Imara Announces Completion of Patient Enrollment in Ardent Phase 2b Clinical Trial of IMR-687 (tovinontrine) for Sickle Cell Disease

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Interim analysis expected in fourth quarter of 2021 and primary endpoint readout now expected in first quarter of 2022

BOSTON, Aug. 05, 2021 (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 and other serious diseases, today announced that the company has completed patient enrollment in the Ardent Phase 2b clinical trial of IMR-687, a potent small molecule inhibitor of PDE9, for the treatment of sickle cell disease (SCD). Imara also announced that the United States Adopted Names (USAN) Council adopted "*tovinontrine*" (pronounced toe" vi non' treen) as the generic name for IMR-687.

"We are pleased to achieve this important milestone for IMR-687," said Rahul Ballal, Ph.D., President and Chief Executive Officer of Imara. "Furthermore, we are excited to have enrolled subjects from across the world, including in Africa, making this a truly global effort. We look forward to reporting interim data for the Ardent trial in the fourth quarter of this year and can now refine guidance and expect to report data from the primary analysis in the first quarter of 2022."

The Ardent Phase 2b clinical trial is a randomized, double-blind, placebo-controlled, multicenter study designed to evaluate the safety and efficacy of IMR-687 administered once daily in approximately 99 adult patients with sickle cell disease. Patients are randomized to IMR-687 higher dose (once daily dose of 300 mg or 400 mg based on patient weight), IMR-687 lower dose (once daily dose of 200 mg or 300 mg based on patient weight), or placebo. The trial is being conducted at approximately 50 sites in 13 different countries.

About IMR-687 (tovinontrine)
IMR-687 (tovinontrine) 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. IMR-687 is designed to have a multimodal mechanism of action that acts on red blood cells, white blood cells, adhesion mediators, and other cell types.

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 and other serious diseases. Imara is currently advancing IMR-687 (tovinontrine), 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 relating to the timing with respect to reporting of data from the Ardent Phase 2b clinical trial in patients with sickle cell disease. 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 ongoing and planned research activities and ability to conduct and readout data from its ongoing clinical trials of IMR-687; 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, 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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