somatostatin Analogues (SSAs) delivered via lifelong, monthly deep subcutaneous or intramuscular injections, this regimen imposes a severe burden on patients. Data shows that up to **77% of patients** experience treatment-related injection site reactions (ISRs), such as

pain, swelling, and bruising [2]. Furthermore, many patients continue to struggle with persistent symptoms and impaired Quality of Life (QoL) despite achieving biochemical control [3, 4]. This demanding and frequent injection schedule, coupled with these persistent issues, is a major source of patient suffering and anxiety. Debio 4126, with its quarterly dosing interval, directly addresses this critical unmet need by offering the prospect of maintained biochemical control with significantly reduced injection frequency.

About Debio 4126
Debio 4126 is an innovative, long-acting octreotide formulation designed for intramuscular administration every three months. Early clinical data and robust pharmacokinetic modeling have demonstrated sustained octreotide release, consistent inhibition of Insulin-like Growth Factor 1 (IGF-1), and a safety profile comparable to marketed SSAs, providing strong support for the initiation of this Phase III trial.

About the OXTEND-03™ Trial
The OXTEND-03™ trial is a Phase III, multi-center, randomized, 3-arm trial (double-blind Debio 4126, placebo control, and open-label Debio 4126 extension). It will enroll approximately 120 adult patients with acromegaly who have been previously treated with octreotide or lanreotide and have IGF-1 levels within the normal range. The trial has an expected duration of up to 2 years of treatment.

About Debiopharm
Debiopharm aims to develop innovative therapies that target unmet needs in oncology and bacterial infections. To bridge the gap between breakthrough discoveries and patient access, Debiopharm identifies high-potential compounds, undertakes clinical development, and then partners with major pharmaceutical companies to bring medicines to the market and make them accessible to as many patients as possible throughout the world.
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