Immuneering Advances Towards Dosing First Patient in Phase 3 Atebimetinib Trial for First-Line Metastatic Pancreatic Cancer Patients, Securing Alignment with FDA and EMA

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– End-of-Phase 2 interactions with FDA complete; scientific advice received from EMA –

– Company expects to dose first patient in global Phase 3 registrational trial, MAPKeeper 301, in mid-2026 –

– Overall survival update for Phase 2a trial of atebimetinib + mGnP in first-line pancreatic cancer patients planned in coming weeks –

NEW YORK, Dec. 17, 2025 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a late-stage clinical oncology company focused on keeping cancer patients alive and helping them thrive, today announced that it is on track to dose the first patient in its planned global Phase 3 registrational trial in first line pancreatic cancer patients in mid-2026, evaluating atebimetinib (320 mg QD) in combination with modified gemcitabine and nab-paclitaxel (mGnP), compared with gemcitabine and nab-paclitaxel (GnP) alone.

Notably, the company completed its End-of-Phase 2 (EOP2) interactions with the U.S. Food and Drug Administration (FDA) and received scientific advice from the European Medicines Agency (EMA). Immuneering achieved alignment with both agencies on the key elements of the company's proposed Phase 3 trial.

“We are very pleased with our interactions with both the FDA and EMA, which we believe speaks to the compelling data we have generated to date in first-line pancreatic cancer, as well as the strength and simplicity of our proposed Phase 3 trial for atebimetinib,” said Ben Zeskind, Ph.D., Co-Founder and Chief Executive Officer of Immuneering. “Importantly, the regulators’ feedback supports our trial design and key primary endpoint of overall survival, and we are confident that our team is well-positioned to begin dosing patients in this global registrational trial in mid-2026. We are also thrilled to expand the planned trial to 510 patients, which gives more first-line pancreatic cancer patients the opportunity to participate, and further increases statistical robustness. In addition, we are excited to provide an update on overall survival in the Phase 2a trial in the coming weeks.”

MAPKeeper 301 is designed as a global Phase 3 trial that will evaluate atebimetinib (320 mg QD) in combination with mGnP, compared to standard of care GnP alone, in first-line metastatic pancreatic ductal adenocarcinoma. The primary endpoint of the trial is overall survival, and secondary endpoints include progression-free survival, overall response rate, disease control rate, and quality of life measurements. Immuneering plans to enroll a total of approximately 510 patients in the Phase 3 trial.

The company expects to dose the first patient in mid-2026 and share topline results from the trial in mid-2028. Immuneering also reiterated management’s belief that the company’s current cash and cash equivalents, based on current operating plans, are sufficient to fund operations into 2029.

“The constructive guidance from both agencies validates our scientific approach and our understanding of the unmet need in first-line metastatic pancreatic cancer,” said Igor Matushansky, M.D., Ph.D., Chief Medical Officer of Immuneering. “We look forward to advancing atebimetinib into Phase 3 and working with investigators worldwide to bring this potentially transformative therapy to patients as expeditiously as possible.”

“New therapies for pancreatic cancer are urgently needed,” said Eileen M. O’Reilly, MD, FASCO, Winthrop Rockefeller Endowed Chair in Medical Oncology at Memorial Sloan Kettering Cancer Center. “The phase IIa data of atebimetinib and chemotherapy shows a promising signal. I am excited to see this combination move forward to a randomized phase III evaluation.”

About Immuneering Corporation

Immuneering is a late-stage clinical oncology company focused on keeping cancer patients alive and helping them thrive. The Company is developing an entirely new category of cancer medicines, Deep Cyclic Inhibitors. Immuneering’s lead product candidate, atebimetinib, is an oral, once-daily Deep Cyclic Inhibitor of MEK, designed to improve durability and tolerability across many cancer indications, including MAPK pathway-driven tumors such as pancreatic cancer. Atebimetinib is currently planned to be evaluated in a Phase 3 trial in first-line pancreatic cancer, which is expected to begin dosing in mid-2026. The Company's development pipeline also includes 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: our plans to develop, manufacture and commercialize our product candidates; the treatment potential of atebimetinib, alone or in combination with other agents to treat cancer, including modified Gemcitabine/nab-paclitaxel (mGnP) in first-line pancreatic cancer; the timing of future data updates; the regulatory feedback supporting our Phase 3 trial design and initiation of the trial, including the key primary endpoint of overall survival and validating our scientific approach, expectations regarding our cash runway; the timing of dosing the first patient and topline readout in our planned phase 3 trial; and our belief that our regulatory interactions speak to the compelling data we have generated to date in first-line pancreatic cancer, as well as the strength and simplicity of our proposed Phase 3 trial for atebimetinib.

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 Quarterly Report on Form 10-Q for the period ended September 30, 2025, 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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