Immuneering Announces FDA Clearance of IND Application for Phase 1/2a Trial of IMM-6-415 to Treat Advanced Solid Tumors with RAF or RAS Mutations

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- Dosing of first patient in the Phase 1/2a clinical trial expected in early 2024 -

CAMBRIDGE, Mass., Dec. 12, 2023 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a clinical-stage oncology company seeking to develop universal-RAS/RAF medicines for broad populations of cancer patients, today announced that the U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for IMM-6-415, paving the way for the company to initiate a Phase 1/2a clinical trial of this oral, twice-daily small molecule, in development for the treatment of advanced RAF or RAS mutant solid tumors.

“The clearance of the IND application for IMM-6-415 is another important milestone in our efforts to create safer, more durable, and more effective treatment options for large groups of cancer patients,” said Ben Zeskind, Chief Executive Officer, Immuneering Corporation. “Our novel deep cyclic inhibition mechanism is designed to deprive malignant cells of the continuous high level of MAPK signaling they need to survive, while providing healthy cells with the access they need to the MAPK pathway. We believe IMM-1-104 is breaking new ground as the first deep cyclic inhibitor in the clinic, with a trial open to solid tumor patients with ANY mutation in KRAS, NRAS, or HRAS who meet the enrollment criteria. We are proud that the IMM-6-415 clinical trial will be open to an even broader group of solid tumor patients with ANY mutation in RAF, KRAS, NRAS, or HRAS who meet the enrollment criteria. We look forward to dosing the first patient in the Phase 1/2a clinical study of IMM-6-415, which is expected in early 2024.”

IMM-6-415 is a deep cyclic inhibitor of the MAPK pathway designed with unique drug-like properties including a shorter half-life for an accelerated cadence that will be evaluated twice-daily in humans. In animal studies, IMM-6-415 strongly inhibited the growth of tumors with RAF or RAS mutations, as both a monotherapy and in combinations.

“In the preclinical data we recently presented at AACR-NCI-EORTC, IMM-6-415 in combination with encorafenib demonstrated better tumor growth inhibition and improved durability when compared head-to-head with binimetinib plus encorafenib in animal models of RAF mutant melanoma and colorectal cancer where there is significant unmet need for new therapies,” said Brett Hall, Chief Scientific Officer, Immuneering Corporation. “Furthermore, IMM-6-415 as a single agent demonstrated high sensitivity in a wide range of MAPK-driven tumor types, including models of RAS or RAF mutant disease. Based on this promising preclinical single-agent and combination anti-tumor activity, we are excited for the opportunity to evaluate IMM-6-415 in the clinic, and hope that it will prove uniquely beneficial to many solid tumor patients.”

About Immuneering Corporation

Immuneering is a clinical-stage oncology company seeking to develop universal-RAS/RAF medicines for broad populations of cancer patients. 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.

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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