Immuneering Granted FDA Fast Track Designation for IMM-1-104 in First-line Pancreatic Cancer

July 31, 2024

- IMM-1-104 Fast Track designation now granted for the treatment of both first and second-line pancreatic ductal adenocarcinoma (PDAC); provides potential to accelerate IMM-1-104's path to U.S. FDA submission for PDAC -

- Phase 2a trial of IMM-1-104 includes multiple arms open to first-line pancreatic cancer patients, as well as arms open to patients with second-line pancreatic cancer, RAS-mutant melanoma, and RAS-mutant lung cancer -

- Company expects initial data from multiple arms of its Phase 2a clinical trial in the second half of 2024 -

CAMBRIDGE, Mass., July 31, 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, as a first-line treatment for patients with pancreatic ductal adenocarcinoma (PDAC). In February 2024, the Company announced Fast Track designation for IMM-1-104 as second-line treatment for patients with PDAC who have failed one previous line of therapy. IMM-1-104 is designed to provide universal-RAS activity through Deep Cyclic Inhibition of the MAPK pathway with once-daily oral dosing.

"First-line pancreatic cancer patients are eligible and actively enrolling in our Phase 2a study, in two arms evaluating IMM-1-104 in combination with chemotherapy," said Ben Zeskind, Ph.D., Co-founder and Chief Executive Officer of Immuneering. "With Fast Track designation now granted for IMM-1-104 in both first and second-line pancreatic cancer, we have the potential to help a broader population of patients impacted by one of the most difficult to treat cancers. Our Phase 2a study also includes an arm evaluating IMM-1-104 as monotherapy in first and second-line pancreatic cancer patients, along with monotherapy arms focused on RAS mutant melanoma and RAS mutant non-small cell lung cancer. We look forward to sharing initial data from multiple arms of the study this year."

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 trial in patients with advanced solid tumors harboring RAS mutations. IMM-6-415 is an oral, twice-daily Deep Cyclic Inhibitor currently in a Phase 1/2a trial 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 regarding: Immuneering's plans to develop, manufacture and commercialize its product candidates; the treatment potential of IMM-1-104, alone or in combination with other agents, the design, enrollment criteria and conduct of the Phase 1/2a clinical trial of IMM-1-104; the potential for fast track designation to accelerate development of IMM-1-104 in pancreatic cancer; and the timing of results of the Phase 2a portion of the trial for IMM-1-104.

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 March 31, 2024, and our other reports filed with the U.S. 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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