Imara Receives Orphan Drug Designation for IMR-687 for Treatment of Beta-thalassemia

June 24, 2020

BOSTON, Mass., June 24, 2020 (GLOBE NEWSWIRE) -- IMARA Inc. (Nasdaq: IMRA), a clinical-stage biopharmaceutical company dedicated to developing and commercializing novel therapeutics to treat patients suffering from rare inherited genetic disorders of hemoglobin, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for IMR-687 for the treatment of patients with beta-thalassemia. The FDA previously granted Orphan Drug Designation for IMR-687 for the treatment of patients with sickle cell disease.

“We are pleased to receive this important designation from the FDA, which underscores the critical need for innovative new treatment options for patients with rare blood disorders such as beta-thalassemia,” said Rahul Ballal, Ph.D., President and Chief Executive Officer of Imara. “This designation comes at an important time for our beta-thalassemia program, where we have recently initiated our Phase 2b clinical trial in the U.S. and expect to dose the first patient in the near-term. In addition, we are progressing regulatory submissions across 14 other countries, making this trial a global effort.”

Orphan Drug Designation is granted by the FDA to drugs or biologics intended to treat a rare disease or condition, defined as one that affects fewer than 200,000 people in the United States. Programs with Orphan Drug status receive partial tax credit for clinical trial expenditures, waived user fees and eligibility for seven years of marketing exclusivity.

About IMR-687

IMR-687 is a highly selective and potent small molecule inhibitor of PDE9. PDE9 uniquely degrades cyclic guanosine monophosphate (cGMP), an active signaling molecule that plays a role in vascular biology. Lower levels of cGMP are often found in people with sickle cell disease and beta-thalassemia and are associated with impaired blood flow, increased inflammation, greater cell adhesion and reduced nitric oxide mediated vasodilation.

Blocking PDE9 acts to increase cGMP levels, which are associated with reactivation of fetal hemoglobin, or HbF, a natural hemoglobin produced during fetal development. Increased levels of HbF in red blood cells have been demonstrated to improve symptomology and lower disease burden in patients with sickle cell disease and patients with beta-thalassemia.

About Imara

Imara Inc. is a clinical-stage biotechnology company dedicated to developing and commercializing novel therapeutics to treat patients suffering from rare inherited genetic disorders of hemoglobin. Imara is currently advancing IMR-687, a highly selective, potent small molecule inhibitor of PDE9 that is an oral, once-a-day, potentially disease-modifying treatment for sickle cell disease and beta-thalassemia. IMR-687 is being designed to have a multimodal mechanism of action that acts on red blood cells, white blood cells, adhesion mediators and other cell types. For more information, please visit www.imaratx.com.

Cautionary Note Regarding Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute “forward-looking statements” within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements made by Dr. Ballal in this press release and statements relating to the (i) design and timing of the recently initiated Phase 2b clinical trial evaluating IMR-687 in patients with beta-thalassemia and (ii) potential advantages of Orphan Drug Designation. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the impact of extraordinary external events, such as the risks and uncertainties resulting from the impact of the COVID-19 pandemic on the Company’s business, operations, strategy, goals and anticipated milestones, including its ability to enroll, dose and readout data from its Phase 2b clinical trial of IMR-687 in beta-thalassemia; and other factors discussed in the “Risk Factors” section of the Company’s most recent Quarterly Report on Form 10-Q, which is on file with the Securities and Exchange Commission and in other filings that the Company makes with the Securities and Exchange Commission in the future. Any forward-looking statements contained in this press release speak only as of the date hereof, and the Company expressly disclaims any obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

Media Contact:
Gina Nugent
Ten Bridge Communications
617-460-3579
gina@tenbridgecommunications.com

Investor Contact:
Michael Gray
617-835-4061
mgray@imaratx.com