Imara Reports Full Year 2021 Financial Results and Business Highlights

March 15, 2022

Completed enrollment in Phase 2b sickle cell disease and beta-thalassemia trials with tovinontrine (IMR-687); expect to report both interim datasets in first week of April 2022

Changed primary endpoint of Ardent Phase 2b trial in sickle cell disease to reductions in annualized rate of VOCs at written request of the FDA

Added clinical indication for tovinontrine to include the treatment of HFpEF; anticipate first subject dosing in Phase 2 trial in second quarter of 2022

Expanded pipeline with addition of IMR-261, an oral, clinic-ready Nrf2 activator with potential indications in hemoglobin and iron overload disorders

Company to host conference call and live webcast today at 8:30 AM ET

BOSTON, March 15, 2022 (GLOBE NEWSWIRE) -- Imara Inc. (Nasdaq: IMRA), a clinical-stage biopharmaceutical company dedicated to developing and commercializing novel therapeutics to treat patients suffering from rare hemoglobin disorders and other serious diseases, today reported financial results for the year ended December 31, 2021 and reviewed recent business highlights.

“In 2021, we executed to plan by completing enrollment in our Phase 2b programs and keeping studies on track for upcoming interim readouts, despite the challenges of the COVID-19 pandemic,” said Rahul Ballal, Ph.D., President and Chief Executive Officer of Imara. “Furthermore, we added an important clinical indication in heart failure with preserved ejection fraction (HFpEF) for tovinontrine, and expanded our pipeline to include another oral, clinic-ready asset in IMR-261. Throughout the year we engaged the FDA on our sickle cell disease (SCD) program and in November 2021, received a written recommendation to change the primary endpoint for our Ardent Phase 2b clinical trial to annualized rate of vaso-occlusive crises (VOCs). We believe that this is a materially positive development since the reduction in annualized VOC rate is an important clinical outcome measure for patients and providers, as well as an established approval endpoint. We look forward to engaging the FDA again after our upcoming Ardent interim analysis on a registration path for tovinontrine.”

Dr. Ballal continued, “At medical meetings in 2021, we presented data from our completed Phase 2a and ongoing Phase 2a open label extension trials of tovinontrine in adults with SCD that demonstrated its potential benefits with respect to VOCs, including a lower annualized rate of VOCs. We hope to build upon these promising results in our interim analysis, which we expect will occur in the first week of April. The interim analysis for the Ardent trial will be a comparison of the annualized rate of VOCs in the high dose arm of tovinontrine versus placebo, as well as safety data for high, low, and placebo dose groups.”

“We also expect to report data from the transfusion-dependent cohort of the Forte Phase 2b clinical trial of tovinontrine in beta-thalassemia and the first clinical data for the non-transfusion-dependent cohort of this trial in the first week of April. We anticipate that these datasets will include safety, biomarker data, and for patients in the transfusion-dependent cohort, data on transfusion burden.”

“While our trials of tovinontrine as a treatment for SCD and beta-thalassemia remain foundational, I am excited about tovinontrine’s potential in HFpEF,” said Dr. Ballal. “In January 2022, the FDA cleared our investigational new drug application for tovinontrine in HFpEF and we expect to dose the first subject in our SP_9IN Phase 2 clinical trial of tovinontrine in HFpEF in the second quarter of 2022. The SP_9IN trial is designed to focus on identifying HFpEF patients with high PDE9 expression, creating a targeted approach to this highly prevalent disease. With tovinontrine, we believe we have the best-in-class PDE9 inhibitor for evaluation in this patient population, with *in vitro* data demonstrating superior potency and selectivity when compared to other PDE9 inhibitors.”

Dr. Ballal continued, “Finally, we are pleased to have expanded our pipeline with the addition of IMR-261, an oral, clinic-ready activator of nuclear factor erythroid 2–related factor 2 (Nrf2). We reported robust data with IMR-261 in validated preclinical models of sickle cell disease and beta-thalassemia at the American Society of Hematology (ASH) Annual Meeting in December 2021. We believe that IMR-261 also has the potential to work on several areas beyond hemoglobin disorders and we are actively exploring diseases of iron overload. It is exciting to add this clinic-ready asset to the pipeline and we look forward to providing further updates on study plans in 2022.”

