



## Cullinan Oncology to Present Data Demonstrating Progress Across Its Broad Immunotherapy-Pipeline at SITC 2023

November 3, 2023

*Five abstracts accepted for poster presentation at the Society for Immunotherapy of Cancer 2023 Annual Meeting*

*Preliminary clinical biomarker data for anti-MICA/B antibody, CLN-619, supports proposed mechanism of action and demonstrates that the observed monotherapy clinical activity was seen in patients with tumors not typically responsive to checkpoint inhibitor therapy*

*Data highlight progress of Cullinan's diverse pipeline including CLN-619, an anti-MICA/B antibody; CLN-418, a B7H4X4-1BB-bispecific immune activator; CLN-978, a CD19XCD3 bispecific T cell engager; and CLN-617, a fusion protein harnessing IL-2 and IL-12 cytokines*

CAMBRIDGE, Mass., Nov. 03, 2023 (GLOBE NEWSWIRE) -- [Cullinan Oncology, Inc.](https://www.cullinanoncology.com) (NASDAQ: CGEM) ("Cullinan"), a biopharmaceutical company focused on modality-agnostic targeted oncology therapies, today announced that it will present data across four distinct immuno-oncology programs in five poster presentations at the Society for Immunotherapy of Cancer (SITC) 2023 Annual Meeting taking place November 1-5 in San Diego.

"We are proud to showcase progress of our diversified pipeline at SITC 2023, where we will present data across multiple targets, mechanisms, and modalities," said Jennifer Michaelson, Ph.D., Chief Scientific Officer of Cullinan Oncology. "Our CLN-619 poster provides evidence for the proposed mechanism of action and demonstrates that clinical activity, including objective response, has been observed in patients with tumor characteristics not typically responsive to checkpoint inhibitor therapy. Additional presentations will highlight preclinical data for three other assets: our B7H4X4-1BB bispecific immune activator (CLN-418), our T cell-engaging, CD19-targeted bispecific antibody (CLN-978), and our collagen-binding IL-2/IL-12 fusion protein (CLN-617), as well as a Trials in Progress presentation for CLN-617."

### **Presentation Details:**

#### **Program:** CLN-619

**Title:** Characterization of the pharmacodynamic activity of CLN-619, an anti-MICA/B monoclonal antibody, in patients from an ongoing Phase 1 trial

**Poster Number:** 194

**Session Date and Time:** Saturday, Nov. 4, 2023 9 a.m. – 8:30 p.m.

Initial clinical biomarker data demonstrates that CLN-619 increases MICA expression on the tumor cell surface, consistent with previously reported preclinical data and supporting the proposed mechanism of action. Data from patients with available biopsy data demonstrate clinical benefit, including objective response, in patients with tumors with characteristics not typically responsive to checkpoint inhibitor therapy. Specifically, tumors from two patients with endometrial cancer and previously reported confirmed partial responses were microsatellite stable (MSS), had low tumor mutational burden, and low neoantigen presentation index. Available biopsies from patients with prolonged stable disease showed similar low mutational burden and neoantigen presentation index characteristics, as well as increased surface MICA/B expression and NK cell activation.

#### **Program:** CLN-418

**Title:** CLN-418, a clinical-stage B7H4 x 4-1BB bispecific antibody with potential to treat patients with a wide range of solid tumors

**Poster Number:** 1171

**Session Date and Time:** Friday, Nov. 3, 2023 9 a.m. – 8:30 p.m.

#### **Program:** CLN-617

**Title:** CLN-617 combines IL-2 and IL-12 in a single molecule to optimally balance safety and efficacy upon intratumoral injection

**Poster Number:** 1093

**Session Date and Time:** Friday, Nov. 3, 2023 9 a.m. – 8:30 p.m.

#### **Program:** CLN-617

**Title:** A Phase 1 study to assess safety, efficacy, pharmacokinetics, and pharmacodynamics of intratumoral CLN-617 (IL2/IL12 Fusion Protein) combined with pembrolizumab in patients with advanced solid tumors

**Poster Number:** 771

**Session Date and Time:** Friday, Nov. 3, 2023 9 a.m. – 8:30 p.m.

**Program:** CLN-978

**Title:** CLN-978, a novel CD19/CD3/HSA T cell engager with extended serum half-life, is effective against lymphoma cells expressing very low levels of CD19

