LABORATOIRES
Pierre Fabre

Pierre Fabre Laboratories announce granting of European marketing authorization for OBGEMSA™ (vibegron) in overactive bladder.

Castres (France), June 28, 2024 - The European Commission (EC) has authorized the marketing of OBGEMSA™ (vibegron) by Pierre Fabre Laboratories for the symptomatic treatment of overactive bladder syndrome in adults, a particularly debilitating condition affecting over 70 million patients* in Europe. In 2022, Pierre Fabre Laboratories acquired the exclusive license for vibegron from Urovant Sciences Gmbh for the registration and commercialization of this innovative treatment in the European Economic Area. The decision of the EC will be applicable to all EU member states as well as Iceland, Liechtenstein, and Norway. OBGEMSA™ is a trademark owned by Urovant Sciences.

"*We are delighted with this development, which will allow European patients to benefit from a new therapeutic option for overactive bladder syndrome and further strengthen our expertise of over 40 years in urology. This decision confirms Pierre Fabre Laboratories' commitment to offering patients innovative therapies that provide better management of chronic debilitating diseases,*" **said Eric Ducournau, CEO of Pierre Fabre Laboratories.**

The decision of the EC follows the favorable opinion issued on April 25 by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA). It is based on the results of two pivotal, multicenter, double-blind, randomized phase 3 studies in adults with overactive bladder symptoms. Study RVT-901-3003 (EMPOWUR) evaluated the efficacy, tolerability, and safety of vibegron (at a dose of 75 mg per day) over 12 weeks compared to placebo and with tolterodine as a positive control. Its extension, study RVT-901-3004 (EMPOWUR Extension), double-blindly evaluated the long-term safety, tolerability, and efficacy of vibegron over 52 weeks, with tolterodine as an active comparator. In these studies, vibegron, as a new selective agonist of beta-3 adrenergic receptors (AR), demonstrated a favorable benefit-risk profile in the symptomatic treatment of urgency, increased frequency of urination, and urge urinary incontinence (UUI) that can occur in patients with overactive bladder syndrome.

The decision is also based on the positive results of study URO-901-1001, a randomized, double-blind, placebo-controlled, parallel-group phase 1 study conducted over 28 days in adult patients with overactive bladder, designed to assess the effect of vibegron (at a dose of 75 mg per day) at steady state on ambulatory systolic blood pressure (SBP). Vibegron had no statistically significant or clinically significant effect on SBP with overactive bladder symptoms.

**Irwin DE, Eur Urol 2006*

LABORATOIRES
Pierre Fabre

About overactive bladder (OAB)

The OAB syndrome is clinically characterized by urinary urgency (i.e. a sudden compelling desire to void that is difficult to defer), with or without urge urinary incontinence UUI, and usually accompanied by urinary frequency and nocturia in the absence of urinary tract infection or other obvious pathology. UUI is the involuntary loss of urine accompanied by urgency. UUI is distinguished from stress urinary incontinence, which is the involuntary loss of urine on effort or physical exertion (e.g., sporting activities), or on sneezing or coughing. When both components are present, the classification is mixed urinary incontinence, with either urgency or stress specified as the predominant component. From a pathophysiological perspective, the OAB symptom complex is suggestive of detrusor overactivity, which may be intrinsic or may be secondary to neurological conditions such as stroke or spinal cord injury.

About vibegron

Vibegron is a novel, potent, and selective human beta-3 adrenergic receptor (β3-AR) agonist. Beta receptors are found throughout the body, but β3-ARs are predominantly found on human detrusor smooth muscle. β3-ARs agonists bind to and activate beta-3 receptors on the detrusor muscle, leading to relaxation of the detrusor muscle to increase vesical capacity and to reduce OAB symptoms. Vibegron received approval in the U.S. in December 2020 (at 75 mg once daily, under the tradename GEMTESA®) for the treatment of OAB with symptoms of UUI, urgency, and urinary frequency in adults and in Japan and in the Republic of Korea, respectively in September 2018 and in October 2022 (at 50 mg once daily, under the tradename BEOVA®) for the treatment of OAB in adults. GEMTESA is a trademark of Urovant Sciences GmbH, and registered in the U.S., and in other countries. In the U.S., GEMTESA is marketed by Sumitomo Pharma America, Inc.

About Pierre Fabre Laboratories

Pierre Fabre Laboratories is the world's second-largest dermo-cosmetics company and one of Europe's leading pharmaceutical companies. Its portfolio includes several international brands and medical franchises such as Pierre Fabre Innovative Oncology, Pierre Fabre Medical Dermatology, Pierre Fabre Pharmaceutical Care, Eau Thermale Avène, Ducray, A-Derma, Klorane, René Furterer, Darrow, Même Cosmetics, Naturactive, Elgydium, Inava and Arthrodont.

In 2023, Pierre Fabre Laboratories posted 2.83 billion euros in revenue, 70% of which came from international sales in 120 countries. Historically based in the southwest of France and manufacturing 95% of its products in France, Pierre Fabre Laboratories employs over 10,000 people worldwide. Its annual R&D budget amounts to nearly 200 million euros, of which about 50% is dedicated to targeted therapies in oncology and 40% to skin health and care solutions.

Pierre Fabre Laboratories' majority shareholder (86%) is the eponymous Foundation, which is recognized by the French government as being a public-interest foundation. This capital structure guarantees the company's independence and long-term vision. Dividends paid to the Pierre Fabre Foundation enable the latter to design and finance humanitarian healthcare-access programs in developing countries. Employees are the company's secondary shareholder, through an international employee shareholding plan.

Pierre Fabre Laboratories' sustainability policy has been assessed by the independent AFNOR Certification body and has been awarded the "Exemplary" level of its CSR label (ISO 26 000 standard for sustainable development).

For more information, visit www.pierre-fabre.com, @PierreFabreGroup.

CONTACT PRESSE :
laurence.marchal@pierre-fabre.com
+33 7 88 88 54 47