Immuneering Reports Fourth Quarter and Full Year 2022 Financial Results and Provides Business Updates

March 6, 2023

First patient dosed in Phase 1/2a clinical trial of IMM-1-104 in advanced solid tumors with any RAS mutation

Provides debut guidance for IMM-1-104 program: initial Phase 1 PK and safety data expected in mid-2023, initial Phase 1 PD modeling and additional PK and safety data expected in 2H 2023, recommended phase 2 dose and additional safety data expected in mid-2024

Continued progress in oncology pipeline - on track to file IND for IMM-6-415 in Q4 2023

Cash runway extended into Q4 2024; sharpened focus on oncology pipeline and suspension of discovery-stage neuroscience programs

Conference call and webcast today at 4:30 p.m. ET.

CAMBRIDGE, Mass., March 06, 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 reported financial results for the fourth quarter and full year ended December 31, 2022, and provided recent business updates.

"2022 was a year of important progress towards our goal of creating impactful new medicines for cancer patients," said Ben Zeskind, Ph.D., MBA, Co-founder, and Chief Executive Officer of Immuneering. "IMM-1-104, the first and only MAPK pathway inhibitor with the potential for universal-RAS activity, entered the clinic as we dosed the first patient in our Phase 1/2a clinical trial in November, enrolling patients with advanced solid tumors harboring RAS mutations. With a unique and counterintuitive mechanism of deep cyclic inhibition, IMM-1-104 was designed to limit toxicity and maximize therapeutic activity by selectively targeting cancer cells based on their increased need for sustained MAPK pathway signaling, while sparing healthy cells which are less dependent on continuous pathway signaling. IMM-1-104 is being evaluated as an oral, once-daily monotherapy. Our goal is to provide newer and better treatment options for patients with tumors driven by *any* mutation in KRAS, NRAS, or HRAS."

Dr. Zeskind continued: "We are very pleased with the progress of our trial, which enables us today to provide debut guidance on when investors can expect to see initial data from our ongoing IMM-1-104 Phase 1/2a clinical trial. Currently, we plan to share (1) initial Phase 1 pharmacokinetic (PK) and safety data in mid-2023, followed by (2) initial Phase 1 pharmacodynamic (PD) modeling and additional PK and safety data in the second half of 2023 and (3) the announcement of a recommended Phase 2 dose and additional safety data in mid-2024. We also plan to provide additional trial updates on a periodic basis. Because observing a unique PK profile in humans is a fundamental aspect of our counterintuitive deep cyclic inhibition mechanism, we believe these initial readouts could provide particularly impactful early validation for our approach and the potential universal-RAS activity of IMM-1-104. With our clinical trial rapidly advancing and continued progress accelerating IMM-6-415 toward an IND filing later this year, we have also taken the opportunity to sharpen our focus exclusively to oncology, by suspending our neuroscience programs. This change as well as other non-core adjustments extend our projected cash runway by an additional quarter, into Q4 2024."

Corporate Highlights

- **Preclinical data on lead program IMM-1-104 presented at American Association for Cancer Research (AACR) special conference targeting RAS:** In March 2023, Immuneering presented preclinical data in a poster titled, "Pan-RAS IMM-1-104 activity in humanized 3D tumor models is independent of specific amino acid substitution." IMM-1-104 demonstrated response across RAS mutant preclinical models regardless of mutation position or amino acid substitution, suggesting potential relevance to a broad universal-RAS-driven patient population.
- **Cash runway extended into Q4 2024 with sharpened focus on oncology pipeline:** In March 2023, Immuneering announced the company would sharpen its focus exclusively to its oncology pipeline, suspending its discovery-stage neuroscience programs. With this change, and other non-core adjustments, based on cash, cash equivalents and marketable securities and current operating plans, the company now expects its cash runway to extend into the fourth quarter of 2024.
- **First patient dosed in Phase 1/2a Clinical Trial of IMM-1-104 in advanced solid tumors with RAS mutations*:*** In September 2022, Immuneering received FDA clearance of the IND application for IMM-1-104 and in November 2022, commenced dosing in a Phase 1/2a open-label study designed to evaluate the safety, tolerability, pharmacokinetics, and preliminary efficacy of IMM-1-104 as an oral, once-daily monotherapy in patients with advanced RAS mutant solid tumors. To the company's knowledge, this is the first and only clinical trial for which patients with *any* mutation in KRAS, NRAS, or HRAS are eligible to be screened for other enrollment criteria. The Phase 1 portion of the study, which is being conducted at five clinical sites in the United States, includes a dose escalation phase and dose evaluation phase in order to establish an optimized Recommended Phase 2 Dose (RP2D) candidate. Subject to Phase 1 results, the Company currently expects to conduct a Phase 2a dose expansion phase in order to assess the safety and efficacy of IMM-1-104 at the RP2D in RAS mutated pancreatic, melanoma, lung, and colorectal cancers. The Company is currently in the dose escalation phase of the trial.

