Immuneering Announces First Patient Dosed in its Phase 1/2a Clinical Trial of IMM-1-104 in Advanced Solid Tumors with RAS Mutations

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IMM-1-104 being tested in first all-comers RAS clinical trial believed to be conducted to date

First patient dosed follows swiftly from IND clearance at the end of September

CAMBRIDGE, Mass., Nov. 28, 2022 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a clinical stage biopharmaceutical company that aims to create medicines for *all* patients with solid tumors driven by RAS mutations and other MAPK pathway activation events, today announced that the first patient commenced treatment on November 21 in its Phase 1/2a (NCT05585320) clinical trial of lead asset, IMM-1-104. IMM-1-104 is designed to provide pan-RAS activity through deep cyclic inhibition of the MAPK pathway with once-daily dosing.

“Now that the first patient has been dosed in our Phase 1/2a clinical trial, we look forward to establishing the safety and tolerability of IMM-1-104,” said Scott Barrett, MD, Chief Medical Officer of Immuneering. “The entire clinical team is very appreciative of all the participants in this important, multi-site trial and thanks our clinical collaborators at each of our five trial sites. The speed at which we reached this milestone speaks to the intense preparation and close cooperation by our clinical team and clinical collaborators, driven by both excitement about the strong pan-RAS activity in IMM-1-104’s preclinical data, and care for the patients who so urgently need better medicines.”

The Phase 1/2a clinical trial is an open-label study designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of IMM-1-104 in patients with advanced RAS mutant solid tumors. The Phase 1 portion of the study, which may enroll up to approximately 42 patients at five clinical sites in the United States, will evaluate IMM-1-104 following a Bayesian mTPI-2 escalation design, which includes a dose escalation phase and dose evaluation phase in order to establish a Recommended Phase 2 Dose (RP2D) candidate. Following the Company’s selection of the RP2D candidate, the Company expects to conduct a Phase 2a dose expansion phase in order to assess the safety and efficacy of IMM-1-104 at the RP2D in RAS mutated pancreatic, melanoma, lung, and colorectal cancers.

“Patients with RAS mutated tumors have no time to waste as we race to identify new therapeutic options. IMM-1-104 brings a differentiated approach to addressing the shortcomings of existing MAPK pathway drugs, and is unique in taking aim at patients with any RAS mutations,” said Dr. Alexander Spira, MD Ph.D. FACP, Clinical Director and Chief Executive Officer of NEXT Oncology Virginia. “We are proud to be the first site to treat a patient with IMM-1-104 and look forward to continuing to work with Immuneering and the other sites to rapidly enroll patients in this critical Phase 1/2a trial.”

About IMM-1-104
IMM-1-104 aims to achieve pan-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 biopharmaceutical company that aims to create medicines for *all* patients with solid tumors driven by RAS mutations and other MAPK pathway activation events. Immuneering is evaluating its lead product candidate, IMM-1-104, in a Phase 1/2a study in patients with advanced solid tumors harboring RAS mutations (NCT05585320). IMM-1-104 aims to achieve pan-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. Deep cyclic inhibition is a novel mechanism that aims to deprive tumor cells of the sustained proliferative signaling required for rapid growth, while providing a cadenced, normalized level of signaling designed to spare healthy cells. This new mechanism was engineered using Immuneering's proprietary informatics-based discovery platform, and the development of Immuneering's pipeline is translationally guided by the Company's proprietary, human-aligned 3D tumor platform combined with patient-aligned bioinformatics. Immuneering's second product candidate, IMM-6-415, is designed to provide deep cyclic inhibition of the MAPK pathway with an accelerated cadence relative to the once daily dosing of IMM-1-104. IMM-6-415 is currently in IND-enabling studies. Immuneering's earlier drug discovery pipeline includes five additional targeted oncology programs as well as two neuroscience programs.

Forward-Looking Statements
This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding Immuneering’s expectations regarding the treatment potential of IMM-1-104 and IMM-6-415, the timing of enrollment and completion of the Phase 1/2a clinical trial for IMM-1-104, the design, number of patients to be enrolled, and conduct of the Phase 1/2a clinical trial, that the Phase 1/2a trial of IMM-1-104 is believed to be the first all-comers RAS trial conducted to date, the timing of submission of the IND and commencement of clinical trials for IMM-6-415 and Immuneering’s ability to advance its pipeline and further diversify its portfolio and make progress towards its longstanding goal of creating better medicines for cancer patients. Forward-looking statements are based on Immuneering’s current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, the risks inherent in oncology and neuroscience drug research and development, including target discovery, target validation, lead compound identification, lead compound optimization, preclinical studies and clinical trials. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in Immuneering’s most recent Form 10-Q filed with the U.S. Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Immuneering undertakes no duty to update such information except as required under applicable law.

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