Viela Bio Announces Positive Interim Results from a Phase 1b Study of VIB7734 in Patients with Cutaneous Lupus Erythematosus

May 13, 2020

-GAITHERSBURG, Md., May 13, 2020 (GLOBE NEWSWIRE) — Viela Bio, Inc. (Nasdaq: VIE), a clinical-stage biotechnology company pioneering treatments for autoimmune and severe inflammatory diseases, today announced positive interim Phase 1b data from a study with VIB7734, its novel anti-ILT7 therapy, in patients with cutaneous lupus erythematosus (CLE). VIB7734 was designed to deplete plasmacytoid dendritic cells (pDCs), an important source of inflammatory mediators in autoimmune diseases. This trial includes three cohorts of patients at ascending dose levels. Cohorts 2 and 3 enrolled patients with CLE. Key measures include safety and tolerability, pDC depletion in peripheral blood and skin lesions of patients with CLE, and Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) scores. Interim results include safety data from patients in cohorts 1 and 2 and a subset of patients in cohort 3, pharmacodynamics results from cohort 2, and CLASI results from cohort 2 and a subset of patients in cohort 3. The interim findings indicated safety and tolerability comparable to placebo control across all cohorts, potent depletion of pDC both in peripheral blood and in inflamed CLE skin lesion biopsies in cohort 2, and dose-dependent reduction in CLASI scores of 4 points or more, which is considered a clinically meaningful change, in cohorts 2 and 3.

“We are very pleased with the interim safety, tolerability and pharmacodynamics results observed in this trial, indicating VIB7734’s potential ability to safely deplete pDCs—a specialized innate immune cell implicated in various autoimmune diseases, including lupus—in inflamed tissues,” said Jorn Drappa, M.D., Ph.D., Viela’s Chief Medical Officer. “The skin biopsy results measuring pDCs and interferon related biomarkers before and after treatment as well as the CLASI scores—a scale that quantifies skin disease activity in CLE patients—indicated clinically meaningful change from baseline in all three measurements when compared to placebo. The safety profile and depletion of pDCs in peripheral blood were consistent with our Phase 1a trial. We look forward to the final data from this trial and providing additional information at a future medical conference.”

Continued Dr. Drappa: “Based on these encouraging results, we intend to advance the program into several Phase 2 clinical studies in indications with high unmet need that are thought to be driven by pDCs.”

Study Details:
This Phase 1b clinical study enrolled three cohorts and is designed to evaluate the safety and tolerability of VIB7734 when given by three monthly subcutaneous doses at escalating dose levels. Cohort 1 enrolled patients with several autoimmune diseases thought to be driven by pDCs. Cohorts 2 and 3 enrolled patients with CLE. In cohorts 2 and 3, skin biopsies were taken before and after treatment to enumerate pDCs and measure interferon mediated gene expression. A clinical disease activity score (CLASI) was also periodically measured in cohorts 2 and 3. The study enrolled a total of 31 patients. Cohort 1 enrolled 8 patients, cohort 2 enrolled 12 patients, and cohort 3 enrolled 11 patients. Each cohort included placebo controls. Final results from cohort 3 are expected in 3Q 2020. The trial was not powered to detect statistically significant changes in pDC depletion and the CLASI scores between placebo and treatment arms.

For more information about the trial, please visit clinicaltrials.gov

About VIB7734
VIB7734 is a novel candidate in development for the treatment of autoimmune diseases caused by the overproduction of type I interferons and other cytokines secreted by specialized innate immune cells called plasmacytoid dendritic cells (pDCs). VIB7734, a monoclonal antibody, is designed to target and bind to ILT7, a cell surface molecule specific to pDCs, leading to their depletion. In turn, this may also decrease other inflammatory cytokines such as TNF-α and IL-6, which are critical to the pathogenesis of a number of autoimmune diseases.

About Viela Bio
Viela Bio, headquartered in Gaithersburg, Maryland, is a clinical-stage biotechnology company pioneering treatments for autoimmune and severe inflammatory diseases. For more information, please visit www.vielabio.com

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, contained in this press release, including statements regarding the timing and progress of our Phase 1b trial of VIB7734 in patients with CLE, and the potential benefits of VIB7734 are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue” or the negative of these terms or other comparable terminology, which are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. Various factors may cause differences between our expectations and actual results as discussed in greater detail in our filings with the Securities and Exchange Commission (SEC), including without limitation, the risks and uncertainties around the duration and severity of the novel coronavirus outbreak and impact of it and COVID-19 on our product candidates clinical trials, development and, if approved, commercialization plans and business operations and the risks and uncertainties described in the section entitled “Risk Factors” in our annual report on Form 10-K for the year ended December 31,
2019 that was filed with the SEC on March 25, 2020 and our subsequent periodic and current reports filed with the SEC. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Source: Viela Bio

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