Cullinan Oncology Provides Corporate Update and Reports First Quarter 2023 Financial Results

May 11, 2023

Zipalertinib pivotal trial now enrolling at the 100mg BID dose only

First clinical data for CLN-049 and CLN-619 to be reported at EHA 2023 Congress and ASCO 2023 Annual Meeting, respectively

Cash and investment position of $503.5 million as of March 31, 2023 continues to give runway into 2026

CAMBRIDGE, Mass., May 11, 2023 (GLOBE NEWSWIRE) -- -- Cullinan Oncology, Inc. (Nasdaq: CGEM; "Cullinan") a biopharmaceutical company focused on modality-agnostic targeted oncology therapies, today reported on recent and upcoming business highlights and announced its financial results for the first quarter ended March 31, 2023.

"We made important progress in the first quarter of this year and believe that 2023 will be a transformational year for Cullinan Oncology," said Nadim Ahmed, Chief Executive Officer of Cullinan. "Consistent with our guidance on reporting first clinical data from two of our ongoing Phase 1 studies by mid-year, preliminary safety data for CLN-049 were published in abstract form today as part of the 2023 EHA Congress and first clinical data for CLN-619 will be presented during a poster session at the upcoming ASCO Annual Meeting. Additionally, enrollment in the zipalertinib pivotal study will now continue at the 100mg BID dose only. We also continue to progress our diverse pipeline: both CLN-978 and CLN-617 received FDA clearance of IND applications in the first quarter, which will allow us to initiate first-in-human studies this year. Finally, we recently expanded our pipeline through the licensing of U.S. development and commercial rights to CLN-418, a potential first-in-class B7H4x4-1BB bispecific immune activator currently in a Phase 1 study across a variety of solid-tumor indications. Together, these achievements position us well with six programs in the clinic this year as we work toward our mission of creating new standards of care for patients with cancer."

Portfolio Highlights

- **Zipalertinib:** Enrollment will continue solely at the 100 mg BID dose level in the pivotal study of zipalertinib in EGFR exon 20 insertion mutation non-small-cell lung cancer patients progressing after prior systemic therapy.
    - Further enrollment in the 150mg BID cohort was recently discontinued based upon recommendation of the safety review committee.
- **CLN-049:** CLN-049 is a FLT3xCD3 T cell-engaging bispecific antibody being investigated in patients with relapsed/refractory acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS).
    - Preliminary safety data from an ongoing first in human study were published in abstract form as part of the 2023 EHA Congress.
    - Cytokine production and low-grade clinical cytokine release syndrome (CRS) consistent with the postulated mechanism of action were observed at the initial dose levels in the now completed single ascending dose study using IV administration.
    - Enrollment continues in the ongoing Phase 1 multi-ascending dose study using subcutaneous administration.
- **CLN-619**: CLN-619 is a monoclonal antibody that stabilizes expression of MICA/B on the tumor cell surface to promote tumor cell lysis by both cytotoxic innate and adaptive immune cells. CLN-619 has broad therapeutic potential and is being investigated as both a monotherapy and in combination with checkpoint inhibitor therapy in an ongoing Phase 1 dose escalation study in patients with advanced solid tumors.
    - First clinical data will be presented during a poster session at the American Society of Clinical Oncology (ASCO) 2023 Annual Meeting on June 3, 2023.
    - New preclinical data on the anti-tumor mechanism of CLN-619 were presented in a poster at the American Association for Cancer Research (AACR) Annual Meeting in April.
- **CLN-418:** CLN-418 is a B7H4x4-1BB fully human bispecific immune activator designed to achieve conditional activation of 4-1BB by targeting B7H4, a tumor-associated antigen that is highly expressed across multiple cancers with minimal expression on normal tissues. Enrollment is ongoing in a Phase 1 dose escalation study at U.S. and Australian sites in patients with advanced solid tumors, with initial clinical data expected in 2024.
    - In February, Cullinan Oncology licensed the exclusive U.S. development and commercial rights to CLN-418 from Harbour Biomed for an upfront fee of $25 million, with the potential for up to an additional $148 million in development and regulatory milestones and up to $415 million in sales-based milestones, as well as tiered royalties on potential U.S. commercial sales.
- **CLN-978:** CLN-978 is a novel CD19xCD3 bispecific therapeutic with extended serum half-life and robust potency against target cells expressing low levels of CD19.
    - Cullinan received FDA clearance of its IND application for CLN-978 in January and anticipates initiating a Phase 1 clinical study in 2023.

- **CLN-617:** CLN-617 is a cytokine fusion protein uniquely combining IL-12 and IL-2 with a collagen binding domain designed for retention in the tumor microenvironment (TME) following intratumoral injection.
    - Cullinan received FDA clearance of its IND application for CLN-617 in March and anticipates initiating a Phase 1 clinical study in 2023.
    - New preclinical data highlighting the therapeutic potential of CLN-617 was presented in a poster at the American Association for Cancer Research (AACR) Annual Meeting in April.

