VectivBio Presents Preclinical Data Supporting Apraglutide for Treatment of Acute Graft-Versus-Host Disease at the 48th Annual Meeting of the European Society for Blood and Marrow Transplantation

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-- Apraglutide, a next-generation GLP-2 analog, protected against chemotherapy-induced gastrointestinal (GI) damage and improved survival in mouse models of GI acute graft-versus-host disease (aGVHD) --

-- Data support regenerative, non-immunosuppressive hypothesis for clinical evaluation; launched Phase 2 STARGAZE clinical study of apraglutide in steroid-refractory GI aGVHD following FDA clearance of the company's Investigational New Drug (IND) application --

BASEL, Switzerland, March 23, 2022 (GLOBE NEWSWIRE) -- VectivBio Holding AG ("VectivBio") (Nasdaq: VECT), a clinical-stage biopharmaceutical company pioneering novel transformational treatments for severe rare conditions, today announced new preclinical data supporting the potential of apraglutide, a next-generation, long-acting GLP-2 analog, as a novel treatment of steroid-refractory GI aGVHD following allogeneic hemopoietic stem cell transplant (HSCT). The data were presented across four posters at the 48th Annual Meeting of the European Society for Blood and Marrow Transplantation (EBMT), taking place virtually March 19-23, 2022.

The GI tract is one of the key target organ systems damaged by the chemotherapy regimen used in HSCT conditioning and the development of aGVHD, contributing to high morbidity and mortality among HSCT patients. Acute GvHD treatment today is based on immunosuppressive approaches which do not directly target impacted organ systems. GLP-2 targets the GI tract, promoting intestinal healing and regeneration through intestinal epithelial repair, restoration of intestinal barrier function, and maintenance of a healthy microbiome.

"We believe these compelling preclinical data presented at EBMT further validate our hypothesis for apraglutide as a first-in-class, regenerative and non-immunosuppressive approach to the treatment of aGVHD. In particular, we are excited to share that apraglutide offered protection against chemotherapy-induced GI damage, without limiting the critical impact of conditioning protocol on a successful transplant, and believe this may ultimately lead to improved survival," said Omar Khwaja, M.D., Ph.D., Chief Medical Officer of VectivBio. "We have recently launched STARGAZE, our Phase 2 study evaluating apraglutide in combination with best available therapy in patients with steroid-refractory GI aGVHD, marking the second clinical indication for our lead candidate. We look forward to sharing interim proof-of-concept data from this study later this year as we hope to translate these preclinical results to patients."

Details of the e-poster presentations are as follows:

Title: Apraglutide Decreases Severity of Intestinal Damage from Gastrointestinal (GI) Acute Graft Versus Host Disease (GvHD) Following Allogeneic Transplantation Without Impacting Engraftment
Poster Number: #P198

Treatment with apraglutide prior to and following allogeneic transplantation in immunodeficient mice was observed to have a protective effect against the GI damage from conditioning chemotherapy. Notably, apraglutide did not appear to affect engraftment rate, and was observed to reduce GI damage and improve mortality rates in allogeneic-transplant-induced GvHD.

Title: Apraglutide Treatment Reduces Chemotherapy-Induced Gastrointestinal (GI) Damage in Mice and Preserves Cellular Integrity During Chemotherapy
Poster Number: #P199

Data showed that apraglutide protected GI epithelium structure from chemotherapy-induced injury, prevented severe body weight loss, and improved survival rates in mice undergoing chemotherapy. Additionally, apraglutide maintained plasma citrulline levels, a marker of intestinal mass, comparable to that in mice that did not undergo chemotherapy. The effects of apraglutide were optimal when it was administered as pre-treatment before chemotherapy.

Title: Treatment with Apraglutide Preserves the Global Homeostatic Environment of Intestinal Microbiota During Chemotherapy in Mice
Poster Number: #P200

In mouse models of aGVHD, the co-administration of apraglutide with conditioning chemotherapy avoided damage to the gut common from chemotherapy alone. Results showed the preservation of intestinal microbiome homeostasis, and improved outcomes including reduced body weight loss and increased survival rates.

