Immuneering Granted FDA Fast Track Designation for IMM-1-104 in Advanced Melanoma

December 12, 2024

- IMM-1-104 has the potential to benefit melanoma patients who have progressed on or are intolerant to immune checkpoint inhibitors -

- IMM-1-104 was observed to be uniquely well tolerated in Phase 1 data shared at ESMO 2024, relative to MEK inhibitors currently used to treat melanoma -

- Melanoma patients actively enrolling in one of five arms in the company's ongoing Phase 2a clinical study of IMM-1-104 -

CAMBRIDGE, Mass., Dec. 12, 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 Fast Track designation for its lead clinical-stage program, IMM-1-104, as a treatment for patients with unresectable or metastatic NRAS-mutant melanoma who have progressed on or are intolerant to PD-1/PD-L1 based immune checkpoint inhibitors. IMM-1-104 is currently being evaluated in a Phase 2a clinical trial in patients with advanced solid tumors, including melanoma.

"Immune checkpoint inhibitors play a vital role in the treatment of melanoma, yet patients who progress on or are intolerant to them have limited options," said Ben Zeskind, Ph.D., Co-Founder and CEO of Immuneering. "Targeted therapies including MEK and RAF inhibitors have shown promise in melanoma but historically are severely limited by toxicity. As we presented at the European Society for Medical Oncology 2024 congress, IMM-1-104 is a new kind of MEK inhibitor that was observed to be uniquely well tolerated in our Phase 1 trial, relative to MEK inhibitors currently used to treat melanoma. We believe this creates opportunities for IMM-1-104 to benefit melanoma patients both alone and in combination with RAF inhibitors and/or immune checkpoint inhibitors. Against this backdrop, we are pleased with the FDA's decision to grant Fast Track designation for IMM-1-104 in advanced melanoma, an area of significant unmet need. Melanoma patients are actively enrolling in one of the five arms of our Phase 2a clinical trial, and this designation follows our announcements earlier this year that IMM-1-104 has also been granted Fast Track designations for the treatment of both first and second-line pancreatic cancer."

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 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; 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

or otherwise benefit development of IMM-1-104 in advanced melanoma; 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 and ability to continue as a going concern; 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 period ended September 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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