MiNK Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results

March 21, 2023

- Clinical update of allo-iNKTs (agenT-797) in solid tumors to be presented at AACR Annual Meeting in April 2023
- AgenT-797 in combination with pembro or nivo in NSCLC and gastric cancer to initiate in 2023
- Allogeneic CAR platform demonstrates differentiation with IL-15-FAP-CAR-iNKT (MiNK-215) and IL-15-BCMA-CAR-iNKT (MiNK-413) in IND enabling studies

NEW YORK, March 21, 2023 (GLOBE NEWSWIRE) -- MiNK Therapeutics, Inc. (NASDAQ: INKT), a clinical-stage biopharmaceutical company pioneering the discovery, development, and commercialization of allogeneic, off-the-shelf, invariant natural killer T (iNKT) cell therapies to treat cancer and other immune-mediated diseases, today reported financial results for the fourth quarter and full year 2022.

“2022 has been an important year for MiNK, with significant progress across our clinical and preclinical programs in iNKT cell therapy, bolstered by the expansion of our in-house manufacturing capabilities," stated Dr. Jennifer Buell, President and Chief Executive Officer of MiNK. "Our advancements have solidified MiNK's position as a leader in the iNKT cell therapy field, with a growing body of clinical data demonstrating the potential of iNKT cells alone and in combination with standard of care agents, as well as novel insights into their unique mechanisms of action. Additionally, we've made strides in our CAR-iNKT program. As we move into 2023, we are eager to build on this momentum and rapidly expand our solid tumor program, leveraging our strong foundation to accelerate the development of potentially life-saving therapies for patients."

Fourth Quarter and Full Year 2022 Business Highlights:

MiNK's focus is on advancing the clinical and preclinical programs of their iNKT cell pipeline, as well as expanding their in-house manufacturing capabilities. Here are some key achievements and upcoming milestones for MiNK:

- **Solid tumor cancers**:
  - AgenT-797, an allogeneic unmodified iNKT cell therapy, has shown clinical activity in solid tumor cancers (data presented at SITC 2022).
  - AgenT-797 alone or in combination with approved anti-PD-1 (pembro or nivo) in advanced solid tumor cancers showed early signals of benefit without lymphodepletion; cells were tolerable to $1x10^9$ cells/dose with no neurotoxicity or CRS.
  - Updated data selected for presentation at the American Association for Cancer Research (**AACR**) on April 18th and expansion planned in relapsed refractory gastric cancer and non-small cell lung cancer (NSCLC).
- **Severe viral ARDS:**
  - Completed phase 1 of allo-iNKTs in severe viral ARDS. Demonstrated improved survival compared to case control and time-relevant CDC data (70 vs. 10-22%).
  - Data publication under review.
  - Program to advance through external public/private financing, discussions underway.
- **Scientific Progress:**
  - MiNK elucidated novel mechanisms by which iNKT cells contribute to immune regulation (data presented at SITC 2022).
  - iNKTs reverse T cell exhaustion, activate dendritic cells, and deplete immuno-suppressive M2 macrophages to eliminate tumor escape mechanisms.
- **Manufacturing**:
  - MiNK is FDA cleared for fully in-house cGMP manufacturing of allogeneic iNKT cells, with a process designed to achieve > 5,000 doses per batch.
- **Pipeline**:
  - First-in-class armored FAP-CAR-iNKT (MiNK-215) and potential best-in-class armored BCMA-CAR-iNKT (MiNK-413) data presented at SITC 2022.

- MiNK-215 demonstrated robust efficacy in NSCLC preclinical models, eliminating tumor burden in the lungs, and enhancing tumor specific CD8+ T cell infiltration through tumor stroma.
- MiNK-413 is a differentiated next generation allogeneic IL-15-armored-BCMA-CAR-iNKT therapeutic candidate designed to overcome the limitations of current autologous cell therapies. MiNK-413 demonstrated superior tumor clearance in a systemic multiple myeloma models, compared to currently available BCMA-CARs.