- **Preclinical data on its second program IMM-6-415 presented at the 37th Annual Meeting of SITC:** In November 2022, Immuneering presented preclinical data in a presentation titled, “Cyclic disruption of the mitogen-activated protein kinase (MAPK) pathway by the Dual MEK inhibitor, IMM-6-415, enhances PD1 and CTLA4 checkpoint blockade in RAS mutant tumors.” IMM-6-415 exhibited preclinical activity as a single-agent in RAF and RAS mutant tumor models, as well as enhanced activity in combination with checkpoint inhibitors (CPIs) in RAS-mutant colorectal cancer (CRC) and non-small cell lung cancer (NSCLC) models driven by diverse MAPK pathway mutations.

- **Chief People Officer appointed:** In October 2022, the company announced the appointment of Leah R. Neufeld to the newly created Chief People Officer position. Ms. Neufeld brings decades of experience in life sciences as well as human resources and will join the senior leadership team in continuing to make the company a great place for the all-star team of Immuneers to work and grow, while also helping to add new talent as the company advances a robust pipeline of novel product candidates.

- **Preclinical data presented at ASCO 2022 Annual Meeting highlighting pan-KRAS/NRAS activity of IMM-1-104**: In May 2022, Immuneering presented two preclinical abstracts. The first abstract, titled “Head-to-head comparison of the dual-MEK inhibitor IMM-1-104 versus sotorasib or adagrasib in KRAS mutant pancreatic tumors,” demonstrated a lack of Tumor Growth Inhibition (TGI) by sotorasib and adagrasib in KRAS-G12V mutant Capan-2 PDAC tumors. In contrast, IMM-1-104 observed TGIs of 49-84% across all doses and schedules tested. Consistent with other IMM-1-104 *in vivo* studies, median body weight loss was no more than 3-5% at top doses. The second abstract titled “Translational modeling for patients with RAS mutant tumors: Profiling the dual-MEK inhibitor IMM-1-104 in a humanized 3D assay,” found KRAS mutant pancreatic cancer and NRAS mutant melanoma were the most broadly sensitive patient-aligned models in the 3D-tumor growth assay and are expected to be included among the target indications planned for the Phase 2a portion of Immuneering’s ongoing Phase 1/2a clinical trial.

Near-Term Milestone Expectations

IMM-1-104

- Initial Phase 1 PK and safety data expected in mid-2023
- Initial Phase 1 PD modeling data and additional PK and safety data expected in the second half of 2023
- Recommended Phase 2 dose and additional safety data expected in mid-2024
- Additional trial updates expected on a periodic basis

IMM-6-415

- IND filing expected in the fourth quarter of 2023

Fourth Quarter and Full Year 2022 Financial Highlights

- **Cash Position**: Cash, cash equivalents and marketable securities as of December 31, 2022 were $105.5 million, compared with $150.2 million as of December 31, 2021.

- **Research and Development (R&D) Expenses**: R&D expenses for the fourth quarter of 2022 were $9.9 million compared with $7.9 million for the fourth quarter of 2021. Full year 2022 R&D expenses were $36.3 million compared to $26.5 million for full year 2021. The increase in R&D expenses from both periods of 2021 was primarily attributable to higher clinical costs related to the company's lead 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 2022 were $4.1 million compared with $3.1 million for the same period of 2021. Full year 2022 G&A expenses were $15.6 million compared to $8.3 million for full year 2021. The increase in G&A expenses for both periods of 2022 was primarily attributable to an increase in headcount in the company's general and administrative functions to support the business, and costs related to operating as a public company.

- **Net Loss**: Net loss attributable to common stockholders was $13.2 million, or $0.50 per share, for the quarter ended December 31, 2022, compared to $10.8 million, or $0.42 per share, for the quarter ended December 31, 2021. Net loss attributable to common stockholders for full year 2022 was $50.5 million, or $1.91 per share compared to $33.5 million, or $2.46 per share, for full year 2021.

2023 Financial Guidance

- Based on cash, cash equivalents and marketable securities, as of December 31, 2022, and current operating plans, the

company expects its cash runway to extend into the fourth quarter of 2024.

