Imara Announces Opening of Higher Dose Arms in Global Phase 2b Clinical Trials of IMR-687 for Sickle Cell Disease and Beta-Thalassemia

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Independent Data Monitoring Committees endorse opening higher dose IMR-687 treatment arms in ongoing Ardent and Forte Phase 2b clinical trials after review of safety and tolerability data at lower doses

Safety Review Committee in Phase 2a open label extension trial supports daily dose increase to align with higher dose arms of Phase 2b clinical trials

BOSTON, March 17, 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, today announced that separate independent data monitoring committees (DMCs) for the Ardent and Forte Phase 2b clinical trials of IMR-687 for sickle cell disease and beta-thalassemia, respectively, have recommended opening of the higher dose IMR-687 treatment arm in each of these studies following review of available safety and tolerability data. These additional arms were pre-specified in the two protocols and enrollment is proceeding in each study at the 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.

“We are pleased that the DMCs’ review of safety data has resulted in opening of the higher dose arms in the Forte Phase 2b clinical trial in patients with beta-thalassemia in January and more recently in the Ardent Phase 2b clinical trial in patients with sickle cell disease in March,” said Rahul Ballal, Ph.D., President and Chief Executive Officer of Imara. “We designed each of these trials to allow for the additional higher dose arm of IMR-687 and expect to report preliminary data from the higher dose arms as part of our planned data readouts in the second half of 2021. Dosing in our recently completed Phase 2a clinical trial in sickle cell disease started as low as 50 mg per day and escalated sequentially to 100 mg or 200 mg per day over 16-24 weeks. Dosing in the Phase 2b clinical trials is substantially higher, both at the starting dose and through the treatment period, which is 36 weeks for the Forte trial and 52 weeks for the Ardent trial.”

Similar to the Phase 2b clinical trials, a separate safety review committee reviewed the available safety and tolerability data from patients in Imara’s ongoing Phase 2a open label extension (OLE) clinical trial of IMR-687 in patients with sickle cell disease and recommended increasing the daily dose from 200mg to either 300 mg or 400 mg, based on patient weight. This dose level is identical to the higher dose arms of the Phase 2b clinical trials and it is anticipated that patients will begin dose escalation to the higher dose under an amended protocol by mid-2021.

Additional information about the Ardent, Forte and OLE clinical trials can be found at www.clinicaltrials.gov.

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. 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. 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. 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 (i) content of, and timing with respect to, the reporting of data from the Ardent and Forte Phase 2b clinical trials in patients with sickle cell disease and beta-thalassemia and (ii) the timing with respect to dose escalation of IMR-687 as part of the OLE clinical trial (iii) the Company’s beliefs regarding the tolerability and 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, 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, replicate scientific and non-clinical data in both subsequent case report readouts and in clinical trials and other factors discussed in the “Risk Factors” section of the Company’s most recent Annual Report on Form 10-K, 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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