Urovant Sciences and Pierre Fabre Médicament Enter into Exclusive License Agreement to Commercialize Vibegron for the Treatment of Overactive Bladder in the European Economic Area, UK, and Switzerland

•Pierre Fabre Médicament SAS (Pierre Fabre) to register and commercialize vibegron for the treatment of Overactive Bladder (OAB) in the European Economic Area, UK, and Switzerland.

•Urovant Sciences GmbH to receive compensation of up to USD $75 million in upfront payment, regulatory, and sales milestones as well as royalties based on sales.

•Urovant Sciences retains full commercialization rights to vibegron (GEMTESA®) in the United States and certain other markets.

Basel, Switzerland, and Castres, France – July 5, 2022 — Urovant Sciences, a wholly-owned subsidiary of Sumitovant Biopharma Ltd., and Pierre Fabre Médicament today announced they have entered into an exclusive license agreement for Pierre Fabre to register and commercialize vibegron for the treatment of Overactive Bladder (OAB) in the European Economic Area, UK, and Switzerland, with some option territories, which notably include French-speaking countries of Sub-Saharan Africa, Turkey, and certain Eastern European countries. Urovant will retain full rights in the United States and other select markets.

“We are thrilled to partner with Pierre Fabre, a leader in the international biopharmaceutical space,” said Jim Robinson, Chief Executive Officer of Urovant Sciences. “Their experience in the global OAB and Benign Prostatic Hyperplasia (BPH) market make them uniquely suited to deliver vibegron to more patients who need it across Europe and surrounding areas.”

Under the terms of the agreement, Urovant Sciences will receive payments up to USD $75 million, based on upfront, regulatory, and sales milestone payments. Additionally, Urovant will receive royalties based on sales performance.

Urovant Sciences and Pierre Fabre will share responsibility for vibegron clinical trials in the pediatric populations in Europe. As part of the transaction, Urovant Sciences will also provide manufacturing services to Pierre Fabre.

“We are delighted to enter into this partnership with Urovant, which will bring effective treatment and improved quality of life to all patients suffering from Overactive Bladder (OAB) in Europe. This partnership confirms Pierre Fabre’s extensive expertise in urology and in women’s health for five decades and the group’s ambitions to offer therapeutic solutions to chronic diseases that are very disabling in everyday life,” said Eric Ducournau, group CEO at Pierre Fabre.

About Overactive Bladder
Overactive Bladder (OAB) is a clinical condition that occurs when the bladder muscle contracts involuntarily. Symptoms may include urinary urgency (the sudden urge to urinate that is difficult to control), urgency incontinence (unintentional loss of urine immediately after an urgent need to urinate), frequent urination (usually eight or more times in 24 hours), and nocturia (waking up more than two times in the night to urinate).[1]

While 33 million US adults experience the bothersome symptoms of OAB, approximately 546 million people ≥20 years are affected by OAB worldwide. [1,2]

About Urovant Sciences
Urovant Sciences is a biopharmaceutical company focused on developing and commercializing innovative therapies for areas of unmet need, with a dedicated focus in Urology. The Company’s lead product, GEMTESA®(vibegron), is an oral, once-daily (75 mg) small molecule beta-3 agonist for the treatment of adult patients with Overactive Bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency. GEMTESA was approved by the U.S. FDA in December 2020 and launched in the U.S. in April 2021. GEMTESA is also being evaluated for the treatment of OAB in men with Benign Prostatic Hyperplasia. The Company’s second product candidate, URO-902, is a novel gene therapy being developed for patients with OAB

who have failed oral pharmacologic therapy. Urovant Sciences, a wholly owned subsidiary of Sumitovant Biopharma Ltd., intends to bring innovation to patients in need in urology and other areas of unmet need. Learn about us at www.urovant.com or follow us on Twitter or LinkedIn.

About Sumitovant Biopharma
Sumitovant is a technology-driven biopharmaceutical company accelerating development of new potential therapies for patients with high unmet medical need. Through our company portfolio and use of embedded computational technology platforms to generate business and scientific insights, Sumitovant has supported development of FDA-approved products and advanced a promising pipeline of early-through-late-stage investigational assets for other serious conditions. Sumitovant's subsidiary portfolio includes wholly owned Enzyvant, Urovant, Spirovant and Altavant, and majority-owned Myovant (NYSE: MYOV). Sumitomo Pharma is Sumitovant's parent company. For more information, please visit www.sumitovant.com.

