IMM-1-104 is Synergistic with Chemotherapy in Pancreatic Cancer Models

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- Preclinical data presented at AACR demonstrate that combining IMM-1-104 with chemotherapies used in the treatment of first-line pancreatic cancer yielded deeper and more durable tumor growth inhibition than either treatment alone -

- Patients are now on treatment in multiple arms of the ongoing Phase 2a trial, including multiple patients with pancreatic cancer who are being treated with IMM-1-104 in combination with chemotherapy in the first-line setting -

- Immuneering expects initial data from multiple IMM-1-104 Phase 2a arms in 2024 -

CAMBRIDGE, Mass., April 09, 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 presented preclinical data at the American Association for Cancer Research (AACR) Annual Meeting, which the company views as supportive of its ongoing Phase 2a clinical trial of IMM-1-104 in RAS-mutated advanced or metastatic solid tumors.

"Combination therapy is an important way to reduce therapeutic resistance, and we believe the emergent activity and tolerability profile of IMM-1-104, reported in our topline Phase 1 readout last month, makes it an excellent prospect for combination treatments," said Brett Hall, Ph.D., Chief Scientific Officer, Immuneering Corporation. "We are evaluating a broad range of combinations for a variety of cancer types in our humanized 3D tumor growth assays, together with animal models. The data we are sharing today at AACR clearly demonstrates IMM-1-104's potential in combination with chemotherapy for pancreatic cancer. Not only do we observe deeper and more durable tumor growth inhibition in the animal models tested, we also demonstrate each half of the combination helps suppress the treatment-acquired mutations that could otherwise drive resistance to the other half. The translational implications are exciting, given that we are already treating multiple patients with IMM-1-104 combinations in the first-line setting in our Phase 2a study."

In a poster titled, "Activity of IMM-1-104 alone or in combination with chemotherapy in RAS-altered pancreatic cancer models," IMM-1-104, gemcitabine (GEM), nab-paclitaxel (PAC), and 5-fluorouracil (5-FU) were evaluated in tumor xenograft models alone or across multiple combinations.

Results:

- IMM-1-104 showed promising combination effects when treated with gemcitabine (GEM), paclitaxel (PAC) or fluorouracil (5FU) in 3D-tumor growth assay (TGA) pancreatic cancer models.
- IMM-1-104 was synergistic with chemotherapy in animal models of pancreatic cancer.
- In a human pancreatic cancer cell line (MIA PaCa-2) tumor xenograft model, IMM-1-104 alone showed greater tumor growth inhibition (TGI) and better durability than any single or combination chemotherapy tested.
- At day 39, antitumor activity (TGI%) was 103% for IMM-1-104 at 125 mg/kg BID PO, 25.2% for GEM at 60 mg/kg IP Q4D, 62.2% for PAC at 10 mg/kg IV Q4D, and 36.6% for 5FU at 50 mg/kg IP Q4D.

In the Phase 2a portion of Immuneering's ongoing IMM-1-104 Phase 1/2a clinical trial, IMM-1-104 is being evaluated as both monotherapy and in select combinations with approved chemotherapeutic agents. The Phase 2a portion includes five arms, three of which focus on patients with pancreatic cancer. Patients are now on treatment in multiple arms of the ongoing Phase 2a trial, including multiple patients with pancreatic cancer who are being treated with IMM-1-104 in combination with chemotherapy in the first-line setting. The company expects initial data from multiple Phase 2a arms in 2024.

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-1-104, alone or in combination with other agents, including chemotherapy; the design, enrollment criteria and conduct of the Phase 1/2a IMM-1-104 clinical trial; the translation of preclinical data into human clinical data; the potential advantages and effectiveness of Immuneering's clinical and preclinical candidates; and the timing of results of the Phase 2a portion of the trial for IMM-1-104.

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.

Media Contact:
Gina Nugent
gina@nugentcommunications.com

Investor Contact:
Laurence Watts
619-916-7620
laurence@newstreetir.com