Imago BioSciences Receives Orphan Designation From European Medicines Agency for Bomedemstat for the Treatment of Essential Thrombocythemia

July 30, 2021

SOUTH SAN FRANCISCO, Calif.--(BUSINESS WIRE)--Jul. 30, 2021-- Imago BioSciences, Inc. (Imago) (Nasdaq: IMGO), a clinical stage biopharmaceutical company discovering new medicines for the treatment of myeloproliferative neoplasms (MPNs), today announced that the European Medicines Agency (EMA) has granted orphan designation for bomedemstat, a lysine-specific demethylase-1 (LSD1) inhibitor, for the treatment of essential thrombocythemia (ET).

“As a company dedicated to providing new, safe and effective treatment alternatives for patients with life-threatening diseases of the bone marrow, we are pleased to receive EMA orphan designation for our lead asset, which provides meaningful validation for our treatment approach,” said Hugh Young Rienhoff, Jr., M.D., chief executive officer of Imago BioSciences.

Data presented at the 26th European Hematology Association Virtual Congress showed that bomedemstat was generally well-tolerated by patients with ET and demonstrated promising clinical activity as a monotherapy in patients who have become resistant to or intolerant of one or more standard-of-care treatments. The Phase 2 clinical trial of bomedemstat for the treatment of ET continues to actively enroll globally (NCT04254978).

“Gaining this designation is an important regulatory milestone that gives us added momentum in advancing the development of bomedemstat. We are planning a pivotal study to address the significant medical needs of these patients,” said Wan- Jen Hong, M.D., chief medical officer of Imago BioSciences.

Orphan designation by the EMA is designed to encourage the development of new treatments for life-threatening or chronically debilitating conditions affecting no more than five in 10,000 people in the European Union. Medicines that meet the criteria for orphan designation potentially qualify for several incentives, including 10-year market exclusivity, protocol assistance, and reduced fees for regulatory activities.

About Essential Thrombocythemia

Essential thrombocythemia is a rare blood cancer resulting from the overproduction of platelets, which increases the risk of blood clots and bleeding. It is one of the MPN family of rare bone marrow diseases and affects approximately 80,000 – 100,000 patients in the U.S. There is a significant unmet need for new ET therapies that can effectively reduce patient platelet levels without general bone marrow suppression, while slowing the progression of the underlying disease. By normalizing elevated platelets, the primary clinical feature of ET, bomedemstat can address an unmet need in the 20% of the high-risk ET patients who are intolerant or resistant to hydroxyurea, the current standard-of-care for those patients with ET at greatest risk for blood clots.

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.

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, expectations of future operating results or financial performance, market size and growth opportunities, plans for future operations, competitive position, technological capabilities, and strategic relationships, 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. 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 publicly update or revise any forward-looking statement, whether as a result of new information, future developments or otherwise.

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