Mural Oncology Announces Fourth Quarter and Year End 2023 Financial Results and Provides Business Update

March 26, 2024

Lead product candidate, nemvaleukin, is being developed to treat a wide range of solid tumors and is currently in two potentially registrational clinical trials with readouts for both expected in 1H 2025

*Newly recommended phase 2 dose of nemvaleukin with increased dosage and less frequent dosing schedule to be explored in a cohort of **ARTISTRY-6**, the company's ongoing phase 2 trial in patients with melanoma*

Mural Oncology intends to nominate development candidates for its engineered therapies targeting interleukin-18 and interleukin-12 in 2024

The company reiterates cash runway projection into 4Q 2025

WALTHAM, Mass. and DUBLIN, Ireland, March 26, 2024 (GLOBE NEWSWIRE) -- Mural Oncology plc (Nasdaq: MURA), a clinical-stage immuno-oncology company developing novel, investigational engineered cytokine therapies designed to address areas of unmet need for patients with a variety of cancers, today announced its financial results for the fourth quarter and year ended December 31, 2023, and provided a business update.

"We have made significant progress since becoming an independent company during the fourth quarter of 2023. We have amplified the company's strong talent by bringing in world-class leaders in immuno-oncology. To date, nemvaleukin has generated promising data with durable responses both in monotherapy and in PD-1 combination across a range of solid tumor types. We expect our current cash reserves to fund our operations, including multiple clinical development programs, into 4Q 2025 and we are selectively exploring partnerships to further investigate the significant potential of both nemvaleukin and our preclinical programs," said Caroline Loew, Ph.D., Chief Executive Officer of Mural Oncology. "This year, we plan to continue to advance our late-stage clinical trials, including evaluating less frequent IV dosing for nemvaleukin. We also look forward to presenting pre-clinical data from our IL-18 and IL-12 programs at multiple oncology conferences and nominating candidates for each this year."

Recent Corporate Highlights and Upcoming Milestones

- Mural Oncology spun out of Alkermes and became an independent, publicly traded immuno-oncology company in November 2023. Now led by an experienced and highly accomplished oncology-focused leadership team and board of directors, the company is leveraging its core competencies in immune cell modulation and protein engineering to develop a portfolio of investigational cytokine therapies designed to address areas of unmet need for patients with solid tumors.

- Mural Oncology has completed evaluation of the less frequent IV (LFIV) dosing regimen of nemvaleukin in **ARTISTRY-3,** and determined the recommended phase 2 dose selection to be 30 µg/kg, to be evaluated in cohort 3 of **ARTISTRY-6**:

    - The new dosing regimen, a shift from five daily infusions (days 1-5) per three-week cycle to two infusions (on days 1 and 8) per three-week cycle, did not result in additional observed tolerability issues compared to previous studies of nemvaleukin. Notably, there were no dose-limiting toxicities at any dose tested and the desired pharmacodynamic effects were seen with twice per cycle dosing.
    - The company plans to evaluate the LFIV nemvaleukin dosing regimen in the open-label cohort 3 of **ARTISTRY-6**, the company's ongoing phase 2 trial, to explore the safety and efficacy of this new dosing regimen in a homogeneous patient population.
    - The company looks forward to presenting data from **ARTISTRY-3** at an upcoming medical conference.

- Enrollment in **ARTISTRY-6** and **ARTISTRY-7** is ongoing:

    - Cohort 2 of **ARTISTRY-6** is a potentially registrational, phase 2 trial evaluating nemvaleukin as a monotherapy in 90 mucosal melanoma patients. The company expects to report top-line data results from cohort 2 of **ARTISTRY-6** in the first half of 2025.
    - Cohort 3 of **ARTISTRY-6** is an open label extension of the trial that will evaluate the recommended phase 2 LFIV dosing regimen from **ARTISTRY-3** as a monotherapy and in combination with pembrolizumab in approximately 50 patients with cutaneous melanoma. The company expects to report top-line data for monotherapy from cohort 3 of **ARTISTRY-6** in the first half of 2025 and for the pembrolizumab combination in the second half of 2025.
    - **ARTISTRY-7** is a potentially registrational, phase 3 trial evaluating nemvaleukin in combination with pembrolizumab compared to investigators' choice chemotherapy in 448 patients with platinum-resistant ovarian cancer. Mural expects to report interim overall survival (OS) results based on approximately 75% of events in the first quarter of 2025 and final OS results in the second quarter of 2026.

- Mural Oncology will present preclinical **IL-18** and **IL-12** data for the first time at the upcoming AACR conference.
    - The company intends to nominate development candidates for these engineered IL-18 and IL-12 therapies later this year.

Financial Results for the Quarter Ended December 31, 2023

- **Cash Position:** As of December 31, 2023, cash and cash equivalents were $270.9 million.
- **R&D Expenses:** Research and development expenses were $42.2 million for the fourth quarter of 2023 and were primarily due to employee-related expenses and expenses related to ARTISTRY-7. These expenses included $5.6 million of non-cash, share-based compensation expenses.
- **G&A Expenses:** General and administrative expenses were $16.3 million for the fourth quarter of 2023, including $9.7 million in non-cash, share-based compensation expenses.
- **Net Loss:** Net loss was $59.5 million for the fourth quarter of 2023. This included $15.2 million non-cash, share-based compensation, of which approximately $11.7 million was driven by one-time charges related to the separation from Alkermes and conversion of employee equity during the fourth quarter of 2023.

