Source: *VIVUS LLC*

May 30, 2024 09:00 ET

Clinical Data Published at ASCO Support the Potential of VIVUS' PANCREAZE® to Stabilize Weight and Improve Gastrointestinal Outputs in Patients with Pancreatic Cancer

CAMPBELL, Calif., May 30, 2024 (GLOBE NEWSWIRE) -- VIVUS LLC, a biopharmaceutical company committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs, announces the publication of new clinical trial data demonstrating that PANCREAZE® (pancrelipase) helped to stabilize weight in patients undergoing chemotherapy for the treatment of pancreatic ductal adenocarcinoma (PDAC) who have cachexia (wasting syndrome) and exocrine pancreatic insufficiency (EPI). The data also suggest that PANCREAZE may reduce stool frequency and improve stool consistency.

Researchers at Cedars-Sinai Medical Center and the Samuel Oschin Cancer Center conducted the investigator-initiated trial. VIVUS provided PANCREAZE and funding to support the clinical trial. PANCREAZE is approved in the United States and Canada for the treatment of EPI due to cystic fibrosis or other conditions. The data was published in an ePoster at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place May 31-June 4, 2024, in Chicago, IL and online.

"PANCREAZE is used to prevent maldigestion, malnutrition, and excessive weight loss in patients with EPI, but it has never been evaluated specifically in patients with PDAC," said Andrew E Hendifar, MD, MPH, Gastrointestinal and Neuroendocrine Oncology, Associate Professor of Medicine David Geffen School of Medicine, Medical Director, Pancreatic Cancer and Co-Director Hematology and Medical Oncology Fellowship Program, Cedars Sinai Medical Center and an author on the ePoster. "Patients with PDAC frequently present with cachexia, and its combined features of anorexia, anemia, and weight loss have been associated with negative impacts on physical function and response to chemotherapy. The results of this study suggest that PANCREAZE may help mitigate several aspects of cachexia in PDAC patients undergoing standard chemotherapy. Additional studies are warranted to confirm these initial findings and evaluate how weight stabilization and improvements in stool frequency and consistency may impact clinical and quality of life outcomes for these patients."

The poster published at ASCO (Abstract # e24059) describes the results of single-site phase 2 trial (NCT0409823) for pancreatic-enzyme replacement therapy (PERT) with PANCREAZE plus standard of care (SOC) chemotherapy in PDAC patients with cachexia and EPI. The primary outcome measure was to assess feasibility of completing PERT during the first 8 weeks of treatment. Feasibility was defined as adherence to therapy of ≥50% of the needed total lipase units in the first 8 weeks of treatment (84,000 IU lipase units per meal, 42,000 IU lipase units per snack). Secondary outcome measures included weight stability, mean change in stool frequency, stool consistency from Cycle 1 (C1) to Cycle 3 (C3) (after 8 weeks of PERT), mean change in serum levels of fat-soluble vitamins (A, D, E, K) from baseline to end of study, functional activity, and safety. The study enrolled 36 patients, of whom 30 were evaluable for the primary endpoint.

Key findings from the 30 evaluable patients include:

- The adherence rate was 96.7% (29/30).
- Weight remained stable (-0.01±0.07 kg/BMI, p=0.511).
- There was a trend toward reduced stool frequency (p=0.052) from C1 to C3.
- Stool consistency from C1 to C3 showed significant association (p=0.035).

- No significant differences were observed from C1 to C3 in serum fat soluble vitamins, functional activity by walk speed and hand grip strength.
- There were no Grade 3/4 adverse events associated with PANCREAZE.

“These data further demonstrate how our products dovetail with our mission to improve patient quality of life and give healthcare providers new treatment options,” said Santosh T. Varghese, MD, President VIVUS Global Pharmaceutical Development and Chief Medical Officer at VIVUS LLC. “PANCREAZE has already helped to improve outcomes for patients with exocrine pancreatic insufficiency from diseases like cystic fibrosis and chronic pancreatitis, and it is gratifying to see that this product may also provide benefits to patients with PDAC. We commend the clinical team at Cedars-Sinai Medical Center and the Samuel Oschin Cancer Center for their efforts to improve outcomes for these critically ill patients.”

The clinical research team expects to report additional data from this trial later this year at the American Pancreatic Association 2024 Annual Meeting.

About VIVUS
VIVUS is a biopharmaceutical company committed to the development and commercialization of innovative therapies that focus on advancing treatments for patients with serious unmet medical needs. For more information about the Company, please visit http://www.vivus.com.

