Immuneering Completes Dose Escalation in the IMM-1-104 Phase 1 Clinical Trial for RAS-Mutant, Advanced Solid Tumors

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- No dose limiting toxicities observed with IMM-1-104 up to 320 mg once daily during the Phase 1a dose escalation portion of ongoing clinical study -

- Phase 1b dose expansion has commenced; plan to enroll 21 additional patients at 240 mg or 320 mg daily -

- Recommended Phase 2 dose (RP2D) and additional safety data expected in early 2024 -

- Additional trial updates expected on a periodic basis -

CAMBRIDGE, Mass., June 05, 2023 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a clinical-stage oncology company developing medicines for broad populations of cancer patients with an initial aim to develop a universal-RAS therapy, today announced the completion of the dose-escalation portion of the Phase 1/2a study for its lead asset IMM-1-104 in patients with advanced solid tumors. The study's Safety Review Committee (SRC) completed its evaluation and determined that doses up to and including 320 mg once daily are tolerable with no dose limiting toxicities. Enrollment in the Phase 1b expansion portion of the study will now commence and is designed to evaluate two dosing cohorts of 12 patients each at an oral dose of 240mg or 320 mg once daily. Three patients already enrolled in the study have been dosed at the 320 mg dose level.

"We are very pleased to have completed the dose escalation portion of our Phase 1 study of IMM-1-104 ahead of our original timeline," said Ben Zeskind, Ph.D., Co-founder and Chief Executive Officer of Immuneering. "We believe the two dose levels we have chosen for our Phase 1b dose expansion study will effectively support the conditions necessary for deep cyclic inhibition, Immuneering's unique approach that aims for Universal-RAS activity: treating patients with any mutation in KRAS, NRAS, or HRAS. As such, the 21 additional patients we plan to enroll in this next part of the study should materially add to our dataset for IMM-1-104 in patients with RAS-mutant solid tumors consistent with Project Optimus. We expect to provide further trial updates on a periodic basis and to share preliminary anti-tumor activity data before we announce a recommended Phase 2 dose in early 2024."

"We are encouraged by the levels of enthusiasm from the investigators at our five clinical sites, who are committed to screening and enrolling patients as quickly and judiciously as possible," said Scott Barrett, M.D., Chief Medical Officer of Immuneering. "We remain grateful to our clinical investigators for their unwavering dedication to evaluating much needed options for these heavily pretreated patients, as well as to the patients and caregivers participating in our trials."

In April 2023, Immuneering presented initial Phase 1 PK, PD and safety data for IMM-1-104 at the American Association for Cancer Research (AACR) annual meeting. IMM-1-104 achieved significant levels of PK Cmax, demonstrated a half-life of approximately two hours, as predicted, and was well tolerated with no dose limiting toxicities. Upon review of the cumulative data from the eight patients dosed in the Phase 1a study, the SRC endorsed 240 mg daily and 320 mg daily as the dose levels for the expansion cohort and agreed with initiating the Phase 1b expansion.

Near-Term Milestone Expectations

IMM-1-104

- Additional trial updates expected on a periodic basis.
- RP2D and additional safety data expected in early 2024.

IMM-6-415

- IND filing expected in the fourth quarter of 2023.

About IMM-1-104

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 oral dosing. IMM-1-104 is currently being evaluated in a Phase 1/2a study in patients with advanced solid tumors harboring RAS mutations for whom there are limited treatment options (NCT05585320).

About Immuneering Corporation

Immuneering is a clinical-stage oncology company developing 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 in a Phase 1/2a study in patients with advanced solid tumors harboring RAS mutations. The company's development pipeline also includes IMM-6-415, a universal-MAPK program, as well as several early-stage programs. For more information, please visit www.immuneering.com.

Forward-Looking Statements

This press release contains "forward-looking statements" including, without limitation, statements regarding Immuneering's expectations regarding the treatment potential of IMM-1-104 and IMM-6-415; the design, enrollment criteria and conduct of the Phase 1/2a clinical trial of IMM-1-104 in patients with advanced solid tumors; the timing of additional trial updates, including recommended phase 2 dose and additional safety and activity data; the

timing of submission of the IND for 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 drug research and 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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