Financial Guidance

- The company's cash resources are expected to fund its operations into the fourth quarter 2025.
- After the spin out from Alkermes on November 15, 2023, the company incurred certain non-cash, share-based compensation, most of which was one-time in nature, and this is reflected in today's reported results. Furthermore, the company's 2023 financial results reflect carve-out financials until the date of the spin out. The company anticipates reporting lower operating expenses in the quarters going forward.

About Nemvaleukin
Nemvaleukin is a novel, engineered cytokine designed to leverage antitumor effects of the IL-2 pathway while mitigating its hallmark toxicities that limit its use. Nemvaleukin selectively binds to the intermediate-affinity IL-2 receptor (IL-2R) and is sterically occluded from binding to the high-affinity IL-2R. Because of this molecular design, nemvaleukin treatment leads to preferential expansion of antitumor CD8+ T cells and natural killer cells, with minimal expansion of immunosuppressive regulatory T cells. Nemvaleukin is currently being evaluated in two potentially registrational late-stage trials.

About Mural Oncology
Mural Oncology is leveraging its novel protein engineering platform to develop cytokine-based immunotherapies for the treatment of cancer. By combining our expertise in cytokine biology and immune cell modulation and our protein engineering platform, we are developing medicines to deliver meaningful and clinical benefits to people living with cancer. Our mission is to broaden the potential and reach of cytokine-based immunotherapies to improve the lives of patients. Our lead candidate, nemvaleukin, is currently in potentially registrational trials in mucosal melanoma and platinum-resistant ovarian cancer. Mural Oncology has its registered office in Dublin, Ireland, and its primary facilities in Waltham, Mass. For more information, visit Mural Oncology's website at www.muraloncology.com and follow us on LinkedIn and X.

Forward-Looking Statements
Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding: the company's pipeline and development programs, including the expected timing of clinical updates and candidate selection, the potential of the company's product candidates and programs to address unmet medical needs, the continued progress of its pipeline and programs, the amount of general and administrative expense to be incurred by the company in future periods and the sufficiency of its cash resources to fund its operations for the period anticipated. Any forward-looking statements in this statement are based on management's current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include, among others, the inherent risks and uncertainties associated with competitive developments, preclinical development, clinical trials, recruitment of patients, product development activities and regulatory approval requirements; that preclinical or interim results and data from ongoing clinical studies of the company's cytokine programs and product candidates may not be predictive of future or final results from such studies, results of future clinical studies or real-world results; future clinical trials or future stages of ongoing clinical trials may not be initiated or completed on time or at all; the company's product candidates, including nemvaleukin, could be shown to be unsafe or ineffective; changes in the cost, scope and duration of development activities; the U.S. Food and Drug Administration may make adverse decisions regarding the company's product candidates; the separation may adversely impact the company's ability to attract or retain key personnel that support the company's oncology business; and those other risks and uncertainties set forth in the company's filings with the Securities and Exchange Commission ("SEC"), including its Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and in subsequent filings the company may make with the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made. The company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Mural Oncology plc
Consolidated Balance Sheets
(in thousands)

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 270,852	$ —

Receivable from Former Parent	5,548	—
Prepaid expenses	150	2,987
Other current assets	787	1,830
Total current assets	$ 277,337	$ 4,817
Property and equipment, net	11,403	10,617
Right-of-use-assets	12,747	18,316
Restricted cash	258	—
TOTAL ASSETS	$ 301,745	$ 33,750
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 5,973	$ 2,966
Accrued expenses	16,946	32,750
Operating lease liabilities – short-term	6,098	5,844
Total current liabilities	$ 29,017	$ 41,560
Operating lease liabilities – long-term	8,911	13,542
Other long-term liabilities	—	304
Total liabilities	37,928	55,406
Net parent investment	—	(21,656)
Preferred shares	—	—
Ordinary shares	167	—
Additional paid-in capital	294,507	—
Accumulated deficit	(30,857)	—
Total equity (deficit)	263,817	(21,656)
TOTAL LIABILITIES AND EQUITY (DEFICIT)	$ 301,745	$ 33,750

Consolidated Statements of Operations
(in thousands except share and per share amounts)

	Three months ended December 31, (unaudited)		Year ended December 31,	
	2023	**2022**	**2023**	**2022**
Operating expenses				
Research and development	$ 42,243	$ 42,393	$ 165,532	$ 167,191
General and administrative	16,270	4,969	30,706	17,732
Total operating expenses	58,513	47,362	196,238	184,923
Operating loss	(58,513)	(47,362)	(196,238)	(184,923)
Other income (expense), net	951	—	951	—
Income tax provision	(1,975)	(1,220)	(12,160)	(4,884)
Net loss and comprehensive loss	$ (59,537)	$ (48,582)	$ (207,447)	$ (189,807)
Net loss per share – basic and diluted	$ (3.57)	$ (2.91)	$ (12.43)	$ (11.37)
Weighted average common shares used in computing net loss per share – basic and diluted	16,689,740	16,689,740	16,689,740	16,689,740

Investors:
David Borah, CFA
david.borah@muraloncology.com

Media:
Katie Sullivan
katie.sullivan@muraloncology.com