



Immuneering Recognizes Melanoma Awareness Month

May 6, 2024

- Two clinical stage product candidates in development for the treatment of melanoma -

- RAS mutant melanoma represents one of five arms in the company's ongoing Phase 2a clinical study of IMM-1-104 -

- Melanoma also being evaluated in ongoing Phase 1/2a clinical study of IMM-6-415 in patients with advanced solid tumors harboring RAF or RAS mutations -

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

CAMBRIDGE, Mass., May 06, 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, recognizes the importance of early detection and treatment during Melanoma Awareness Month, and highlights RAS mutant melanoma as the focus of one of the five arms in its ongoing Phase 2a clinical study for its lead program IMM-1-104. RAF or RAS mutant melanoma is also being evaluated in its Phase 1/2a clinical study of IMM-6-415 in patients with advanced solid tumors.

Melanoma Awareness Month is held each May to raise awareness, galvanize advocates and support research efforts toward new treatments and methods of detecting melanoma, the most serious type of skin cancer.

"We encourage people diagnosed with melanoma to speak with their physicians about having their tumors tested for biomarkers which can help determine the most appropriate next steps in their treatment," said Joan Levy, Ph.D., Chief Science Officer, Melanoma Research Alliance. "Several biomarkers are known to drive the growth and progression of melanoma and there are therapies being clinically evaluated with the potential to target these tumor biomarkers."

"Immuneering is proud to acknowledge Melanoma Awareness Month, especially since melanoma is a key area of focus in our development of IMM-1-104 and mutations in the RAS gene family are known to be present in approximately 20-25% of all melanomas," said Brett Hall, Ph.D., Chief Scientific Officer, Immuneering Corporation. "We chose RAS mutant melanoma to be one of five arms in our Phase 2a trial of IMM-1-104, where we are investigating our lead development candidate as either monotherapy or in combination and are also evaluating RAF or RAS mutant melanoma in our Phase 1/2a clinical study with IMM-6-415. We are excited at the prospect of adding IMM-1-104 and IMM-6-415 to the melanoma treatment armamentarium and look forward to updating patients and physicians as we report data."

At the AACR-NCI-EORTC conference in October 2023, Immuneering [presented](#) preclinical data including expanded benchmarking of IMM-1-104 as a single agent across more than 190 patient-aligned models in humanized 3D-tumor growth assays, which demonstrated high sensitivity in a wide range of MAPK-driven tumor types, including models of RAS and RAF mutant melanoma, as well as pancreatic cancer, and lung cancer. Preclinical data the company has presented related to melanoma includes data showing that IMM-1-104 inhibits tumor growth in an animal model of NRAS mutant melanoma to a greater extent than binimetinib, and that IMM-6-415 in combination with encorafenib inhibits tumor growth in an animal model of BRAF mutant melanoma to a greater extent than binimetinib plus encorafenib.

IMM-1-104 aims to achieve universal-RAS activity that selectively impacts cancer cells to a greater extent than healthy cells, through Deep Cyclic Inhibition of the MAPK pathway with once-daily dosing. In the Phase 2a portion of Immuneering's ongoing IMM-1-104 Phase 1/2a clinical trial ([NCT05585320](#)), IMM-1-104 is being evaluated as both monotherapy and in select combinations with approved chemotherapeutic agents. The Phase 2a portion includes five arms, one of which focuses on RAS-mutant melanoma, another focused on RAS mutant non-small cell lung cancer (NSCLC), and three arms focused on patients with pancreatic cancer. The company expects initial data from multiple Phase 2a arms in 2024.

IMM-6-415 is a Deep Cyclic Inhibitor of the MAPK pathway designed with unique drug-like properties including a shorter half-life for an accelerated cadence. IMM-6-415 is currently being evaluated in a Phase 1/2a study in patients with advanced solid tumors harboring RAF or RAS mutations. ([NCT06208124](#)). The Phase 1 portion of the Phase 1/2a clinical trial is an open-label study designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of IMM-6-415 in patients with advanced RAF/RAS mutant solid tumors. The trial will include solid tumor patients with any mutation in RAF, KRAS, NRAS, or HRAS who meet the enrollment criteria. The company expects initial PK, PD and safety data for IMM-6-415 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.

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