Recent Corporate Highlights and Updates

- **Changed Ardent Phase 2b Clinical Trial Primary Endpoint to Annualized Rate of VOCs**: The primary endpoint of the Phase 2b clinical trial of tovinontrine in patients with SCD was changed from fetal hemoglobin (HbF) response to annualized rate of VOCs based on a written recommendation from the FDA. The endpoint revisions did not affect the conduct of the trial or operational aspects of the study. The interim analysis from the Ardent study, including annualized VOC rate from the high dose (once daily dose of 300 mg or 400 mg based on patient weight) and placebo groups, is conducted when all subjects have completed assessment at Week 24 or terminated early. Imara expects to report data from this interim analysis in the first week of April 2022.

- **Presented 12-Month Phase 2a Open Label Extension (OLE) clinical data at the American Society of Hematology (ASH) annual meeting:** 12-month VOC data from the ongoing Phase 2a OLE clinical trial was presented at the ASH Annual Meeting in December 2021 and showed patients who were on tovinontrine in the completed Phase 2a clinical trial

maintained a reduced annualized rate of VOCs in the OLE trial. In addition, a 38% reduction in median annualized VOC rate was observed in patients that were dosed with placebo in the Phase 2a clinical but dosed with tovinontrine as part of the OLE. These data build upon previously reported positive VOC results from the Phase 2a and OLE clinical trials that were presented at the European Hematology Association Annual Congress in June 2021.

- **Reported First Clinical Data for Tovinontrine in Beta-Thalassemia:** Imara reported interim clinical data from the Forte Phase 2b clinical trial exploring tovinontrine's potential in patients with beta-thalassemia. Interim data from the Forte trial demonstrated tovinontrine was well-tolerated and showed a positive trend for transfusion burden reduction at the higher dose of tovinontrine in patients in the transfusion-dependent cohort. Imara plans to report additional interim data from the transfusion-dependent and non-transfusion-dependent cohorts at 24 weeks in the first week of April 2022.

- **FDA Cleared the Investigational New Drug (IND) Application for Commencement of Tovinontrine Clinical Development for the Treatment of HFpEF:** The FDA cleared the IND application for tovinontrine to commence clinical development for the treatment of HFpEF, previously announced in January 2022, and Imara expects to dose the first subject in its SP_9IN Phase 2 clinical trial in the second quarter of 2022. Imara previously reported results of studies of tovinontrine in preclinical models of HFpEF at the American Heart Association Scientific Sessions in November 2021 that supported the further development of tovinontrine as a potential treatment for HFpEF.

- **Enhanced Pipeline with Addition of IMR-261**: Imara announced the addition of IMR-261 to its pipeline in the fourth quarter of 2021 and preclinical data on IMR-261 was presented at the ASH Annual Meeting in December 2021. In preclinical SCD models, IMR-261 was observed to increase HbF and reduce VOCs. In a preclinical beta-thalassemia model, IMR-261 increased hemoglobin and enabled red blood cell maturation. Imara has initiated work on drug product manufacturing for IMR-261, as it explores potential clinical development paths, including in iron overload disorders.

Full Year 2021 Financial Results

- **Cash Position:** Cash, cash equivalents and investments were $90.3 million as of December 31, 2021, as compared to cash, cash equivalents and investments of $88.2 million as of December 31, 2020.

- **Research and Development Expenses:** Research and development expenses were $38.4 million for the year ended December 31, 2021, as compared to $32.2 million for the year ended December 31, 2020. The increase of $6.2 million was primarily related to the development and manufacturing of clinical materials, clinical research and oversight of the Company's clinical trials and investigative fees related to the development of IMR-687, as well as increased personnel-related and other research and development operating costs.