About Pierre Fabre Group
Pierre Fabre is the 2nd largest dermo-cosmetics laboratory in the world, the 2nd largest private French pharmaceutical group and the market leader in France for products sold over the counter in pharmacies. Its portfolio includes several medical franchises and international brands including Pierre Fabre Oncology, Pierre Fabre Dermatology, Eau Thermale Avène, Klorane, Ducray, René Furterer, A-Derma, Naturactive, Pierre Fabre Oral Care.

In 2021, Pierre Fabre generated €2.5 billion in revenues, 66% of which came from international sales. Established in the South-West of France since its creation, the Group manufactures over 95% of its products in France and employs some 9,500 people worldwide. Its products are distributed in about 115 countries. Pierre Fabre is 86%-owned by the Pierre Fabre Foundation, a government-recognized public-interest foundation, and secondarily by its own employees through an international employee stock ownership plan.

To learn more, please go to https://www.pierre-fabre.com/en. You can also join us on Twitter at @PierreFabre and Facebook at www.facebook.com/laboratoirespierrefabre.

About GEMTESA® tablets for oral use (US market)
GEMTESA® is a prescription medicine for adults used to treat the following symptoms due to a condition called overactive bladder:

- urge urinary incontinence: a strong need to urinate with leaking or wetting accidents
- urgency: the need to urinate right away
- frequency: urinating often

It is not known if GEMTESA is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Do not take GEMTESA if you are allergic to vibegron or any of the ingredients in GEMTESA.

Before you take GEMTESA, tell your doctor about all your medical conditions, including if you have liver problems; have kidney problems; have trouble emptying your bladder or you have a weak urine stream; take medicines that contain digoxin; are pregnant or plan to become pregnant (it is not known if GEMTESA will harm your unborn baby; talk to your doctor if you are pregnant or plan to become pregnant); are breastfeeding or plan to breastfeed (it is not known if GEMTESA passes into your breast milk; talk to your doctor about the best way to feed your baby if you take GEMTESA).

Tell your doctor about all the medicines you take , including prescription and over-the-counter medicines, vitamins, and herbal supplements. Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

What are the possible side effects of GEMTESA?
GEMTESA may cause serious side effects including the inability to empty your bladder (urinary retention). GEMTESA may increase your chances of not being able to empty your bladder, especially if you have bladder outlet obstruction or take other medicines for treatment of overactive bladder. Tell your doctor right away if you are unable to empty your bladder. The most common side effects of GEMTESA include headache, urinary tract infection, nasal congestion, sore throat or runny nose, diarrhea, nausea, and upper respiratory tract infection. These are not all the possible side effects of GEMTESA. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

Please click here for full Product Information for GEMTESA.

References:

1. Irwin DE, Kopp ZS, Agatep B, Milsom I, Abrams P. Worldwide prevalence estimates of lower urinary tract symptoms, overactive bladder, urinary incontinence and bladder outlet obstruction. *BJU Int.* 2011;108(7):1132-1138. doi:10.1111/j.1464-410X.2010.09993.x

2. Leron E, Weintraub AY, Mastrolia SA, Schwarzman P. Overactive bladder syndrome: evaluation and management. *Curr Urol.* 2017;11:117-125. doi:10.1159/000447205

Urovant Sciences
Alana Darden Powell
Vice President, Corporate Communications
949-436-3116
alana.darden@Urovant.com

Sumitovant Biopharma
Maya Frutiger
VP, Head of Corporate Communications
media@sumitovant.com

Pierre Fabre
Anne Kerveillant
Media Relations PF Pharmaceuticals Direction
Tél. : +33 (0)6 20 88 54 57
annekerveillant@pierre-fabre.com

Source: Urovant Sciences, Inc.

---

https://news.us.sumitomo-pharma.com/2022-07-05-Urovant-Sciences-and-Pierre-Fabre-Medicament-Enter-into-Exclusive-License-Agreement-to-Commercialize-Vibegron-for-the-Treatment-of-Overactive-Bladder-in-the-European-Economic-Area,-UK,-and-Switzerland