Immuneering Announces First Patient Dosed in its Phase 1/2a Trial of IMM-6-415 to Treat Advanced Solid Tumors with RAF or RAS Mutations

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- Deep Cyclic Inhibitor of the MAPK pathway demonstrated strong tumor growth inhibition in preclinical studies of RAF or RAS mutant tumors, both as monotherapy and in combination -

- Phase 1 portion of the Phase 1/2a trial designed to evaluate the safety, tolerability, pharmacokinetics (PK), and pharmacodynamics (PD) of IMM-6-415 and establish a candidate recommended Phase 2 dose (RP2D) -

-Initial PK, PD and safety data expected in 2024 -

CAMBRIDGE, Mass., March 27, 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 first patient has been dosed in its Phase 1/2a trial of IMM-6-415 to treat advanced solid tumors with RAF or RAS mutations.

IMM-6-415 is a Deep Cyclic Inhibitor (DCI) of the MAPK pathway designed with unique drug-like properties including a shorter half-life than IMM-1-104 for an accelerated cadence that will be evaluated as an oral, twice-daily treatment 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.

During the 2023 AACR-NCI-EORTC conference, Immuneering presented data showing that IMM-6-415 in combination with encorafenib achieved greater 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, consistent with the thesis that DCI can outperform chronic MAPK inhibition.

"We are pleased to have dosed the first patient in our Phase 1/2a trial for IMM-6-415, our second product candidate to enter the clinic," said Ben Zeskind, Chief Executive Officer, Immuneering Corporation. "IMM-6-415 is designed to deprive malignant cells of the continuous MAPK signaling they need by strongly inhibiting the pathway twice per day, while also providing healthy cells with MAPK signaling twice per day through near-zero drug troughs. We believe the shorter half-life of IMM-6-415 could provide a potential treatment option for a broad patient population with RAS or RAF mutations. We look forward to sharing initial PK/PD and safety data from the Phase 1 portion of our Phase 1/2a trial in 2024."

The Phase 1 portion of the Phase 1/2a clinical trial is an open-label study designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of IMM-6-415 in patients with advanced RAF/RAS mutant solid tumors. The trial will include solid tumor patients with any mutation in RAF, KRAS, NRAS, or HRAS who meet the enrollment criteria. The Phase 1 portion of the trial will evaluate IMM-6-415 following a Bayesian mTPI-2 escalation design, which includes a dose escalation phase and dose evaluation phase to establish a candidate recommended phase 2 dose (RP2D), with the RP2D to be evaluated in specific tumor cohorts in the Phase 2a portion of the trial.

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-6-415; the design, enrollment criteria and conduct of the Phase 1/2a IMM-1-104 and IMM-6-415 clinical trials; the translation of preclinical data into human clinical data; the potential advantages and effectiveness of Immuneering's clinical and preclinical candidates; and the indications to be pursued by Immuneering including in the Phase 2a portion of the IMM-6-415 trial and timing of results.

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 Annual Report on Form 10-K for the annual period ended December 31, 2023, 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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