- **General and Administrative Expenses:** General and administrative expenses were $13.0 million for the year ended December 31, 2021, as compared to $9.5 million for the year ended December 31, 2020. The increase of $3.5 million was primarily due to increased cost associated with directors' and officers' insurance premiums, as well as increased personnel-related and other general and administrative operating costs as a result of operating as a public company.

- **Net Loss Attributable to Common Stockholders:** Net loss attributable to common stockholders was $51.4 million, or $2.37 per share, for the year ended December 31, 2021, as compared to a net loss of $49.2 million, or $3.53 per share, for the year ended December 31, 2020.

Financial Guidance

The Company currently expects that its full-year 2022 research and development expenses will range between $60 million and $65 million and that its full-year 2022 general and administrative expenses will range between $13 million and $15 million. The Company expects that its cash, cash equivalents and investments as of December 31, 2021, will be sufficient to enable it to fund its planned operations substantially through the first quarter of 2023.

Conference Call and Webcast Information

Imara will host a conference call and live webcast today at 8:30 a.m. ET to discuss its full year 2021 financial results and other business updates.

The live webcast will be available under "Events and Presentations" in the Investors section of the Company's website at imaratx.com. The conference call can be accessed by dialing +1 (833) 519-1307 (U.S. domestic) or +1 (914) 800-3873 (international) and referring to conference ID 5889355. A replay of the webcast will be archived on the Imara website following the presentation.

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 advancing tovinontrine (IMR-687), a highly selective, potent small molecule inhibitor of PDE9 that is an oral, potentially disease-modifying treatment in Phase 2b clinical trials for sickle cell disease and beta-thalassemia. Imara expects to initiate a Phase 2 clinical trial of tovinontrine in heart failure with preserved ejection fraction (HFpEF) in the second

quarter of 2022. Imara is also advancing IMR-261, an oral activator of nuclear factor erythroid 2–related factor 2, or Nrf2. 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 (i) the timing and content of interim data from the Company's ongoing Ardent and Forte Phase 2b clinical trials of tovinontrine (IMR-687) in patients with sickle cell disease and beta-thalassemia (ii) the Company's timing and clinical development plans for tovinontrine in HFpEF, (iii) the Company's clinical development plans for the potential future development of IMR-261, and (iv) financial guidance regarding the Company's projected operating expenses and sufficiency of the Company's capital resources to fund its operations substantially through the first quarter of 2023. 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 readout data from its open label extension clinical trial of tovinontrine in sickle cell disease and its Phase 2b clinical trials of tovinontrine in sickle cell disease and beta-thalassemia and to initiate its planned Phase 2 clinical trial of tovinontrine in HFpEF; the Company's ability to advance the development of tovinontrine 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 tovinontrine; 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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IMARA INC.

CONSOLIDATED BALANCE SHEET DATA

(in thousands)
(Unaudited)

	December 31, 2021	December 31, 2020
Cash, cash equivalents and investments	$ 90,278	$ 88,222
Working capital [1]	85,486	84,158
Total assets	93,646	90,842
Total liabilities	7,616	6,407
Convertible preferred stock	—	—
Accumulated deficit	(147,497)	(96,113)
Total stockholders' equity	86,030	84,435

(1) Working capital is defined as current assets less current liabilities.

IMARA INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except share and per share data)
(Unaudited)

	Years ended December 31,	
	2021	2020
Operating expenses:		
Research and development	$ 38,442	$ 32,154
General and administrative	13,000	9,544
Total operating expenses	$ 51,442	$ 41,698
Loss from operations	(51,442)	(41,698)
Total other income, (net):		
Interest income	233	483

Other expense	(175)	(145)
Total other income, (net)	$ 58	$ 338
Net loss	$ (51,384)	$ (41,360)
Accretion of Series B convertible preferred stock	—	(7,858)
Net loss attributable to common stockholders—basic and diluted	$ (51,384)	$ (49,218)
Net loss per share applicable to common stockholders—basic and diluted	$ (2.37)	$ (3.53)
Weighted-average common shares outstanding—basic and diluted	$ 21,661,450	$ 13,924,730