Imago BioSciences Announces Completion of Enrollment in Phase 2 Clinical Study of Bomedemstat in Essential Thrombocythemia

May 3, 2022

Interim Data Update at European Hematology Association (EHA) meeting in June and Results from Completed Phase 2 Study Expected in Second Half of 2022

End-of-Phase 2 Meeting with U.S. Food and Drug Administration (FDA) Expected in Second Half of 2022

SOUTH SAN FRANCISCO, Calif., May 03, 2022 (GLOBE NEWSWIRE) -- Imago BioSciences, Inc. ("Imago") (Nasdaq: IMGO), a clinical stage biopharmaceutical company discovering and developing new medicines for the treatment of myeloproliferative neoplasms (MPNs) and other bone marrow diseases, today announced that enrollment has been completed for the Phase 2 clinical study of bomedemstat for the treatment of essential thrombocythemia (ET) with 73 patients enrolled, exceeding the initial target enrollment of 60 patients. This study is designed to evaluate the safety, efficacy, pharmacokinetics and pharmacodynamics of bomedemstat, an oral lysine-specific demethylase 1 (LSD1) inhibitor, in patients with ET who have failed at least one standard therapy.

"We are pleased to have completed enrollment in our global Phase 2 clinical study of bomedemstat for the treatment of patients with ET and gratified to have exceeded our initial enrollment target. This is an important milestone taking us one step further in the development of a novel treatment for patients with ET who lack adequate treatment options," said Hugh Young Rienhoff, Jr., M.D., Chief Executive Officer of Imago. "I thank the patients who enrolled in the trial, the clinical investigators and Imago team who worked tirelessly to advance the study to this point. We will present interim data from this study at the June EHA meeting and results from the completed study later this year. We are also planning for an end-of-Phase 2 meeting with the FDA in the second half of 2022 to lay the groundwork for a Phase 3 registrational study."

In December 2021, Imago presented a positive data update at the 2021 American Society of Hematology (ASH) Annual Meeting and Exposition from the Phase 2 ET clinical study. As a monotherapy in a 2nd line ET population, bomedemstat demonstrated significant and durable hematologic control and symptom improvement while maintaining hemoglobin levels. The data demonstrated that 93% of patients dosed for more than 6 weeks with bomedemstat achieved a reduced platelet count to within the normal range, a primary clinical objective. Based on the ASH data, bomedemstat continued to be generally well-tolerated and demonstrated an encouraging safety profile in ET patients.

About the Phase 2 Clinical Study of Bomedemstat in ET

This Phase 2 multi-center, open-label study is designed to assess the safety, efficacy, pharmacokinetics and pharmacodynamics of bomedemstat, an oral inhibitor of LSD1, an enzyme, that plays a central role in the production of blood cells in the bone marrow (www.clinicaltrials.gov Identifier NCT04254978). Eligible patients aged 18 or older with ET who had failed at least one standard therapy and required treatment in order to lower their platelet count were considered eligible for participation in this study. Study objectives include: safety and tolerability, reduction of platelet count to ≤400 x 10^9/L in the absence of thromboembolic events and disease progression, durability of platelet as well as white blood cell (WBC) count reduction and reduction in mutant allele frequency (MAF). The trial is being conducted in the United States, the United Kingdom, Europe, New Zealand, and Australia. We plan to provide interim data at the June EHA meeting and results from the completed study in the second half of this year.

About Imago BioSciences

Imago BioSciences is a clinical-stage biopharmaceutical company discovering and developing novel small molecule product candidates that target lysine-specific demethylase 1 (LSD1), an enzyme that plays a central role in the production of blood cells in the bone marrow. Imago is focused on improving the quality and length of life for patients with cancer and bone marrow diseases. Bomedemstat, an orally available, small molecule inhibitor of LSD1, is the lead product candidate discovered by Imago for the treatment of certain myeloproliferative neoplasms (MPNs), a family of related, chronic cancers of the bone marrow. Imago is evaluating Bomedemstat as a potentially disease-modifying therapy in two Phase 2 clinical trials for the treatment of essential thrombocythemia (NCT04254978) and myelofibrosis (NCT03136185). Bomedemstat has U.S. FDA Orphan Drug and Fast Track Designation for the treatment of ET and MF, European Medicines Agency (EMA) Orphan Designation for the treatment of ET and MF, and PRIority MEdicines (PRIME) Designation by the EMA for the treatment of MF. The company is based in South San Francisco, California. To learn more, visit www.imagobio.com, www.myelofibrosisclinicalstudy.com, www.etclinicalstudy.com and follow us on Twitter @ImagoBioRx, Facebook and LinkedIn.

Forward Looking Statements

This press release contains forward looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "anticipates," "may," "will," "should," "expect," "believe" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements.

These statements may relate to, but are not limited to, the results, conduct, progress and timing of Imago clinical trials, the regulatory approval path for bomedemstat, including a planned registrational clinical program or review of the Phase 3 Protocol and plans for future operations, as well as assumptions relating to the foregoing. Forward looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Important factors that could affect future results and cause those results to differ materially from those expressed in the forward-looking statements include: our limited operating history and lack of products for commercial sale; our significant losses since inception and for the foreseeable future; our need for substantial additional financing; our unpredictable operating results; our business's dependence on development, regulatory approval and commercialization of our product candidates; difficulties in enrolling patients and risks of substantial delays in our clinical trials;

our minimal control over product candidates in investigator-initiated clinical trials; uncertainties in the outcomes of our clinical studies; uncertainties in the regulatory review and approval of our product candidates if our pivotal studies are positive; potentially material changes to the interim, top-line and preliminary data from our clinical trials; potential undesirable effects of our product candidates and safety or supply issues with combination-use products; our potential inability to obtain and maintain orphan drug designation and delays in approvals despite Fast Track designation; risks related to clinical trials outside of the United States; our need to manufacture multiple batches of bomedemstat using a commercial current Good Manufacturing Process; risks related to COVID-19 or other pandemics, natural disasters and wars; risks related to competition; difficulties in expanding our organization and managing growth, attracting and retaining senior management and key scientific personnel and establishing sales and other commercialization functions; risks related to information technology system and cybersecurity; risks related to misconduct of our employees and independent contractors; risks related to hazardous materials and our compliance with environmental laws and regulations; risks related to litigation and other claims; risks related to reliance on third parties to conduct and support preclinical studies and clinical trials, and to manufacture our product candidates; risks related to third-party intellectual property infringement claims and our ability to protect our own intellectual property; risks related to governmental policies and regulations including with respect to drug prices and reimbursement, and changes thereof; risks related to our common stock; risks related to our public company, “emerging growth company” and “smaller reporting company” status; risks related to internal control over financial reporting; and other risks and uncertainties, including those listed in the section titled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 and our subsequent quarterly reports. You should not put undue reliance on any forward-looking statements. Forward looking statements should not be read as a guarantee of future performance or results and will not necessarily be accurate indications of the times at, or by, which such performance or results will be achieved, if at all.

Except as required by law, Imago does not undertake any obligation to update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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