Immuneering Doses First Patient in Phase 2a Clinical Trial of IMM-1-104 in RAS-mutant Solid Tumors

March 11, 2024

- First patient dosed with IMM-1-104 in combination with modified gemcitabine plus nab-paclitaxel for first-line treatment of pancreatic ductal adenocarcinoma (PDAC) -

- Phase 2a portion of Phase 1/2a clinical trial will evaluate IMM-1-104 as monotherapy in PDAC, non-small cell lung cancer (NSCLC) and melanoma, and as combination therapy in PDAC -

- Topline data from the Phase 1 portion of Phase 1/2a trial of IMM-1-104 expected in March 2024 -

- Initial data from multiple Phase 2a arms expected in 2024 -

CAMBRIDGE, Mass., March 11, 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 announced that the first patient has been dosed in the Phase 2a portion of its Phase 1/2a clinical trial of IMM-1-104, its lead program. IMM-1-104 is designed to provide universal-RAS activity through deep cyclic inhibition of MEK in the MAPK pathway with once-daily oral dosing.

“The initiation of our Phase 2a study is an important milestone for Immuneering, as we evaluate IMM-1-104 in larger numbers of patients with specific types of cancer, at earlier stages of disease, with a broader set of endpoints, and a growing team of both investigators and study sites,” said Ben Zeskind, Ph.D., Co-founder and Chief Executive Officer of Immuneering. “The Phase 2a portion includes both monotherapy and combination arms, all in tumor types where we believe IMM-1-104 has the greatest potential to make a positive impact. We are excited to be evaluating IMM-1-104 as a combination therapy for the first time in the clinic, with an initial focus on PDAC in the first-line setting based on compelling, previously generated preclinical data, well-understood disease biology, and a vast unmet medical need. We look forward to sharing our topline Phase 1 data this month, and then reporting initial results from multiple arms of our Phase 2a later in 2024, which is shaping up to be a data-rich year for our company.”

The Phase 2a portion of the Phase 1/2a clinical trial of IMM-1-104 is expected to include approximately 150 patients in five arms at our recommended Phase 2 dose of 320 mg once daily. The five arms are as follows:

- IMM-1-104 monotherapy in patients with pancreatic ductal adenocarcinoma (PDAC) in the first- or second-line setting (n=30).
- IMM-1-104 monotherapy in patients with RAS-mutant melanoma in the second- or third-line setting post-immunotherapy, or in the first-line setting for patients who are not candidates for existing therapies (n=30).
- IMM-1-104 monotherapy in patients with RAS-mutant non-small cell lung cancer (NSCLC) in the second- or third-line setting (n=30).
- IMM-1-104 in combination with mFOLFIRINOX in patients with PDAC in the first-line setting (n=30).
- IMM-1-104 in combination with modified gemcitabine plus nab-paclitaxel in patients with PDAC in the first-line setting (n=30).

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 study in patients with advanced solid tumors harboring RAS mutations. IMM-6-415 is an oral, twice-daily deep cyclic inhibitor and will be evaluated in a Phase 1/2a study 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 concerning: the expected design, timing, enrollment and advancement of, and data results from, preclinical studies and clinical trials involving our product candidates; the potential of our product candidates to be used as monotherapies and/or in combination with other therapeutic agents, including to treat RAS or RAF mutant diseases; and the clinical development of IMM-1-104 and IMM-6-415.

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 period ended December 31, 2023, and our other reports filed with the United States 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.

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