Anticipated Upcoming Milestones:

- Present updated clinical data readout from phase 1 study of agenT-797 full solid tumor cohort at AACR Annual Meeting, April 2023
- Present clinical data from phase 1/2 study of agenT-797 in viral ARDS at American Thoracic Society (ATS) Annual Meeting (Abstract Number: 10725) on May 21, 2023
- Launch expansion combination studies with agenT-797 in NSCLC and Gastric in 2023
- FAP-CAR-iNKT IND filing in 2024
- Progress existing and new collaborations

Fourth Quarter and Full Year 2022 Financial Results

We ended the fourth quarter 2022 with a cash balance of $19.6 million as compared to $38.9 million at December 31, 2021. Cash used in operations for the year and fourth quarter ended December 31, 2022, was $18.9 million, and $4.4 million respectively, compared to $12.8 million and $1.7 million for the same periods in 2021. The increased funding was related to the internalization of our cGMP manufacturing of agenT-797 for clinical trial supply, which has increased our production and will result in decreased supply cost prospectively.

Net loss for the quarter ended December 31, 2022, was $7.8 million or $0.23 per share, compared to a net loss for the same period of 2021 of $5.8 million or $0.18 per share. Net loss for the year ended December 31, 2022, was $28.0 million, or $0.83 per share compared to $30.2 million and $1.16 per share for the year ended December 31, 2021.

Summary Consolidated Financial Information

Condensed Consolidated Balance Sheet Data
(in thousands)
(unaudited)

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 19,636	$ 38,889
Total assets	21,472	40,242
Total stockholders' equity (deficit)	(401)	23,776

Other Financial Information
(in thousands)
(unaudited)

	Three months ended December 31, 2022	Three months ended December 31, 2021	Year ended December 31, 2022	Year ended December 31, 2021
Cash used in operations	$ 4,431	$ 1,702	$ 18,867	$ 12,827
Non-cash expenses	706	740	358	13,650

Condensed Consolidated Statements of Operations Data
(in thousands, except per share data)
(unaudited)

	Three months ended December 31, 2022	Three months ended December 31, 2021	Year ended December 31, 2022	Year ended December 31, 2021

Operating expenses:				
Research and development	5,812	3,951	23,115	13,967
General and administrative	2,077	2,362	7,834	4,640
Change in fair value of convertible affiliated note (non-cash)	-	49	-	9,752
Operating loss	7,889	6,362	30,949	28,359
Other expense (income), net	(120)	(597)	(2,958)	1,854
Net loss	$ 7,769	$ 5,765	$ 27,991	$ 30,213
Per common share data, basic and diluted:				
Net loss	$ 0.23	$ 0.18	$ 0.83	$ 1.16
Weighted average number of common shares outstanding, basic and diluted	33,806	31,482	33,673	26,025

Conference Call and Webcast

MiNK will host a conference call and webcast to discuss its fourth quarter and full year 2022 financial results and business updates today, Tuesday, 21st March 2023 at 8:30 AM ET. The webcast is available on the events and presentations page of the company website and at https://edge.media-server.com/mmc/p/ctv5wn5g. The conference ID is 6075772. To access live by phone, call 646-307-1963 (United States - New York) or 800-715-9871 (USA & Canada - Toll-Free).

Forward Looking Statements

This release contains forward-looking statements. You can identify these forward-looking statements by the fact they use words such as “could,” “expect,” “anticipate,” “estimate,” “target,” “may,” “project,” “intend,” “plan,” “believe,” “will,” “potential,” “opportunity,” “future” and other words and terms of similar meaning and include statements that they do not relate strictly to historical or current facts. In particular, these statements relate to, among other things, the mechanism of action, efficacy and safety of our iNKT technology and therapeutic candidates, business strategy, our research and development plans, our product development efforts, funding and partnering opportunities, future operating plans, results, objectives, expectations, and intentions. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes to differ materially from current expectations. Therefore, we caution investors such statements need to be evaluated in light of all the information contained in our filings with the SEC on our Annual Report on Form 10-K, among others. Furthermore, the statements speak only as of the date of this document, and we undertake no obligation to update or revise these statements, except as required by law.

About MiNK Therapeutics

MiNK Therapeutics is a clinical-stage biopharmaceutical company pioneering the discovery, development, and commercialization of allogeneic invariant natural killer T (iNKT) cell therapies to treat cancer and other immune-mediated diseases. MiNK is advancing a pipeline of both native and next generation engineered iNKT programs, with a platform designed to facilitate scalable and reproducible manufacturing for off-the-shelf delivery. The company is headquartered in New York, NY. For more information, visit https://minktherapeutics.com/. Follow us on Twitter @MiNK_iNKT.

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