Immuneering Announces FDA Clearance of IND Application for Phase 1/2a Clinical Trial of IMM-1-104 to Treat Advanced Solid Tumors with RAS Mutations

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Initiation of Phase 1/2a Clinical Trial Expected to Occur in Q4 2022

CAMBRIDGE, Mass., Sept. 30, 2022 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a 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 U.S. Food and Drug Administration (FDA) has cleared its Investigational New Drug (IND) application for IMM-1-104, paving the way for the company to initiate a Phase 1/2a clinical trial of this oral, once daily small molecule, in development for the treatment of advanced RAS mutant solid tumors.

“Clearance of the IND for IMM-1-104 brings us one step closer to our goal of developing medicines with the potential to benefit every cancer patient with a RAS mutant solid tumor, not just those harboring specific mutations,” said Ben Zeskind, Chief Executive Officer of Immuneering Corporation. “In keeping with this goal, the Phase 1 portion of the clinical trial is designed to enroll solid tumor patients with evidence of any RAS mutation. This design is driven by 104’s novel deep cyclic inhibition mechanism, which aims to selectively target tumor cells in a mutation-agnostic way while largely sparing healthy cells. We believe this will be the first all-comers RAS clinical trial conducted to date.”

“Based on the robust preclinical, single-agent anti-tumor activity seen in RAS mutated pancreatic, melanoma, colorectal, and lung cancers, we eagerly anticipate evaluating IMM-1-104 in patients,” said Scott Barrett, Chief Medical Officer of Immuneering Corporation. “This decision from the FDA is a critical achievement, as we are dedicated to developing better treatment options for patients with RAS mutated solid tumors. Our clinical team has been diligently preparing for this moment and is now laser focused on enrolling our first patient, which we continue to expect will occur in the fourth quarter of 2022.”

The Phase 1/2a clinical trial is designed to assess the safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary anti-cancer activity of IMM-1-104 for the treatment of advanced RAS mutant solid tumors. The study, expected to enroll patients at five internationally recognized clinical sites in the United States, will evaluate IMM-1-104 following a Bayesian mTPI-2 escalation design in order to establish a Recommended Phase 2 Dose (RP2D). Immuneering plans to follow the Phase 1 portion of the study with a dose expansion Phase 2a in RAS mutated pancreatic, melanoma, colorectal, and lung cancers.

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. It is designed to be a highly selective third generation MEK inhibitor that modulates the signaling dynamics of the MAPK pathway by driving deep cyclic inhibition that deprives tumor cells of the sustained proliferative signaling required for rapid growth, while providing a cadenced, normalized level of signaling designed to spare healthy cells. IMM-1-104 is being developed to treat advanced solid tumors in patients harboring RAS mutations.

About Immuneering Corporation
Immuneering aims to create medicines for *all* patients with solid tumors driven by RAS mutations and other MAPK pathway activation events. Immuneering has more than a decade of experience applying translational bioinformatics to generate insights into drug mechanism of action and patient treatment response. Building on this experience, Immuneering's disease-agnostic discovery platform enables the company to create product candidates based on 1) biological insights that are both counterintuitive and deeply rooted in data, and 2) novel chemistry. Immuneering's lead product candidate, IMM-1-104, aims to achieve pan-RAS activity that selectively impacts cancer cells to a greater extent than healthy cells. IMM-1-104 is designed to be a highly selective third generation MEK inhibitor that modulates the signaling dynamics of the MAPK pathway by driving deep cyclic inhibition that deprives tumor cells of the sustained proliferative signaling required for rapid growth, while providing a cadenced, normalized level of signaling designed to spare healthy cells. IMM-1-104 is being developed to treat advanced solid tumors in patients harboring RAS mutations, and is translationally guided by Immuneering's proprietary, human-aligned 3D tumor modeling platform combined with patient-aligned bioinformatics. In addition to IMM-1-104, Immuneering is evaluating IMM-6-415 in IND-enabling studies, and has five other oncology programs in the discovery stage that are designed to target components of the MAPK or mTOR pathway, as well as two discovery stage 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 commencement and enrollment of the Phase 1/2a clinical trial for IMM-1-104, the design, enrollment criteria and conduct of the Phase 1/2a clinical trial, 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 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.

Corporate Contact:
Rebecca Kusko, Ph.D.
Immuneering Corporation
617-500-8080

rkusko@immuneering.com

Investor Contact:
Susan A. Noonan
S.A. Noonan Communications
917-513-5303
susan@sanoonan.com