First Quarter 2023 Financial Results

- **Cash Position:** Cash, cash equivalents, investments, and interest receivable were $503.5 million as of March 31, 2023. This balance reflects the $25 million upfront payment to Harbour Biomed upon the execution of the licensing agreement for CLN-418. Cullinan expects its cash resources to provide runway into 2026 based on its current operating plan.
- **R&D Expenses:** Research and development (R&D) expenses were $52.1 million for the first quarter of 2023, compared to $21.3 million for the fourth quarter of 2022. R&D expenses for the first quarter of 2023 and fourth quarter of 2022 included $3.1 million and $2.9 million of equity-based compensation expenses, respectively. Excluding the impact of equity-based compensation expenses, the increase in R&D expenses was primarily related to the upfront payment to Harbour Biomed upon the execution of the licensing agreement for CLN-418, and higher clinical and clinical supply costs driven by the advancement and expansion of our pipeline.
- **G&A Expenses:** General and administrative (G&A) expenses were $10.7 million for the first quarter of 2023, compared to $11.3 million for the fourth quarter of 2022. G&A expenses in the first quarter of 2023 and fourth quarter of 2022 included $4.2 million and $4.6 of equity-based compensation expenses, respectively. The decrease in G&A expenses, excluding equity-based compensation, was primarily driven by a decrease in professional fees.
- **Net Loss:** Net loss (before items attributable to noncontrolling interest) for the first quarter of 2023 was $58.1 million, compared with net loss of $27.1 million for the fourth quarter of 2022. Net losses included the items described above, partially offset by interest income of $4.5 million and $3.4 million in the first quarter of 2023 and fourth quarter of 2022, respectively, and an income tax benefit of $1.9 million in the fourth quarter of 2022.

About Cullinan Oncology

Cullinan Oncology, Inc. (Nasdaq: CGEM) is a biopharmaceutical company dedicated to creating new standards of care for patients with cancer. We innovate without borders to find the most promising clinic-ready cancer therapies, whether from our own discovery efforts or through exceptional engagement with our academic and industry partners. Anchored in a deep understanding of immuno-oncology and translational cancer medicine, we leverage our scientific excellence in small molecules and biologics to create differentiated ideas, identify unique targets, and select the optimal modality to develop transformative therapeutics across cancer indications. Powered by our novel research model, we push conventional boundaries from candidate selection to cancer therapeutic, applying rigorous early experimentation to fast-track only the most promising assets to the clinic and ultimately commercialization. As a result, our diversified pipeline is strategically built with assets that activate the immune system or inhibit key oncogenic drivers across a wide range of modalities, each with the potential to be the best or first in their class.

Our people possess deep scientific expertise, seek innovation openly, and exercise creativity and urgency to deliver on our promise to bring new therapeutic solutions to patients with cancer. Learn more about our Company at www.cullinanoncology.com, and follow us on LinkedIn and Twitter.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, express or implied statements regarding Cullinan's beliefs and expectations regarding our preclinical and clinical development plans and timelines, clinical trial designs, clinical and therapeutic potential, and strategy of our product candidates; our ability to evaluate strategic opportunities to accelerate development timelines; our ability to optimize the impact of our collaborations and license agreements with external parties; our ability to continue our growth; our expectations regarding our use of capital; and our plans regarding future data presentations. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "hope," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

Any forward-looking statements in this press release are based on management's current expectations and beliefs of future events and are subject to known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any expressed or implied by the forward-looking statements. These risks include, but are not limited to, the following: uncertainty regarding the timing and results of regulatory submissions; success of our clinical trials and preclinical studies; risks related to our ability to protect and maintain our intellectual property position; risks related to manufacturing, supply, and distribution of our product candidates; the risk that any one or more of our product candidates, including those that are co-developed, will not be successfully developed and commercialized; the risk that the results of preclinical studies or clinical studies will not be predictive of future results in connection with future studies; and success of any collaboration, partnership, license or similar agreements. These and other important risks and uncertainties discussed in our filings with the Securities and Exchange Commission, including under the caption "Risk Factors" in our most recent Annual Report on Form 10-K and subsequent filings with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change, except to the extent required by law. 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. Moreover, except as required by law, neither Cullinan nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements included in this press release. Any forward-looking statement included in this press release speaks only as of the date on which it was made.

Cullinan Oncology, Inc.
Condensed Consolidated Balance Sheets

(in thousands)

	March 31, 2023	December 31, 2022
	(unaudited)	*(unaudited)*
Cash, cash equivalents, investments, and interest receivable	$ 503,494	$ 550,118
Total assets	$ 514,990	$ 561,117
Total current liabilities	$ 26,171	$ 22,498
Total liabilities	$ 29,341	$ 26,088
Total stockholders' equity	$ 485,649	$ 535,029
Total liabilities and stockholders' equity	$ 514,990	$ 561,117

Cullinan Oncology, Inc.
Consolidated Statements of Operations
(in thousands, except per share amounts)

	Three Months Ended	
	March 31, 2023	**December 31, 2022**
	(unaudited)	*(unaudited)*
Operating expenses:		
Research and development	$ 52,096	$ 21,321
General and administrative	10,660	11,287
Total operating expenses	62,756	32,608
Income (loss) from operations	(62,756)	(32,608)
Other income (expense):		
Interest income	4,508	3,364
Other income (expense), net	107	298
Net loss before income taxes	(58,141)	(28,946)
Income tax benefit	—	(1,858)
Net loss	(58,141)	(27,088)
Net loss attributable to noncontrolling interests	(179)	(306)
Net loss attributable to common stockholders of Cullinan	$ (57,962)	$ (26,782)
Net loss per share:		
Basic and diluted	$ (1.42)	$ (0.59)
Weighted-average shares used in computing net loss per share:		
Basic and diluted	40,682	45,751

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