**Poster Number:** 1024

**Session Date and Time:** Saturday, Nov. 4, 2023 9 a.m. – 8:30 p.m.

**About CLN- 619**

CLN-619 is a potential first-in-class humanized IgG1 monoclonal antibody that binds to the stress induced ligands MICA and MICB, which are expressed on a wide variety of solid tumors and hematological malignancies. Engagement of MICA/B by the activating receptor NKG2D, present on both cytotoxic innate and adaptive immune cells, results in target cell lysis. However, tumor cells can shed MICA/B via proteases they release into the tumor microenvironment, resulting in evasion of immune-mediated destruction. CLN-619 functions by restoring MICA/B expression on the surface of tumor cells, enhancing the interaction between MICA and NKG2D, and inducing antibody-dependent cellular toxicity (ADCC), together promoting anti-tumor activity via multiple immune-mediated mechanisms. CLN-619 is being studied in an ongoing Phase 1 clinical trial ([NCT05117476](#)) both as a monotherapy and in combination with pembrolizumab. The study design allows dose level extensions as well as expansion in tumor-specific cohorts.

**About CLN-418**

CLN-418 is a B7H4X4-1BB bispecific immune activator in clinical studies. Both B7H4 and 4-1BB have been targets of high interest and both have been evaluated clinically. Their distinct biology and mechanisms of action provide strong rationale to combine them as a bispecific antibody.

B7H4 is an attractive tumor associated antigen (TAA) highly expressed on multiple tumor types, including triple negative breast cancer, ovarian cancer, and lung cancer, while expression on normal tissue is low. A coinhibitory immune checkpoint in the B7 family, B7H4 has minimal overlap with PD-L1 expression. Targeting B7H4 has the potential to address tumor types for which PD-L1-based immunotherapies have exhibited limited efficacy.

4-1BB is a key costimulatory molecule for both T- and NK-cell engagement and is being studied in multiple clinical programs. However, safety concerns such as hepatic toxicity remain despite the biological validation of the 4-1BB pathway. Conditional activation of 4-1BB in the tumor microenvironment that is dependent on B7H4 expression presents a novel approach to harness the potential of both targets. CLN-418/HBM7008, with strict TAA crosslinking-dependent T-cell activation, can potentially translate to better safety and a more favorable therapeutic window.

The ongoing Phase 1 trial ([NCT05306444](#)) is an open-label, multicenter study being conducted at U.S. and Australian sites evaluating the safety, tolerability, pharmacokinetics and anti-tumor activity of CLN-418 administered intravenously in patients with advanced solid tumors.

**ABOUT CLN-978**

CLN-978 is a novel, highly potent, half-life extended CD19xCD3-bispecific T cell engager construct. CLN-978 contains two single-chain variable fragments (scFv), one binding with very high affinity the CD19 target on malignant cells and the other binding CD3 on T cells. While CLN-978 resembles the canonical BiTE format, it also contains a single-domain antibody (VHH) binding to human serum albumin (HSA). CLN-978 redirects and activates T cells to destroy CD19-expressing cancer cells via T cell mediated cytotoxicity.

CLN-978 has the potential to offer a convenient, off-the-shelf therapeutic option that may provide an alternative to CD19 CART cell therapies. High-affinity binding of CLN-978 to CD19 allows for increased potency against tumor cells expressing very low levels of CD19. An HSA-binding domain increases the serum half-life of CLN-978 and, with subcutaneous delivery, permits more patient-friendly dosing and potentially reduced toxicity.

CLN-978 has the potential to become a highly effective treatment option for patients across a range of B cell malignancies, including those who have relapsed on other CD19-directed therapies due to reduced CD19 target expression. CLN-978 is currently being evaluated in a Phase 1 clinical trial ([NCT05879744](#)) as a novel treatment for B-NHL and has potential applicability across the entire spectrum of B cell mediated diseases, including autoimmune diseases.

**About CLN-617**

CLN-617 is a potential first-in-class cytokine therapy comprised of two potent and synergistic antitumor cytokines, IL-2 and IL-12, in a single molecule. The molecule is intended for intratumoral injection and employs collagen-binding and size-enhancing domains designed to retain the CLN-617 molecule inside the tumor and thereby enhance efficacy and reduce toxicity. While CLN-617 is injected and retained locally in the tumor, it directs a broad immune response that may help eradicate not only the injected tumor, but also attack distant tumor sites, as observed in preclinical studies. Preclinical studies have also demonstrated the potential for enhanced efficacy when CLN-617 is combined with checkpoint inhibitor therapy. Cullinan plans to evaluate CLN-617 in a Phase 1 clinical trial ([NCT06035744](#)) in patients with advanced solid tumors.

**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 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](http://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, including but not limited to our expectations and beliefs around their safety and efficacy. 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.

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