VectivBio Announces First Patient Dosed in Pivotal Phase 3 Trial of Apraglutide for the Treatment of Short Bowel Syndrome

– Phase 3 STARS trial of apraglutide, a next-generation GLP-2 analog, to be conducted globally

– The successful phase 2 program established enhanced fluid and nutrient absorption upon once-weekly administration of apraglutide

BASEL, Switzerland, February 3, 2021 — VectivBio Holding AG, a clinical-stage biotechnology company developing innovative treatments for severe rare conditions with high unmet medical need, today announced that the first patient has been dosed in its pivotal phase 3 trial of apraglutide in short bowel syndrome (SBS).

“SBS is a devastating and life-threatening condition with great unmet medical need, for which the standard-of-care presents a significant daily burden for people living with SBS, their families and caregivers,” said Luca Santarelli, M.D., Chief Executive Officer of VectivBio. “We are excited to commence patient dosing in our pivotal phase 3 trial which was designed with feedback from the FDA and the EMA. We see the potential for apraglutide to become the best-in-class GLP-2 analog.”

The phase 3 STARS (STudy of APraglutide in SBS) trial is a global clinical trial that represents the largest phase 3 trial ever conducted in short bowel syndrome with intestinal failure (SBS-IF). STARS is the first trial of a next-generation, long-acting GLP-2 analog, designed to exclusively evaluate a once-weekly dosing interval and to take into account remnant bowel anatomy and individual caloric needs during weaning patients off of parenteral support.

“SBS-IF is a condition that requires deep understanding of the unique clinical presentation and the need for individualized assessment,” said Dr. Kishore Iyer, Chairman of the VectivBio phase 3 Scientific Steering Committee supporting the design and conduct of the STARS trial. “The unique design of the STARS trial considers a patient's remnant bowel anatomy when adapting parenteral support and evaluating the clinical impact of apraglutide. Remnant bowel anatomy is highly relevant to fully harness the therapeutic potential of apraglutide across the diverse spectrum of SBS patients, potentially offering better information on how to use apraglutide in distinct patient subtypes. We look forward to further clinical investigation of apraglutide and its potential to positively impact the quality of life and transform the care for people with SBS.”
The phase 2 clinical program for apraglutide included two independent trials evaluating the safety and efficacy of once-weekly administration in patients with SBS. Apraglutide was found to be safe and well tolerated in both trials and achieved clinically meaningful improvement in intestinal fluid and nutrient absorption compared with placebo. The trials supported the potential advantages of apraglutide on energy absorption to improve outcomes for patients with SBS. These data, as well as those from a metabolic balance trial, were presented at the 2020 ESPEN Virtual Congress and are available in Clinical Nutrition ESPEN.

About Short Bowel Syndrome
Short Bowel Syndrome (SBS) is a malabsorptive disorder caused by the loss of functional small intestine. SBS typically occurs as a consequence of extensive intestinal resection due to chronic inflammatory bowel disease (IBD), acute events such as trauma, mesenteric infarction, bariatric surgery or congenital abnormalities. The severity of SBS ranges across an anatomical spectrum, and some patients who are initially diagnosed with intestinal insufficiency suffer from progressively worse food and fluid absorption, leading to SBS with chronic intestinal failure (SBS-IF). As an organ failure condition with unmet medical need, patients with SBS-IF require parenteral support (PS), the intravenous delivery of essential fluids and nutrients, to survive. Patients with the most severe SBS-IF require PS infusions for up to 10 to 15 hours per day. SBS is associated with frequent complications, significant morbidity and mortality, high economic burden and an impaired quality of life. An estimated 32,000 people are thought to suffer from SBS in the U.S. and Europe, of whom 15,000 suffer from SBS-IF and require lifelong PS.

About Apraglutide
Apraglutide is an investigational drug being developed as a once-weekly treatment for patients who have SBS with intestinal failure (SBS-IF). It is a next-generation, long-acting, potent, synthetic GLP-2 analog that acts as a selective, full agonist of the GLP-2 receptor. Apraglutide is designed to enable patients to minimize the burden from PS by increasing intestinal absorption of fluids, calories and nutrients. Apraglutide has successfully completed phase 2 studies and is currently being evaluated in a pivotal phase 3 clinical trial. Based on preclinical and clinical data to date, apraglutide has the potential to advance the treatment SBS-IF, by establishing less frequent dosing and improving outcomes in a clinically meaningful fashion to address the needs of patients across the anatomical spectrum that characterizes the disease.

About VectivBio AG
VectivBio is a global, clinical-stage biotechnology company focused on the discovery, development and commercialization of innovative treatments for severe rare conditions with high unmet medical need. The company is committed to pursuing rare diseases with well-defined biology that can be targeted with best-in-disease therapies that have the potential to meaningfully transform and improve the lives of patients and their families, overcoming the limitations of the standard-of-care. VectivBio’s product candidate, apraglutide, is a next-generation GLP-2 analog for the treatment of short bowel syndrome with intestinal failure (SBS-IF).
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