PRESS RELEASE

FIRST PATIENTS DOSED IN DEBIOPHARM'S PHASE III TRIAL (LIBELULA) INVESTIGATING DEBIO 4326, A 12-MONTH TRIPTORELIN FORMULATION FOR CHILDREN WITH CENTRAL PRECOCIOUS PUBERTY

Debiopharm's expertise in extended-release formulations could lighten the burden of treatment for children with Central Precocious Puberty (CPP) and their families by reducing injection frequency to once a year

Lausanne, Switzerland – September 9th, 2024 – Debiopharm (www.debiopharm.com), a privately-owned, Swiss-based biopharmaceutical company aiming to develop innovative therapies and to improve patient quality of life, today announced the dosing of the first sentinel patients in its open-label, single-arm, multi-center Phase III study, **NCT06129539 'A Study to Assess the Efficacy, Safety and Pharmacokinetics of Debio 4326 in Pediatric Participants Receiving Gonadotropin-Releasing Hormone Agonist Therapy for Central Precocious Puberty (LIBELULA)'**. Triptorelin is an established treatment for CPP as a 1-, 3- and 6-month formulation. This new phase III study evaluating the novel 12-month triptorelin formulation is being carried out in North and South America.

In pursuit of developing safe, effective, and convenient treatment options for patients, Debiopharm, is applying its expertise in extended-release formulations to achieve the first yearly injectable Gonadotropin-Releasing Hormone agonist (GnRHa). Reducing treatment burden while preserving triptorelin's well-known efficacy and safety are key elements that Debiopharm is eager to assess through this study.

"It is always disheartening to see such young children burdened by the effects of central precocious puberty and the lifelong complications it may cause. We are thankful that treatments like triptorelin are already on the market, and that companies like Debiopharm continue to invest in lightening the patient care burden with formulations that reduce injection frequency." expressed **Prof. Fernando Cassorla, Principal Investigator, Pediatrics Department at the Hospital San Borja Arriarán in Santiago, Chile**.

"As patients are at the center of all we do, we recognize that convenience matters. Reducing injection frequency to once a year can lower the burden for CPP patients and their caretakers by reducing children's stress and improving overall compliance. We are enthusiastic about the first patients enrolled in this phase III trial that can bring both medical and practical advancements." expressed **Bertrand Ducrey**, **CEO of Debiopharm**.

About Central Precocious Puberty

Central precocious puberty (CPP) occurs at an unusually early age, before 8 years of age in girls and before 9 years of age in boys [1-2]. It is characterized by a premature development of secondary sexual characteristics (e.g. breasts for girls and enlarged testicles for boys), accelerated growth, and bone maturation leading to reduced adult height. CPP is triggered by the early release of the gonadotropin-releasing hormone in the brain and premature activation of the hypothalamic-pituitary-gonadal axis. This early activation can be due to specific genetic alterations, central nervous system lesions, and social stressors but frequently has no identified etiology [3]. The approximative prevalence of CPP is 1 in 5,000-10,000 among Caucasians, more frequent in girls than in boys globally [4]. Precocious puberty may be associated with psychosocial difficulties and carries potential negative implications for long-term health including increased risk of metabolic complications, such as type 2 diabetes, weight gain, obesity, cardiovascular disease, as well as depression, and even premature death [5-10]. Early puberty has also been associated with an increased risk of breast cancer in women. In men, it may increase the risk of prostate cancer [11-13]. Since the early 1980s, Gonadotropin-Releasing Hormone agonists (GnRHa) such as triptorelin have been the standard of

care for the treatment of CPP [14-16]. Treatment aims to preserve adult height and prevent social and psychological difficulties and the various potential consequences on long-term health. Currently, there are several different extended-release GnRHa formulations ranging from monthly injections to subcutaneous implants for annual use [17]. While the latter may have a longer duration of action, it requires yearly surgical positioning.

About Debio 4326

Debio 4326 is a unique injectable, biodegradable 12-month extended-release formulation of triptorelin designed to further reduce the frequency of injections and burden of administrations, particularly considering its intended use in a pediatric population. Based on favorable efficacy and safety data with the different triptorelin 1-, 3- and 6-month formulations, Debio 4326 aims to preserve efficacy while providing increased comfort, ensure long-term compliance, and reduce stress for children and their parents.

Debiopharm's commitment to patients

Debiopharm aims to develop innovative therapies that target high unmet medical needs primarily in oncology and bacterial infections. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy, and then hand stewardship to large pharmaceutical commercialization partners to maximize patient access globally.

For more information, please visit www.debiopharm.com

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