Immuneering Granted Orphan Drug Designation for IMM-1-104 by FDA in the Treatment of Pancreatic Cancer

October 15, 2024

- Immuneering recently announced positive initial Phase 2a data, including complete and partial responses, with IMM-1-104 in combination with chemotherapy in first-line pancreatic cancer patients -

-Initial data from at least one additional arm of the Phase 2a portion of the Company's Phase 1/2a trial is expected by year-end -

CAMBRIDGE, Mass., Oct. 15, 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) has granted orphan drug designation to IMM-1-104 in the treatment of pancreatic cancer. IMM-1-104 is currently being evaluated in a Phase 2a clinical trial in patients with advanced solid tumors, including pancreatic cancer, in which positive initial response data was recently reported for first line pancreatic cancer patients treated in combination with modified gemcitabine/nab-paclitaxel.

"The FDA's granting of orphan drug designation for IMM-1-104 underscores the urgent need for new therapies that meaningfully improve outcomes for pancreatic cancer patients and represents an important milestone in the development of our lead asset," said Ben Zeskind, Ph.D., Co-Founder and CEO of Immuneering. "I believe our recently announced positive initial Phase 2a data, from our arm investigating IMM-1-104 in combination with modified gemcitabine/nab-paclitaxel in pancreatic cancer, speaks to IMM-1-104's potential to improve upon the current standard of care in this indication. Importantly, in the same trial we are also studying IMM-1-104 in combination with modified FOLFIRINOX, as well as in monotherapy for pancreatic cancer. We look forward to providing initial data from at least one additional arm of the Phase 2a portion of our Phase 1/2a trial before the end of the year."

FDA orphan drug designation is granted to investigational therapies addressing rare medical diseases or conditions that affect fewer than 200,000 people in the United States. Orphan drug designation may qualify sponsors for incentives, including tax credits for qualified clinical trials, exemptions from certain FDA fees and additional time for post-approval marketing exclusivity. Earlier this year, Immuneering was granted FDA Fast Track designation for IMM-1-104 for the treatment of both first and second-line pancreatic cancer.

About IMM-1-104

IMM-1-104 aims to achieve universal-RAS activity that selectively impacts cancer cells to a greater extent than healthy cells, through Deep Cyclic Inhibition of the MAPK pathway with once-daily dosing. IMM-1-104 is currently being evaluated in a Phase 1/2a study in patients with advanced solid tumors harboring RAS mutations (NCT05585320).

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 2a trial in patients with advanced solid tumors including those 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, including chemotherapy; the design, enrollment and conduct of the Phase 1/2a IMM-1-104 clinical trial; the possible incentives and other benefits that could result from orphan drug designation of IMM-1-104; and the timing of additional results from 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 three month period ended June 30, 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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