Immuneering Reports Fourth Quarter and Full Year 2024 Financial Results and Provides Business Updates

March 20, 2025

- Reported positive data updates from its ongoing Phase 2a trial of lead program IMM-1-104, including encouraging responses in combination with chemotherapy in first-line pancreatic cancer -

- Announced a clinical trial supply agreement with Regeneron Pharmaceuticals to evaluate IMM-1-104 in combination with Libtayo® (cemiplimab) in non-small cell lung cancer -

- Additional IMM-1-104 Phase 2a data updates and initiation of new IMM-1-104 combination arms expected in 2025; planning underway for potential IMM-1-104 global pivotal trial -

- Named industry veteran Dr. Igor Matushansky as Chief Medical Officer -

- Cash runway extended into 2026 -

CAMBRIDGE, Mass., March 20, 2025 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a clinical-stage oncology company seeking to develop and commercialize more effective *and* better tolerated therapies for cancer patients, today reported financial results for the fourth quarter and full year ended December 31, 2024, and provided recent business updates.

"We were delighted to report updates from our ongoing Phase 2a trial of IMM-1-104 in January 2025 demonstrating excellent response rates for IMM-1-104 in combination with chemotherapy in first-line pancreatic cancer patients. Highlights of these data included an observed ORR of 43% and DCR of 86% for IMM-1-104 in combination with modified gemcitabine/nab-paclitaxel (mGnP) and an observed ORR of 50% for IMM-1-104 in combination with modified FOLFIRINOX (mFFX). Historic benchmarks for either chemotherapy agent alone are 23% ORR and 32% ORR, respectively. IMM-1-104 in combination with each of mGnP and mFFX was observed to be generally well tolerated. Based on these promising results, we have begun planning for a potential IMM-1-104 global pivotal trial in combination with modified gemcitabine/nab-paclitaxel in first-line pancreatic cancer, as we aim to get this exciting potential new treatment option to patients as quickly as possible," said Ben Zeskind, Ph.D., Co-founder and Chief Executive Officer of Immuneering.

"Importantly, the results demonstrated with IMM-1-104 to date point to its potential combinability, set to continue with our recently announced plans to study IMM-1-104 in combination with a BRAF inhibitor in melanoma, with a G12C inhibitor in non-small cell lung cancer, and with a PD-1 inhibitor in both melanoma and non-small cell lung cancer. We subsequently announced a clinical trial supply agreement with Regeneron for Libtayo in combination with IMM-1-104 in patients with non-small cell lung cancer and aim to get these new trials up and running this year. In support of these plans, we were pleased to announce that Dr. Igor Matushansky has joined Immuneering as Chief Medical Officer to oversee clinical activities, including medical and operational leadership for our development programs."

Zeskind concluded: "As we look ahead to the rest of the year – with our cash balance recently fortified – we expect multiple data events, beginning with an update from our IMM-1-104 Phase 2a trial in the second quarter of 2025. We are continuing to build a growing data set that we believe positions our lead asset with the potential to offer an improved profile in comparison to current MEK inhibitors, which currently represents an existing approximately $2.4 billion annual global opportunity in the aggregate."

Corporate Highlights

- **Phase 1 Pancreatic Cancer Patient Passes 13-month Mark on IMM-1-104 Monotherapy:** Today, Immuneering provided a case study update for a Phase 1 pancreatic cancer patient in the third-line setting who has been receiving IMM-1-104 monotherapy for over 13 months so far. The patient – who previously progressed on first-line FOLFIRINOX and second-line Gem/Cis/nab-Pac – has been on IMM-1-104 monotherapy at 240 mg once daily. As of the most recent available scan, the patient has maintained stable disease with a RECIST SLD change of -24.2%. In addition to a 91% reduction in peak CA 19-9 levels, IMM-1-104 has been well tolerated by the patient, who has reported improved quality of life and approximately 12% weight gain.
- **Named Dr. Igor Matushansky as Chief Medical Officer:** In March, Immuneering announced that Igor Matushansky, MD, PhD, joined the company as Chief Medical Officer. In this role, Dr. Matushansky will direct Immuneering's clinical activities, providing medical and operational leadership for the company's development programs including the ongoing Phase 2a study of IMM-1-104 in pancreatic cancer, lung cancer, and melanoma, and plans to initiate a pivotal Phase 3 clinical trial in pancreatic cancer.
- **Announced Clinical Trial Supply Agreement with Regeneron Pharmaceuticals to Evaluate IMM-1-104 in Combination with Libtayo (cemiplimab)**: In February, Immuneering announced a clinical trial supply agreement with Regeneron Pharmaceuticals for its anti-PD-1 therapy, Libtayo. The agreement supports the intended evaluation of Immuneering's lead product candidate, IMM-1-104, in combination with Libtayo in patients with unresectable or metastatic RAS-mutant non-small cell lung cancer (NSCLC).
- **Positive Data Update from Three Pancreatic Cancer Arms of Ongoing Phase 2a Trial of IMM-1-104**: In January,

