Imara Announces First Patient Dosed in Forte Phase 2b Clinical Trial of IMR-687 in Beta-Thalassemia

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Forte is the first clinical trial of IMR-687 in patients with beta-thalassemia and follows the initiation of Ardent Phase 2b clinical trial of IMR-687 in sickle cell disease

BOSTON, Oct. 16, 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 dosing of the first patient in the company's Forte Phase 2b clinical trial of IMR-687 for patients with beta-thalassemia.

"There are currently no approved oral therapies to increase fetal hemoglobin in beta-thalassemia, a rare inherited red blood cell disorder which if left untreated, causes severe anemia, enlarged spleen, skeletal abnormalities, organ failure and early death," said Perla Eleftheriou, Consultant Hematologist in the Red Cell Hematology department at University College London Hospitals NHS Foundation Trust and Honorary Clinical Senior Lecturer at University College London and national lead investigator in the United Kingdom on the Forte trial. "We believe there is a clear rationale to expand development of IMR-687 to include beta-thalassemia and we look forward to working alongside multiple clinical centers globally to advance IMR-687 in the Forte clinical trial."

"Dosing of the first patient in the Forte Phase 2b clinical trial marks an important milestone for Imara as we begin clinical evaluation of IMR-687 for the first time in patients with beta-thalassemia," said Rahul Ballal, Ph.D., President and Chief Executive Officer of Imara. "Multiple preclinical studies show that treatment with IMR-687 enhances both the maturation and production of red blood cells in beta-thalassemia and we are looking forward to advancing this potentially transformative oral therapy for patients."

Dr. Ballal continued, "Patient dosing in the Forte 2b clinical trial follows initiation of dosing this August in our Ardent Phase 2b clinical trial in patients with sickle cell disease. These advancements transform Imara into a company with a drug candidate in multiple indications across global, multi-center clinical trials. Managing the various clinical manifestations of beta-thalassemia and sickle cell disease is complex and patients around the world have few accessible treatment options. At Imara, we remain committed to working together with our clinical trial partners, investigators and the patient community to evaluate the therapeutic potential of IMR-687 as an oral, once-a-day, potentially disease-modifying treatment for these rare inherited blood disorders."

The global, randomized, double-blind, placebo-controlled, multicenter Forte Phase 2b clinical trial will evaluate the safety and tolerability of IMR-687 in approximately 120 adult beta-thalassemia patients. Patient randomization will be stratified by transfusion dependence (TDT) or non-transfusion dependence (NTDT) and weight-based dosing will be employed to optimize drug exposure and tolerability. For TDT patients, the clinical trial will also evaluate the effect of IMR-687 versus placebo in reducing the average number of days between red blood cell transfusions and change in iron load rate as a result of transfusion. For NTDT patients, the effect of IMR-687 versus placebo on fetal hemoglobin as well as on anemia will also be evaluated. The Forte trial will also examine pharmacokinetic and additional exploratory efficacy endpoints. There are pre-specified interim analyses planned in the trial, with the first such interim analysis to be conducted when 30 patients have reached 24 weeks of treatment and an additional interim analysis being conducted when 30 patients have reached 36 weeks of treatment. For more information about the Forte trial visit https://www.clinicaltrials.gov/ct2/show/NCT04411082.

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

Blocking PDE9 acts to increase cGMP levels, which is associated with reactivation of fetal hemoglobin (HbF), a natural hemoglobin produced during fetal development. Increased levels of HbF in RBCs have been demonstrated to improve symptomology and substantially lower disease burden in both patients with SCD and patients with beta-thalassemia.

About Beta-Thalassemia
Beta-thalassemia, a hemoglobinopathy, is a rare inherited red blood cell disorder. Beta-thalassemia presents as a spectrum of disease, with patients categorized based on hemoglobin levels, genotype and clinical manifestations. If left untreated, the disease causes severe anemia, splenomegaly, skeletal abnormalities, organ failure and early death.

The prevalence of beta-thalassemia globally is estimated to be 288,000, with an incidence of 60,000 births per year, and it is especially prevalent in developing countries of Africa, South Asia, Southeast Asia, the Mediterranean region and the Middle East. The total combined prevalence of beta thalassemia in the European Union and United States is estimated to be approximately 19,000 patients.

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 from Dr. Eleftheriou and Dr. Ballal and statements relating to the design of the Forte Phase 2b clinical trial and the Company’s beliefs regarding the therapeutic potential of IMR-687 and advancement of its clinical program. 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; the Company’s ability to advance the development of IMR-687 under the timelines it projects in current and future clinical trials, demonstrate in any current and future clinical trials the requisite safety and efficacy of IMR-687, replicate scientific and non-clinical data in clinical trials, obtain and maintain necessary regulatory approvals, obtain, maintain and enforce necessary patent and other intellectual property protection, identify, enter into and maintain collaboration agreements with third parties, manage competition, manage expenses, raise the substantial additional capital needed to achieve its business objectives, attract and retain qualified personnel, and successfully execute on its business strategies; 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.

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