Immuneering Reports Compelling Preclinical Data on IMM-1-104 at AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics

October 11, 2021

Preclinical Data Demonstrated Broad Antitumor Activity Across KRAS, NRAS and BRAF Mutant Tumor Models, Established Novel Mechanism of Action for its Dual MEK Inhibition and Showed Synergies with Sotorasib in KRAS-G12C Mutant Pancreatic Cancer

Company Hosting Key Opinion Leader Event on October 12, 2021 at 11:30 am Eastern Time

CAMBRIDGE, Mass., Oct. 11, 2021 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a biopharmaceutical company advancing a robust pipeline of oncology and neuroscience product candidates that are designed to uniquely disrupt cellular signaling dynamics, today announced that three key preclinical datasets highlighting the potential of its lead product candidate, IMM-1-104, were presented at the recent AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics that took place virtually from October 7-10, 2021.

IMM-1-104 is designed to be a highly selective dual-MEK inhibitor that further disrupts the kinase suppressor of RAS 1 and 2 (KSR1/2) for the treatment of advanced solid tumors in patients harboring RAS mutant tumors. The Company anticipates submission of an Investigational New Drug application (IND) for IMM-1-104 to the U.S. Food and Drug Administration (FDA) in the first quarter of 2022.

"We are delighted to share compelling data from multiple animal studies that underscore IMM-1-104's potential for activity against a wide range of RAS and RAF mutant tumors and further elucidate its novel mechanism of action for dual MEK inhibition," said Ben Zeskind, Ph.D., Co-Founder, President and Chief Executive Officer of Immuneering. "The totality of these data, along with the tolerability profile that we consistently observe across animal models, are particularly encouraging and further validate our plans to advance IMM-1-104 into human clinical trials in the first half of next year."

In a poster titled, ***"IMM-1-104: a novel, oral, selective dual-MEK inhibitor that displays broad antitumor activity and high tolerability across RAS and RAF mutant tumors in vivo,"*** and presented by Brett Hall, Ph.D., Chief Scientific Officer at Immuneering, study authors concluded that, "IMM-1-104 was uniquely designed to normalize MAPK signaling dynamics while resisting pathway reactivation in RAS and RAF mutant tumors. Preclinical data showed broad activity in multiple animal models bearing tumors with diverse RAS and RAF mutations, including KRAS-G12C, KRAS-G12D, KRAS-G12S, NRAS-Q61R and BRAF-V600E. Further, IMM-1-104 demonstrated superior activity and tolerability versus other U.S. FDA registered MEK inhibitors in head-to-head animal studies."

Data presented by Peter King, Ph.D., Vice President, Head of Discovery at Immuneering, in a poster titled, ***"Benchmarking the novel dual-MEK inhibitor, IMM-1-104, head-to-head and in combination with sotorasib (AMG-510) in the MIA PaCa-2 (KRAS-G12C) pancreatic cancer xenograft model,"*** demonstrated that "IMM-1-104 treatment resulted in tumor regressions similar to that observed for sotorasib in the recently benchmarked KRAS-G12C mutant pancreatic cancer xenograft model (MIA PaCa-2). IMM-1-104 in combination with sotorasib promoted deep, durable tumor regressions, when compared to either drug alone. Future drug-drug combinations with upstream inhibitors such as sotorasib may afford greater durability in combination for patients with KRAS-G12C and other select tumor types. Collectively, these data suggest the potential for broad, single agent activity of IMM-1-104 in tumors with inappropriately elevated MAPK signaling, including a large percentage of KRAS mutant pancreatic cancer."

Data highlighted in a third poster titled, ***"Transcriptional effects in C26 tumor highlight mechanistic aspects of a novel dual MEK inhibitor, IMM-1-104,"*** was delivered by Sarah Kolitz, Ph.D., Vice President, Translational Medicine at Immuneering. She noted that "IMM-1-104 achieves deep cyclic inhibition of the pathway rather than constant blockade and prevents pathway reactivation, which has hampered U.S. FDA approved MEKi. These transcriptome level observations confirmed a pattern of deep cyclic inhibition by IMM-1-104, demonstrating strong MAPK pathway inhibition in tumors two hours after treatment and near complete release at 12 hours following treatment. This pattern was observed both after the initial dose as well as following chronic oral BID dosing for 18 days, indicating that deep cyclic inhibition was sustainable during chronic dosing."

Videos of each of the presentations can be viewed on the Company's website at www.immuneering.com/publications/

Key Opinion Leader Event

Tomorrow, Immuneering management will be hosting a Key Opinion Leader Event, which will review the presented data in greater detail and highlight its broader application and potential. Event details are below:

Title:	Better Medicines for MEK, RAS and Beyond Through Signaling Dynamics
Day/Time:	October 12, 2021 from 11:30 am – 1:00 pm Eastern Time
Presenters:	Alexander Spira, MD, PHD, FACP, Director of the Virginia Cancer Specialists Research Institute and US Oncology Research Anthony W. Tolcher, MD, FRCPC, FACP, FASCO, Director of Clinical Research Founder and CEO of NEXT Oncology
Registration:	Better Medicines for MEK, RAS and Beyond Through Signaling Dynamics Registration (onlinexperiences.com)

About Immuneering Corporation
Immuneering is a biopharmaceutical company with an emerging pipeline focused on improving patient outcomes across a spectrum of debilitating oncologic and neurologic diseases by applying its deep knowledge of translational bioinformatics to every stage of the drug development process. Immuneering has more than a decade of experience in translational bioinformatics and generating insights into drug mechanisms of action and patient treatment responses. Building on this experience, Immuneering has developed a disease-agnostic platform that enables the company to utilize human data, novel biology and chemistry, and translational planning to create and advance its wholly owned pipeline. Immuneering's current development programs in oncology are focused on providing potential treatments for patients with solid tumors caused by mutations of oncologic signaling pathways, including the MAPK pathway. Immuneering's lead product candidate, IMM-1-104, is designed to be a highly selective dual-MEK inhibitor that further disrupts KSR for the treatment of advanced solid tumors in patients harboring RAS mutant tumors. Additionally, Immuneering has six other oncology programs in the discovery stage that are designed to target either the MAPK or mTOR pathway, and two neuroscience programs in the discovery stage.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding Immuneering's progress toward drugs targeting cancers driven by alterations that activate the RAS/MAPK pathway, the treatment potential of IMM-1-104, the timing of regulatory filings for IMM-1-104 with the FDA and commencement of clinical trials for IMM-1-104. 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 the Company's most recent Form 10-Q filed with the U.S. Securities and Exchange Commission (SEC) as well as in Immuneering's subsequent filings it makes with the SEC. 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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