Immuneering announced a positive data update from three pancreatic cancer arms of its ongoing Phase 2a trial of lead program IMM-1-104, as well as plans to expand the Phase 2a trial to include additional combination arms.

- **Launched Pancreatic Cancer Advisory Board**: In December, Immuneering announced the formation of its Pancreatic Cancer Advisory Board. The advisory board, which comprises world-renowned oncology clinical researchers, will provide strategic medical and clinical guidance to the company as its pipeline, including lead clinical program IMM-1-104, continues to advance.
- **FDA Fast Track Designation for IMM-1-104 in Advanced Melanoma**: In December, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for IMM-1-104, as a treatment for patients with unresectable or metastatic NRAS-mutant melanoma who have progressed on or are intolerant to PD-1/PD-L1 based immune checkpoint inhibitors.
- **FDA Orphan Drug Designation for IMM-1-104 in the Treatment of Pancreatic Cancer**: In October 2024, the FDA granted Orphan Drug designation to IMM-1-104 in the treatment of pancreatic cancer.

Near-Term Milestone Expectations
IMM-1-104

- Further IMM-1-104 Phase 2a data expected in the second quarter of 2025.
- Initiation of Phase 2a arm of IMM-1-104 in combination with Libtayo in NSCLC planned for 2025.
- Initiation of Phase 2a arm of IMM-1-104 in combination with a G12C inhibitor in NSCLC planned for 2025.
- Initiation of Phase 2a arm of IMM-1-104 in combination with a PD-1 inhibitor in melanoma planned for 2025.
- Initiation of Phase 2a arm of IMM-1-104 in combination with a BRAF inhibitor in melanoma planned for 2025.

Fourth Quarter and Full Year 2024 Financial Highlights

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2024, were $36.1 million, compared with $85.7 million as of December 31, 2023. These amounts exclude net proceeds of $13.7 million from the Company's ATM facility raised in January 2025.
- **Research and Development (R&D) Expenses:** R&D expenses for the fourth quarter of 2024 were $14.9 million compared with $11.9 million for the fourth quarter of 2023. Full year 2023 R&D expenses were $48.0 million compared to $41.6 million for full year 2023. The increase in fourth quarter and full year 2024 R&D expenses as compared to the same respective periods of 2023 was primarily attributable to higher clinical costs related to the Company's lead IMM-1-104 program and increased personnel to support ongoing research and development activities.
- **General and Administrative (G&A) Expenses:** G&A expenses for the fourth quarter of 2024 were $3.7 million compared with $4.4 million for the fourth quarter of 2023. Full year 2024 G&A expenses were $16.1 million compared to $16.8 million for full year 2023. The decrease in fourth quarter and full year 2024 G&A expenses as compared to the same respective periods of 2023 was primarily due to lower external professional fees and a reduction in employee-related costs, partially offset by higher stock-based compensation related to the general and administrative functions supporting the business.
- **Net Loss:** Net loss attributable to common stockholders was $18.1 million, or $0.58 per share, for the quarter ended December 31, 2024, compared to $15.1 million, or $0.52 per share, for the quarter ended December 31, 2023. Net loss attributable to common stockholders for full year 2024 was $61.0 million, or $2.04 per share, compared to $53.5 million, or $1.88 per share, for full year 2023.

