VectivBio Announces Third Quarter 2021 Business Update

November 10, 2021

-Pivotal STARS Program of Apraglutide in SBS-IF Progressing with Majority of Sites Activated and Screening; STARS Nutrition Interim Results Expected 1H 2022-

-Expanded Rare Disease Pipeline with the Acquisition of CoMET Small Molecule Platform for Inherited Metabolic Diseases (IMDs)-

-IND Application for Apraglutide for Acute Graft-Versus-Host Disease (aGVHD) Cleared by FDA; First Patient in Expected 1Q 2022, Interim Data Expected 2H 2022-

BASEL, Switzerland, Nov. 10, 2021 (GLOBE NEWSWIRE) -- VectivBio Holding AG ("VectivBio") (Nasdaq: VECT), a clinical-stage biopharmaceutical company pioneering novel transformational treatments for severe rare conditions, today provided a business update for the third quarter ended September 30, 2021.

"VectivBio made tremendous progress this quarter, including the achievement of key milestones and strategic advancements that have expanded the breadth of our efforts to transform the treatment of rare conditions," said Luca Santarelli, M.D., Ph.D., Founder and Chief Executive Officer of VectivBio. "In October, the FDA cleared our IND to initiate STARGAZE, a Phase 2 trial evaluating apraglutide for the treatment of aGVHD, the second indication for our lead candidate. We expect the first patient to enter this trial during the first quarter of next year and expect initial interim data in the second half of 2022. Notably, this follows successful initiations earlier this year of our pivotal program of apraglutide in patients with short bowel syndrome with intestinal failure (SBS-IF), encompassing the Phase 3 STARS study and the Colon-in-Continuity (CIC) focused STARS Nutrition study. We're happy to report that the Phase 3 Trial is steadily progressing, with the majority of sites activated and screening. We also expect to announce interim results for the STARS Nutrition study in the first half of 2022. These results aim to provide clinically meaningful evidence that apraglutide can improve intestinal absorption and reduce parenteral support volume in CIC patients who represent the majority of SBS and respond poorly to current standard-of-care GLP-2 treatment."

Dr. Santarelli continued, "Additionally, in September, we acquired CoMET, a modular platform to develop small molecules addressing the deficit of Coenzyme A-mediated energy metabolism that underlies often-fatal and currently intractable inherited metabolic diseases. With this transaction, we have immediately added four new programs to our R&D pipeline and laid a foundation supporting our vision to become a fully integrated rare disease company."

Third Quarter 2021 and Recent Business Updates

Apraglutide: *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).*

Apraglutide for SBS-IF:

- Enrollment is ongoing in STARS (**ST**udy of **A**p**R**aglutide in **S**BS), a pivotal Phase 3 trial of apraglutide for SBS-IF. The global trial, which represents the largest Phase 3 trial ever conducted in SBS-IF, is designed to evaluate once-weekly dosing of apraglutide and accounts for patients' remnant bowel anatomy and individual caloric needs when adapting parenteral support across patient subtypes. The Company expects to report topline data in the second half of 2023.
- In July, the Company initiated STARS Extend study. Emerging real-world evidence suggests that SBS-IF patients may benefit from longer treatment duration with meaningful reductions in number of days of parenteral support (PS) per week or the ability to completely wean off PS. STARS Extend is an open-label extension trial to evaluate the long-term safety and efficacy of apraglutide in SBS-IF for up to 104 weeks.
- In June, VectivBio initiated 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 and Colon-in-Continuity (CIC). CIC patients represent over half of the total SBS-IF patients and are underserved by current treatment options. The Company is on track to report interim results in the first half of 2022.

Apraglutide for aGVHD:

- In October, VectivBio announced that the U.S. Food and Drug Administration (FDA) cleared the Company's Investigational New Drug (IND) application to evaluate apraglutide in a Phase 2 clinical trial, STARGAZE (Study of Apraglutide in Graft-Versus-Host Disease). VectivBio expects the first patient to enter this trial during the first quarter of 2022, with interim data expected in the second half of 2022. Apraglutide previously received orphan drug designation by the FDA for the prevention of aGVHD in June 2021.

CoMET Platform: *Modular, small molecule platform applying innovative chemistry to address severe Inherited Metabolic Diseases (IMDs) in pediatric populations with a deficit of energy metabolism caused by the depletion of functional Coenzyme A ("CoA").*

- In September, VectivBio successfully acquired Comet Therapeutics, Inc., a privately held company developing drugs to address previously untreatable IMDs. The CoMET platform expands VectivBio's pipeline with the immediate addition of four programs targeting organic acidemias, urea cycle disorders, fatty acid oxidation disorders and amino acidopathies.
- VectivBio plans to initiate a first-in-human trial of VB-1197, the first candidate from the CoMET platform, in 1Q 2023. VB-1197 will initially being evaluated for the treatment of methylmalonic acidemia (MMA) and propionic acidemia (PA).

Corporate Updates:

- In September, the Company announced the appointment of Scott Applebaum as Chief Legal Officer & Corporate Secretary. Mr. Applebaum brings over two decades of legal, regulatory and operational experience in the biopharmaceutical industry to VectivBio. Mr. Applebaum has extensive experience with rare diseases, and spent 10 years at Shire Pharmaceuticals in various senior management roles. Most recently he was the Chief Legal & Compliance Officer and Senior Vice President of Regulatory Affairs at Trevena, where he played a key role in gaining FDA approval for their lead product, Olinvyk®.
- In September, VectivBio announced the election of Paul R. Carter and Dr. Murray W. Stewart to the Company's Board of Directors as Independent Non-Executive Directors. Most recently, Mr. Carter served as Executive Vice President of Commercial Operations at Gilead where he led launch and commercialization efforts globally. Dr. Stewart is the Chief Medical Officer of Rhythm Pharmaceuticals, a biopharmaceutical company focused on the treatment of rare genetic disorders of obesity, and guided Imcivree® to FDA approval in November 2020. Paul and Murray are expected to play a prominent role in guiding VectivBio in its preparation for the potential approval and commercialization of apraglutide.

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. Our lead product candidate, apraglutide, is a next-generation GLP-2 analog currently in a global Phase 3 clinical trial for short bowel syndrome with intestinal failure (SBS-IF). It is being developed for a range of rare gastrointestinal diseases where GLP-2 can play a central role in addressing disease pathophysiology, including Acute Graft-Versus-Host Disease (aGVHD).

With the CoMET platform, we also aim to address severe and often fatal Inherited Metabolic Diseases (IMDs) in pediatric populations. IMDs represent a group of genetic disorders in which dysregulated Co-enzyme A (CoA) metabolism is a key pathophysiological defect. Candidates from the CoMET platform are initially being evaluated in methylmalonic acidemia (MMA) and propionic acidemia (PA). Additional targets include urea cycle disorders, fatty acid oxidation disorders, and amino acidopathies.

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

VectivBio Contacts:

Investors:
Investor Relations
ir@vectivbio.com

Media:
Morgan Warners
Finsbury Glover Hering
+1 (202) 295-0124
morgan.warners@fgh.com