Title: Apraglutide Does Not Impact Anti-tumor and Immunosuppressive Efficacy of Conditioning Chemotherapy in Mice
Poster Number: #P201

The administration of apraglutide as a pre- and concomitant treatment in mouse models of aGVHD did not impair the anti-tumor and immunosuppressive effects of chemotherapy. The pharmacologic effects of apraglutide were observed to be specific to the intestine.

All posters are available to view on the EBMT website throughout the duration of the conference and are also accessible on the Investors & Media page of VectivBio's website under Scientific Publications.

About aGVHD

Acute Graft Versus Host Disease (aGVHD) is a severe condition which occurs when immune cells from the donor attack a recipient's healthy cells after an allogeneic hematopoietic stem cell transplant (HSCT), the standard last-line treatment for many forms of cancer. aGVHD typically emerges within 6 months of transplant and predominantly affects the skin, gastrointestinal (GI) tract and liver. GI aGVHD is a condition marked by direct injury to the GI tract from conditioning regimen and donor immune response. The significant intestinal injury can lead to increased infections from impaired barrier function, malabsorption and poor nutrition with compromised ability for fluids and nutrients absorption, and a disturbed microbiome that leads to inflammation. GI aGVHD is one of the leading causes of morbidity and mortality following HSCT. The predominant manifestations of GI aGVHD are abdominal pain and debilitating diarrhea. The diarrhea is secretory, occurs independently of oral intake, and can exceed 10 liters per day, often requiring parenteral support to feed and hydrate patients. More than 26,000 allogeneic HSCTs take place in the U.S., Europe and Japan annually and aGVHD occurs in an estimated 30-50% of patients. Corticosteroids are the first line standard of care for aGVHD, but approximately half of patients will become steroid-refractory. Mortality of 50% at six months is driven in significant part by the severity of GI symptoms which impact approximately 70% of patients in this setting.

About Apraglutide

Apraglutide is a next-generation, synthetic GLP-2 analog rationally designed with the potential to offer an improved safety and efficacy profile relative to other agents in its class and less frequent dosing. VectivBio is pursuing a novel clinical strategy across a range of applications for apraglutide, beginning with STARS, a global Phase 3 program for the treatment of short bowel syndrome with intestinal failure (SBS-IF).

SBS-IF patients live with a burdensome standard of care, often requiring routine parenteral support (PS), the intravenous delivery of essential fluids and nutrients, to survive. A heterogenous population, the therapeutic needs and patient journey differ depending on an individual's remnant bowel anatomy (stoma or colon-in-continuity (CIC)). Apraglutide has the potential to advance the treatment of SBS-IF by establishing less frequent dosing and increasing intestinal absorption of fluids, calories and nutrients, leading to improved clinical outcomes and quality of life for patients across the anatomical spectrum that characterizes the disease. The Company expects to report topline data from the Phase 3 trial in the second half of 2023, and interim results from STARS Nutrition, a multicenter, open-label metabolic balance study of apraglutide designed to evaluate the efficacy of once-weekly apraglutide in increasing intestinal energy absorption and reducing the parenteral support requirement in patients with SBS-IF CIC in the first half of 2022.

About VectivBio AG

VectivBio (Nasdaq: VECT) 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.

Learn more at www.vectivbio.com, and follow us on LinkedIn and Twitter.

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 the success of development and commercialization efforts with respect to apraglutide, VectivBio's lead product, VectivBio's plans to initiate additional clinical studies of apraglutide, the success of development and commercialization of the CoMET platform, and the ability to expand its rare disease product portfolio. 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 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 lead product candidate 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 Registration Statement on Form F-1 declared effective by the Securities and Exchange Commission on April 8, 2021 and its other subsequent filings with the Securities and Exchange Commission. 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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