2025 Financial Guidance

- Based on cash and cash equivalents as of December 31, 2024, plus proceeds from the Company's subsequent utilization of its ATM facility, and current operating plans, the Company expects its cash runway to be sufficient to fund operations into 2026.

About Immuneering Corporation

Immuneering is a clinical-stage oncology company seeking to develop and commercialize more effective *and* better tolerated therapies for cancer patients. The Company's lead product candidate, IMM-1-104, is an oral, once-daily deep cyclic inhibitor of MEK designed to improve tolerability and expand indications to include RAS-driven tumors such as most pancreatic cancers. IMM-1-104 is currently in a Phase 1/2a trial in patients with advanced solid tumors including pancreatic cancer. IMM-6-415 is an oral, twice-daily deep cyclic inhibitor of MEK 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 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 IMM-1-104, alone or in combination with other agents, including chemotherapy, checkpoint inhibitors and BRAF inhibitors; the plans and objectives of Company management for future operations, including with respect to the planning and execution of additional IMM-1-104 combination trials and potential pivotal trial of IMM-1-104 in combination with modified gemcitabine/nab-paclitaxel; the timing for release of additional results from the Phase 2a portion of the trial for IMM-1-104; and expectations regarding our cash runway.

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 and ability to continue as a going concern; 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, 2024, 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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IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2024	**2023**	**2024**	**2023**
Operating expenses				
Research and development	$14,857,166	$11,910,183	$47,964,388	$41,624,018
General and administrative	3,693,672	4,384,488	16,077,746	16,759,602
Amortization of intangible asset	7,317	7,317	29,267	29,267
Total operating expenses	18,558,155	16,301,988	64,071,401	58,412,887
Loss from operations	(18,558,155)	(16,301,988)	(64,071,401)	(58,412,887)
Other income (expense)				
Interest income	415,240	754,144	2,593,300	3,606,996
Other income, net	91,430	464,352	441,493	1,334,269
Net loss	**$(18,051,485)**	**$(15,083,492)**	**$(61,036,608)**	**$(53,471,622)**
Net loss per share attributable to common stockholders, basic and diluted	$(0.58)	$(0.52)	$(2.04)	$(1.88)
Weighted-average common shares outstanding, basic and diluted	31,050,448	29,269,842	29,981,565	28,416,558
Other comprehensive income (loss):				
Unrealized gains from marketable securities	(7,846)	(6,385)	778	29,342
Comprehensive Loss	**$(18,059,331)**	**$(15,089,877)**	**$(61,035,830)**	**$(53,442,280)**

IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	December 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$36,144,720	$59,405,817
Marketable securities	-	26,259,868
Prepaids and other current assets	3,442,849	3,417,984
Total current assets	39,587,569	89,083,669
Property and equipment, net	1,122,865	1,400,582
Goodwill	6,690,431	6,690,431
Intangible asset, net	350,413	379,680
Right-of-use assets, net	3,667,352	3,995,730
Other assets	1,295,783	1,034,446
Total assets	$52,714,413	$102,584,538
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$1,958,536	$2,111,666
Accrued expenses	4,973,129	5,173,960
Other liabilities	233,665	259,770
Lease liabilities	338,438	300,107
Total current liabilities	7,503,768	7,845,503
Long-term liabilities:		
Lease liabilities, net of current portion	3,824,419	4,162,852
Total liabilities	11,328,187	12,008,355
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2024 and December 31, 2023; 0 shares issued or outstanding at September 30, 2024 and December 31, 2023	-	-
Class A common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2024 and December 31, 2023; 31,050,448 and 29,271,629 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	31,050	29,272
Class B common stock, $0.001 par value, 20,000,000 shares authorized at September 30, 2024 and December 31, 2023; 0 shares issued and outstanding at September 30, 2024 and December 31, 2023	-	-
Additional paid-in capital	265,650,362	253,806,267
Accumulated other comprehensive loss	-	(778)
Accumulated deficit	(224,295,186)	(163,258,578)
Total stockholders' equity	41,386,226	90,576,183
Total liabilities and stockholders' equity	$52,714,413	$102,584,538