VectivBio and Asahi Kasei Pharma Announce the Start of a Phase 1 Study of Apraglutide in Japan

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Single-dose study to assess pharmacokinetics, pharmacological activity, safety and tolerability in healthy Japanese men and women

BASEL, Switzerland, March 13, 2023 (GLOBE NEWSWIRE) -- VectivBio Holding AG ("VectivBio") (Nasdaq: VECT), a clinical-stage biopharmaceutical company pioneering novel transformational treatments for severe rare conditions, and Asahi Kasei Pharma Corporation ("Asahi Kasei Pharma") today announced the start of a Phase 1 study investigating the pharmacokinetics, pharmacological action, safety, and tolerability of apraglutide when a single subcutaneous dose is given to healthy Japanese adult men and women. Pharmacological actions and safety will be investigated by comparison with a placebo control.

In March 2022 VectivBio entered into an exclusive licensing agreement with Asahi Kasei Pharma to develop and commercialize apraglutide, a next-generation, long-acting GLP-2 analog, for the treatment of short bowel syndrome with intestinal failure (SBS-IF), steroid-refractory acute graft-versus-host disease (aGVHD) and future indications in Japan. VectivBio received an upfront cash payment of approximately $30 million ($5 million of which was the first installment of development cost-sharing) and is eligible for up to approximately $170 million* in further development activities and milestone payments upon the achievement of certain development, regulatory and commercial milestone events. VectivBio is also eligible to receive tiered, double-digit, escalating royalties on sales of apraglutide in Japan. VectivBio is conducting the STARS Phase 3 global program studying apraglutide in patients with SBS-IF with 93 sites in 18 countries, including multiple sites in Japan. This newly initiated Phase 1 study in healthy Japanese volunteers, conducted by Asahi Kasei Pharma, is expected to be the only Japan-specific clinical study necessary to file a marketing authorization application in Japan.

"The initiation of the Phase 1 study is a significant milestone for VectivBio and Asahi Kasei Pharma as this brings us one step closer to making apraglutide available for SBS-IF patients in Japan," said Omar Khwaja, MD, Chief Medical Officer of VectivBio.

* Using exchange rates in effect at the time of Agreement's effective date.

About Apraglutide

Apraglutide is an investigational new drug that is a next-generation, long-acting synthetic GLP-2 analog being developed for a range of rare gastrointestinal diseases where GLP-2 can play a central role in addressing disease pathophysiology, including short bowel syndrome with intestinal failure (SBS-IF) and Acute Graft-Versus-Host Disease (aGVHD).

About The STARS Phase 3 Program

STARS is a pivotal, global Phase 3 study enrolling approximately 144 patients with SBS-IF stratified 50/50 for CIC and stoma, with patients being evaluated over 48 weeks and 24 weeks respectively. This stratification will allow for the evaluation of anatomy-specific key secondary endpoints. Patients are randomized 2:1 for either once-weekly-apraglutide or placebo. The study includes an improved PS weaning algorithm tailored to remnant bowel anatomy to enhance signal detection. STARS is designed to establish a new standard of care for all patients with SBS-IF and to tailor apraglutide treatment to patients with distinct remnant bowel anatomy. The Phase 3 study is being conducted globally in 18 countries and over 80 sites.

About VectivBio AG

VectivBio is a global clinical-stage biotechnology company focused on transforming and improving the lives of patients with severe rare conditions. Lead product candidate apraglutide is a next-generation, long-acting synthetic GLP-2 analog being developed for a range of rare gastrointestinal diseases where GLP-2 can play a central role in addressing disease pathophysiology, including short bowel syndrome with intestinal failure (SBS-IF) and Acute Graft-Versus-Host Disease (aGVHD).

VectivBio is also advancing its modular, small molecule CoMET platform to address a broad range of previously undruggable Inherited Metabolic Diseases (IMDs). CoMET leverages innovative chemistry, based on a proprietary stabilized pantetheine backbone, to restore fundamental cellular metabolism in pediatric populations with IMDs characterized by a deficit of energy metabolism caused by the depletion of functional Coenzyme A ("CoA"). Candidates from the CoMET platform are initially being evaluated in methylmalonic acidemia (MMA), propionic acidemia (PA), and other organic acidemias.

About Asahi Kasei Pharma

In accordance with the Asahi Kasei Pharma Mission "To sincerely care for each individual life and solve their unmet medical needs with a wealth of ideas and solid science," Asahi Kasei Pharma operates pharmaceutical and diagnostic businesses in the Health Care Business Unit of the Asahi Kasei Group. For more information, please visit https://www.asahikasei-pharma.co.jp/en/.

Forward Looking Statements

Forward-looking statements are statements that are not historical facts. Words and phrases such as "anticipated," "forward," "will," "would," "may," "remain," "potential," "prepare," "expected," "believe," "plan," "near future," "belief," "guidance," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements concerning the clinical development of apraglutide, as well as interim data and potential upcoming data readouts from VectivBio's STARS Nutrition clinical trial, and statements regarding VectivBio's CoMET

platform. All of such statements are subject to risks and uncertainties, many of which are difficult to predict and generally beyond VectivBio's control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking statements. Such risks and uncertainties include, but are not limited to: the impacts of the Russian/Ukrainian war and the ongoing COVID-19 pandemic, including interruptions or other adverse effects on clinical trials and delays in regulatory review; delay in or failure to obtain regulatory approval of VectivBio's product candidates and successful compliance with FDA and other governmental regulations applicable to product approvals; the risks inherent in drug development and in conducting clinical trials; and those risks and uncertainties identified in the "Risk Factors" section of VectivBio's Annual Report for the year ending December 31, 2021 on Form 20-F filed with the Securities and Exchange Commission on April 7, 2022. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, VectivBio undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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