Conference Call

Immuneering will host a corresponding conference call and a live webcast at 1:30 p.m. PT / 4:30 p.m. ET on March 6, 2023, to discuss the results and provide a business and pipeline update. To access the call by phone, please use this registration link, and you will be provided with dial in details. To avoid delays, we encourage participants to dial into the conference call fifteen minutes ahead of the scheduled start time. After the live webcast, the event will be archived for 90 days in the Investor Relations section of Immuneering's website at Events & Presentations.

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, our universal-MAPK inhibitor, as well as several early-stage programs. For more information, please visit www.immuneering.com.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding Immuneering's expectations regarding the sufficiency of Immuneering's cash, cash equivalents and marketable securities, current operating plans and cash runway, the treatment potential of IMM-1-104 and IMM-6-415, including estimates of the patient population that may ultimately benefit from treatment, statements regarding the design, enrollment and conduct of the Phase 1/2a clinical trial for IMM-1-104, the timing of initial Phase 1 PK and safety data, initial PD modeling data and additional PK and safety data, additional trial updates, recommended phase 2 dose and additional safety data, the ability of initial readouts to validate the company's therapeutic approach, 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 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-K 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.

Media Contact:
Gina Nugent
Nugent Communications
617-460-3579
gina@nugentcommunications.com

Investor Contact:
Laurence Watts
Gilmartin Group
619-916-7620
laurence@gilmartinir.com

IMMUNEERING CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended December 31		Twelve Months Ended December 31	
	2022	**2021**	**2022**	**2021**
Revenue	$ 456	$ 189,591	$ 316,952	$ 2,079,961
Cost of revenue	—	206,221	158,122	1,153,073
Gross profit	456	(16,630)	158,830	926,888
Operating expenses				
Research and development	9,871,761	7,950,488	36,267,116	26,540,959
General and administrative	4,106,385	3,148,637	15,606,529	8,271,998
Amortization of intangible asset	7,317	—	30,053	—
Total operating expenses	13,985,463	11,099,125	51,903,698	34,812,957
Loss from operations	(13,985,007)	(11,115,755)	(51,744,868)	(33,886,069)
Other income (expense)				
Interest income	516,167	142,885	1,014,456	169,899
Other income (expense)	223,278	(118,974)	216,844	(127,063)

Loss before income taxes	(13,245,562)	(11,091,844)	(50,513,568)	(33,843,233)
Income tax benefit	—	307,485	—	307,485
Net loss	$ (13,245,562)	$ (10,784,359)	$ (50,513,568)	$ (33,535,748)
Net loss per share attributable to common stockholders, basic and diluted	(0.50)	(0.42)	(1.91)	(2.46)
Weighted-average common shares outstanding, basic and diluted	26,406,933	25,977,246	26,386,864	13,612,677
Other comprehensive loss:				
Unrealized losses from marketable securities	112,353	(44,258)	18,889	(49,009)
Comprehensive Loss	$ (13,133,209)	$ (10,828,617)	$ (50,494,679)	$ (33,584,757)

IMMUNEERING CORPORATION
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 72,636,886	$ 74,888,145
Marketable securities, current	32,887,970	74,311,203
Accounts receivable	12,417	246,040
Prepaids and other current assets	3,209,536	2,888,608
Total current assets	108,746,809	152,333,996
Marketable securities, non-current	—	996,560
Property and equipment, net	1,369,608	807,223
Goodwill	6,690,431	6,701,726
Intangible asset	408,947	439,000
Right-of-use assets, net	4,407,785	5,324,198
Other assets	743,703	102,129
Total assets	**$ 122,367,283**	**$ 166,704,832**
Liabilities, convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable	$ 3,154,557	$ 1,394,340
Accrued expenses	4,500,993	3,965,447
Other liabilities, current	19,796	—
Lease liabilities, current	378,723	274,039
Total current liabilities	8,054,069	5,633,826
Long-term liabilities:		
Lease liabilities, non-current	4,462,959	5,090,897
Total liabilities	12,517,028	10,724,723
Commitments and contingencies (Note 13)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2022 and December 31, 2021; No shares issued or outstanding	—	—
Class A common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2022 and December 31, 2021; 26,418,732 and 26,320,199 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	26,419	26,320
Class B common stock, $0.001 par value, 20,000,000 shares authorized at December 31, 2022 and December 31, 2021; 0 shares issued and outstanding at December 31, 2022 and December 31, 2021	—	—
Additional paid-in capital	219,640,912	215,276,186
Accumulated other comprehensive loss	(30,120)	(49,009)
Accumulated deficit	(109,786,956)	(59,273,388)
Total stockholders' equity	109,850,255	155,980,109
Total liabilities, convertible preferred stock and stockholders' equity	**$ 122,367,283**	**$ 166,704,832**