VIVUS

VIVUS Announces Enrollment of First Patient in Phase 2 Clinical Trial Assessing Ethanol-Free Carmustine as a Component of High-Dose Chemotherapy Prior to Transplant in Patients with Hodgkin or Non-Hodgkin Lymphoma

— Innovative ethanol-free formulation intended to provide improved safety and advance care for patients undergoing high-dose conditioning therapy prior to autologous hematopoietic cell transplantation (AHCT)

— First patient dosed at City of Hope National Medical Center

CAMPBELL, Calif., APRIL 14, 2025, (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, today announced the first patient has been enrolled in a Phase 2 clinical trial evaluating VI-0609, an innovative ethanol-free formulation of carmustine, as a component of high-dose conditioning chemotherapy in patients with refractory or relapsed Hodgkin or non-Hodgkin lymphoma undergoing autologous hematopoietic cell transplant (AHCT). While the most commonly used conditioning regimen (BEAM) includes carmustine formulated with ethanol, VI-0609 is expected to improve safety of this important chemotherapy agent.

“The initiation of this trial further demonstrates VIVUS’ commitment and ability to advance innovative drug formulations that can improve patient outcomes,” said John Amos, Chief Executive Officer at VIVUS LLC. “Conditioning regimens prior to AHCT are arduous, and VI-0609 may help to reduce patient burden by improving the safety profile and enabling shorter infusion times compared with high-dose BiCNU. Consequently, we believe that VI-0609 will provide benefit to treatment centers, health systems and patients.”

The Phase 2 study (NCT06915246) is a randomized multicenter trial designed to evaluate the effects of VI-0609 versus BiCNU in the BEAM high-intensity conditioning regimen for AHCT in subjects with lymphomas. The primary objectives are to evaluate infusion-related toxicities for VI-0609/BiCNU within 24 hours post infusion and unacceptable toxicities for VI-0609/BiCNU from start of BEAM through Day 30 post-AHCT.

“While BEAM is an effective conditioning regimen for AHCT, it is associated with toxicities harmful to patients, such as facial pain, vomiting and swelling of the tongue, some of which likely result from the high levels of ethanol that patients receive during BiCNU infusion,” said Geoffrey Shouse, D.O., Ph.D., Principal Investigator and Assistant Professor, Division of Lymphoma, Department of Hematology & Hematopoietic Cell Transplantation, City of Hope. “As an ethanol-free carmustine formulation, VI-0609 holds promise as an alternative component of BEAM that can effectively prepare patients for AHCT with fewer toxicities. City of Hope is a world leader in setting high standards for stem cell transplantation and improving patient outcomes and this would be an important advancement in the treatment of relapsed and refractory lymphomas.”

“We’re incredibly excited to embark on the launch of our carmustine pipeline. This program, fueled by our strong development engine, represents a significant leap forward in our commitment to patients,” said Santosh T. Varghese, MD, President VIVUS Global Pharmaceutical Development and Chief Medical Officer at VIVUS LLC. “At VIVUS, we believe that by leveraging our robust scientific expertise and pushing the boundaries of innovation, we aim to deliver hope and improved outcomes to patients facing refractory or relapsed Hodgkin or non-Hodgkin lymphoma.”

City of Hope National Medical Center is one of the largest and most advanced cancer research and treatment organizations in the United States, with its National Medical Center in Los Angeles ranked among the nation’s top 5 cancer centers by U.S. News & World Report.

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 VI-0609

VIVUS has developed VI-0609, an innovative ethanol-free formulation of carmustine for injection. This formulation is expected to decrease infusion related reactions versus the current BiCNU ethanol based formulation utilized in high-dose carmustine treatment for myeloablative conditioning.

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 VI-0609, including its potential benefits, approvals in potential markets in the U.S. and anticipated product availability, involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied in this press release. Risks and uncertainties include, among other things, the uncertainties inherent in research and development, including the ability to meet anticipated clinical endpoints, commencement and/or completion dates for our clinical trials, regulatory submission dates, regulatory approval dates and/or launch dates, as well as the possibility of unfavorable new clinical data and further analyses of existing clinical data; the risk that clinical trial data are subject to differing interpretations and assessments by regulatory authorities; whether regulatory authorities will be satisfied with the design of and results from our clinical studies; whether and when drug applications may be filed in any other markets or approved, whether VI-0609 will be commercially successful; decisions by regulatory authorities impacting labeling, manufacturing processes, safety and/or other matters that could affect the availability or commercial potential of VI-0609; uncertainties regarding the impact of COVID-19 on our business, operations, and financial results; and competitive developments.

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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