Immuneering Receives FDA Fast Track Designation for IMM-1-104 in Pancreatic Cancer

February 20, 2024

– Fast Track designation has the potential to accelerate lead asset IMM-1-104's path to U.S. FDA submission for pancreatic ductal adenocarcinoma –

– Company expects multiple readouts from its Phase 1/2a clinical trial in 2024 -

CAMBRIDGE, Mass., Feb. 20, 2024 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a clinical-stage oncology company seeking to develop and commercialize universal-RAS/RAF medicines for broad populations of cancer patients, today announced that the U.S. Food and Drug Administration (FDA) granted Fast Track designation for its lead clinical-stage program, IMM-1-104, for the treatment of patients with pancreatic ductal adenocarcinoma (PDAC) who have failed one line of treatment. IMM-1-104 is designed to provide universal-RAS activity through deep cyclic inhibition of the MAPK pathway with once-daily oral dosing.

"We welcome FDA's decision to grant Fast Track designation for IMM-1-104. Our Phase 1/2a study is designed to evaluate IMM-1-104 in pancreatic cancer, as well as a number of other tumor types associated with the RAS pathway. We look forward to a data-rich 2024 as we plan to provide multiple readouts from our study this year," said Ben Zeskind, Ph.D., Co-founder and Chief Executive Officer of Immuneering.

Vincent Chung, M.D., FACP, Professor, Department of Medical Oncology and Therapeutics Research, is principal investigator of the Phase 1/2a clinical study with IMM-1-104 at City of Hope, one of the largest cancer research and treatment organizations in the United States.

"The FDA's decision reinforces the importance of developing effective, novel treatments to improve the health outcomes of patients with pancreatic ductal adenocarcinoma. The development of well-tolerated oral medicines would improve the lives of these patients. City of Hope offers many clinical trials testing innovative treatments for people with pancreatic cancer," Chung said.

About Fast Track Designation

Fast Track Designation is a program designed to facilitate the development and expedite the review of medicines with the potential to treat serious conditions and fulfill an unmet medical need. An investigational medicine that receives Fast Track Designation may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan and, if relevant criteria are met, may be eligible for accelerated approval and priority review.

About Immuneering Corporation

Immuneering is a clinical-stage oncology company seeking to develop and commercialize universal-RAS/RAF medicines for broad populations of cancer patients with an initial aim to develop a universal-RAS therapy. The Company aims to achieve universal activity through deep cyclic inhibition of the MAPK pathway, impacting cancer cells while sparing healthy cells. Immuneering's lead product candidate, IMM-1-104, is an oral, once-daily deep cyclic inhibitor currently in a Phase 1/2a study in patients with advanced solid tumors harboring RAS mutations. IMM-6-415 is an oral, twice-daily deep cyclic inhibitor and will be evaluated in a Phase 1/2a study in patients with advanced solid tumors harboring RAS or RAF mutations. The company's development pipeline also includes several early-stage programs. For more information, please visit www.immuneering.com.

Forward-Looking Statements

This press release contains forward-looking statements, including within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements concerning: the expected design, timing, enrollment and advancement of, and data results from, preclinical studies and clinical trials involving our product candidates; the potential of our product candidates to be used as monotherapies and / or in combination with other therapeutic agents, including to treat RAS or RAF mutant diseases; and the clinical development of IMM-1-104 and IMM-6-415, including the potential for fast track designation to accelerate development of IMM-1-104 in pancreatic cancer.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the risks inherent in oncology drug research and development, including target discovery, target validation, lead compound identification, and lead compound optimization; we have incurred significant losses, are not currently profitable and may never become profitable; our projected cash runway; our need for additional funding; our unproven approach to therapeutic intervention; our ability to address regulatory questions and the uncertainties relating to regulatory filings, reviews and approvals; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in or failure to obtain regulatory approvals; our reliance on third parties and collaborators to conduct our clinical trials, manufacture our product candidates, and develop and commercialize our product candidates, if approved; failure to compete successfully against other drug companies; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; our patents being found invalid or unenforceable; costs and resources of operating as a public company; and unfavorable or no analyst research or reports.

These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended September 30, 2023, and our other reports filed with the United States Securities and Exchange Commission, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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