Imara Presents IMR-687 Phase 2a Open Label Extension Case Reports on Two Patients with Sickle Cell Disease at the 62nd ASH Annual Meeting and Exposition

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Preliminary data as of August 2020 from ongoing Phase 2a open label extension trial showed increases in HbF percentage and F-cells after approximately six months of treatment

Case reports showed additional improvements in clinical outcomes, hemoglobin and related biomarkers of hemolysis

IMR-687 continued to be well tolerated as a monotherapy and in combination with hydroxyurea

BOSTON, Dec. 07, 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 it presented two case reports from the ongoing IMR-687 Phase 2a open label extension (OLE) clinical trial in adult patients with sickle cell disease (SCD) at the 62nd American Society of Hematology (ASH) Annual Meeting and Exposition. IMR-687 is an oral, once-a-day, potentially disease modifying investigational treatment for sickle cell disease (SCD) and beta-thalassemia.

Preliminary data in these case reports, as of an August 2020 review, showed that the first two SCD patients treated for approximately six months or greater in the OLE trial demonstrated higher HbF percentage and F-cell increases compared to baseline when treated with IMR-687, as a monotherapy or in combination with stable dose hydroxyurea (HU). Treatment with IMR-687 was also associated with improvements in clinical outcomes and red cell markers, including hemoglobin (Hb) levels and measures of hemolysis in both patients. IMR-687 was well tolerated by both patients.

“We are encouraged by these case reports presented at ASH demonstrating that treatment with IMR-687, at approximately six months or greater, provided benefit to these two patients with sickle cell disease,” said Rahul Ballal, Ph.D., President and Chief Executive Officer of Imara. “We believe these reports may help elucidate the potential benefit of longer term use with IMR-687 and are pleased that we have recently enrolled the 24th patient in the OLE trial. We expect to report additional data on approximately 10 to 15 patients from the OLE trial during the first quarter of 2021.”

Dr. Ballal continued, “Imara is also continuing to dose adult patients with sickle cell disease in our Ardent Phase 2b clinical trial, a randomized, double-blind, placebo controlled clinical trial evaluating the potential treatment benefit of IMR-687 for up to one year of therapy and at higher doses than the OLE.”

Both patients in the case reports were initially administered a daily dose of 100 mg of IMR-687 on the OLE trial, and in the second quarter of 2020, a protocol amendment increased their daily dose to 200 mg. The reported VOC comparisons involve retrospective reviews of the patients’ medical records and is therefore not a statistical approach. Highlights of the reports include:

- Patient #1 received 100 mg (3 months) and 200 mg (3 months) of IMR-687 as monotherapy during the Phase 2a trial. As of June 2020, this patient had been on IMR-687 for 18 months, either as part of the Phase 2a trial (six months) or as part of the OLE trial (additional 12 months). This patient experienced a 55% reduction (38 to 17) in reported vaso-occlusive crises (VOCs) when comparing the 18 months prior to treatment with the 18 months on IMR-687 treatment. Importantly, reductions in VOCs correlated with increased time on therapy. Improvements as compared to baseline across key red cell markers, including HbF, F-cells, Hb and other markers of hemolysis were also observed.

- Patient #2 completed approximately six months of treatment with IMR-687 (100mg for 4 months/200 mg for ~2 months) on the OLE trial as of August 2020. This patient entered the Phase 2a trial as part of the HU combination sub-study and was randomized to the placebo dose group, and therefore never received IMR-687 during the Phase 2a trial. This patient started the OLE trial with IMR-687 approximately 14 months after completing the Phase 2a trial while remaining on a stable background dose of HU during this period and throughout the OLE trial. This patient experienced zero VOCs in the six month period while on IMR-687 in combination with HU, as compared to 15 reported VOCs in the 6 months prior to commencing treatment with IMR-687, while on HU alone. Improvements as compared to baseline across key red cell markers were also observed, including, HbF, F-cells, Hb and other markers of hemolysis.

The presentation, titled “Benefits and Safety of Long-Term Use of IMR-687 as Monotherapy or in Combination with a Stable Dose of Hydroxyurea (HU) in 2 Adult Sickle Cell Patients,” was made by Lanetta Bronte-Hall, M.D., M.P.H., M.S.P.H., President and Chief Executive Officer of the Foundation for Sickle Cell Disease Research and shared virtually on the ASH website on Sunday, December 6, 2020. The presentation can be found at the Investors section of Imara’s website.

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) content of, and timing with respect to, reporting of data from the OLE trial evaluating IMR-687 in patients with sickle cell disease, (ii) clinical trial design with respect to the Ardent Phase 2b clinical trial and (iii) the Company's beliefs regarding the strength of its clinical data, 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, 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 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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