About PANCREAZE
PANCREAZE is a prescription medicine used to treat people who cannot digest food normally because their pancreas does not make enough enzymes due to cystic fibrosis or other conditions. PANCREAZE may help your body use fats, proteins, and sugars from food. PANCREAZE contains a mixture of digestive enzymes including lipases, proteases, and amylases from pig pancreas. PANCREAZE is safe and effective in children when taken as prescribed by your doctor.

Important Safety Information for PANCREAZE

What is the most important information I should know about PANCREAZE?

- PANCREAZE may increase your chance of having a serious, rare bowel disorder called fibrosing colonopathy that may require surgery.
- The risk of having this condition may be reduced by following the dosing instructions that your healthcare provider gave you.

Call your doctor right away if you have any unusual or severe stomach area (abdominal) pain, bloating, trouble passing stool (having bowel movements), nausea, vomiting, or diarrhea.

Take PANCREAZE exactly as prescribed by your doctor. Do not take more or less PANCREAZE than directed by your doctor.

What are the possible side effects of PANCREAZE?

PANCREAZE may cause serious side effects, including:

- **A rare bowel disorder** called fibrosing colonopathy.
- **Irritation of the inside of your mouth.** This can happen if PANCREAZE is not swallowed completely.
- **Increase in blood uric acid levels**. This may cause worsening of swollen, painful joints (gout) caused by an increase in your blood uric acid levels.
- **Allergic reactions** including trouble with breathing, skin rashes, or swollen lips.

Call your doctor right away if you have any of these symptoms.

The most common side effects include pain in your stomach (abdominal pain) and gas.

Other possible side effects: PANCREAZE and other pancreatic enzyme products are made from the pancreas of pigs, the same pigs people eat as pork. These pigs may carry viruses. Although it has never been reported, it may be possible for a person to get a viral infection from taking pancreatic enzyme products that come from pigs.

These are not all the side effects of PANCREAZE. Talk to your doctor about any side effect that bothers you or does not go away.

You may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

What should I tell my doctor before taking PANCREAZE?

Tell your doctor if you:

- are allergic to pork (pig) products.
- have a history of blockage of your intestines, or scarring or thickening of your bowel wall (fibrosing colonopathy).
- have gout, kidney disease, or high blood uric acid (hyperuricemia).
- have trouble swallowing capsules.
- have any other medical condition.
- are pregnant or plan to become pregnant.
- are breast-feeding or plan to breast-feed.

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements.

The Product Information and Medication Guide for PANCREAZE is available at www.pancreaze.com.

Forward-Looking Statements

Important Information and Cautionary Note Regarding Forward-Looking Statements

Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and/or covered by the "Bespeaks Caution" doctrine applied by the courts under the antifraud provisions of the federal securities laws, and other applicable provisions of the federal securities laws. Such forward-looking statements are based on current expectations, management's beliefs and certain assumptions made by the Company's management. These statements may be identified by the use of forward-looking words such as "will," "shall," "may," "believe," "expect," "forecast," "intend," "anticipate," "predict," "should," "plan," "likely," "opportunity," "estimated," and "potential," and/or the negative use of these words or other similar words. All forward-looking statements included in this document are based on our current expectations, and the Company assumes no obligation to update any such forward-looking statements except to the extent otherwise required by law.

Forward-looking information about PANCREAZE, risks and uncertainties related to our ability to maintain the relationship with the sole manufacturer for PANCREAZE; risks and uncertainties related to our ability to accurately forecast PANCREAZE demand; risks and uncertainties related to our ability to maintain a satisfactory level of PANCREAZE inventory; risks and uncertainties related to the timing, strategy, tactics and success of the marketing and sales of PANCREAZE; risks and uncertainties related to our ability to transition to the improved formulation of PANCREAZE; risks and uncertainties related to our ability to successfully maintain and increase market share against current competing products and potential competitors that may develop alternative formulations of the drug; and risks and uncertainties related to the ability of our partners to maintain regulatory approvals to manufacture and adequately supply our products to meet demand. These risks and uncertainties could cause actual results to differ materially from those referred to in these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements.

The above factors, risks and uncertainties are difficult to predict, contain uncertainties that may materially affect actual results and may be beyond the Company's control. New factors, risks and uncertainties emerge from time to time, and it is not possible for management to predict all such factors, risks and uncertainties. Although the Company believes that the assumptions underlying the forward-looking statements contained herein are reasonable, any of the assumptions could be inaccurate, and therefore any of these statements may prove to be inaccurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation or warranty by the Company or

any other person that the Company's objectives and plans will be achieved. These forward-looking statements speak only as of the date such statements were made or any earlier date indicated, and the Company does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events, changes in underlying assumptions or otherwise, unless otherwise required by law.

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