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

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CAMBRIDGE, Mass., Sept. 02, 2022 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a biopharmaceutical company using translational bioinformatics to advance a pipeline of product candidates designed to benefit large populations of patients with cancer and other diseases, today announced it submitted an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA). The IND application supports a Phase 1/2a clinical trial of IMM-1-104, an oral once daily small molecule in development for the treatment of advanced RAS mutant solid tumors. In contrast to the narrow approach of targeting specific mutations such as KRAS-G12C, IMM-1-104 is a third generation MEK inhibitor designed for broad pan-RAS activity as well as activity in other MAPK-activated tumors. Based on preclinical data to date, IMM-1-104 has demonstrated robust single-agent anti-tumor activity across a broad range of *in vitro* and *in vivo* tumor models driven by MAPK pathway activation events. This includes animal models of KRAS mutant pancreatic cancer, NRAS mutant melanoma, KRAS mutant colorectal cancer, and KRAS mutant lung cancer, regardless of the specific mutation upstream of MEK that drives activation of the MAPK pathway, and all while maintaining a well-tolerated safety profile in such models.

“At Immuneering we aim to create medicines for *all* patients with tumors driven by RAS mutations and other challenging MAPK pathway activation events. In our animal studies, IMM-1-104 strongly inhibited the growth of some of the most aggressive and deadly RAS mutant tumor models out there, without the need to combine with other agents and with good preclinical tolerability. Filing the IND brings us one step closer to evaluating IMM-1-104 in patients with a broad range of RAS mutant tumors,” said Ben Zeskind, Chief Executive Officer, Immuneering Corporation. “IMM-1-104 was created in-house at Immuneering, based on insights from our patented Disease Cancelling Technology. I am so incredibly proud of our world-class team of Immuneers, who worked tirelessly to move this program from concept to IND submission with exceptional speed and efficiency – an urgency befitting the strength of the preclinical data and the patients in need who are waiting. We look forward to the next steps of clinical development for IMM-1-104, and pending regulatory review of our IND, expect to enroll our first patient in the fourth quarter of this year.”

“IMM-1-104 has the potential to be a game-changer for the large population of patients with RAS mutant tumors,” said Brett Hall, Chief Scientific Officer, Immuneering Corporation. “We believe that its deep cyclic inhibition mechanism represents a fundamentally new way to selectively target tumor cells while largely sparing healthy cells. Our goal is to create a therapy that is tolerable for healthy cells but catastrophic for tumor cells. The preclinical data package for IMM-1-104 is uniquely compelling, and we are excited to now evaluate this compound in patients who so urgently need new options.”

The FDA will review the company’s IND application and determine whether the data package is acceptable to predict the safety of IMM-1-104, before clinical trial initiation. In the interim, the company continues to prepare for the planned Phase 1/2a trial evaluating IMM-1-104 for the treatment of advanced solid tumors with RAS mutations. The company is planning to sponsor the recruitment of patients at five internationally recognized clinical sites in the United States.

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 improve patient outcomes by advancing a pipeline of product candidates designed to benefit large populations of patients with cancer and other diseases, developed using its translational bioinformatics platform. 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 its MEK-io product candidate, 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 submission and clearance of the IND and commencement of clinical trials for IMM-1-104 and 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.

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