MiNK Presents Clinical Data at SITC 2022 Showcasing iNKT Cell Therapy Pipeline

November 10, 2022

- Allogeneic off-the-shelf iNKT cell therapy, agenT-797, alone and in combination with pembro/nivo reports early clinical activity in solid tumors, with 27% and 66% of patients, respectively, had a reduction of target and non-target lesions or disease stabilization
- First immune cell therapy (agenT-797) to show a survival benefit (70% vs. 10%) in patients with viral acute respiratory distress syndrome (ARDS) on respiratory bypass
- agenT-797 can be administered without lymphodepletion; with no reports of cytokine release syndrome or neurotoxicity
- Next-generation pipeline advances with two novel armored CAR-iNKTs, a FAP-CAR-iNKT and a BCMA-CAR-iNKT in IND-enabling studies
- MiNK to host R&D Day on November 10, 2022, from 4:00-6:00pm ET in Boston and via webcast

NEW YORK, Nov. 10, 2022 (GLOBE NEWSWIRE) -- MiNK Therapeutics, Inc., 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, announced the presentation of new data from five presentations at the 2022 Society for Immunotherapy of Cancer (SITC) Annual Meeting.

Invariant natural killer T (iNKT) cells are a powerful subset of T cells which act as master regulator of immune response, making them an ideal immunotherapy. MiNK has developed off-the-shelf, allogeneic iNKT (allo-iNKT) cell therapeutic candidates, agenT-797, in its native form or engineered for super targeting of a broad spectrum of diseases, including in solid cancers and viral diseases of the lung.

“Our five presentations at SITC demonstrate the strength of progress at MiNK, including important new clinical data for agenT-797, advances across our differentiated next-generation programs, as well as our proprietary engineering technology,” said Dr. Jennifer Buell, President and CEO, of MiNK Therapeutics. “These collective data signify important advances in our understanding of iNKT cell science, elucidating novel mechanisms, and providing compelling clinical data of unmodified allo-iNKTs alone and combination with backbone immune checkpoint therapy in solid tumors. Our SITC 2022 data also represents the first immune cell therapy to show a survival benefit in patients with severe respiratory distress treated with respiratory bypass procedures.”

Allogeneic unmodified iNKTs (agenT-797) show reductions in target and non-target lesions or disease stabilization in patients with solid tumor cancers when administered alone [27%] and in combination with pembrolizumab (KEYTRUDA®) or nivolumab (OPDIVO®) [66%].

- Phase 1 data show early signals of activity with disease stabilization in patients refractory to standard of care and those who have progressed on KEYTRUDA or OPDIVO.
- agenT-797 preferentially kills tumor-promoting M2 macrophages while preserving pro-inflammatory M1 macrophages associated with anti-tumor responses.
- agenT-797 can be dosed up to $1000x10^6$ cells without lymphodepletion showing no signs of neurotoxicity and cytokine release syndrome (CRS grade ≥ 3).
- Allo-iNKTs show signals of durable disease stabilization and modulation of M-spike protein seen in heavily pre-treated r/r multiple myeloma patients (2/8) after ≥6 prior lines of therapy.

agenT-797 shows 70% survival in severe viral ARDS compared to site reference controls (~10%); potential for a variant agnostic approach to infections.

- In Phase 1/2 study, agenT-797 shows survival of 70% in mechanically ventilated patients compared to ~10% in a comparative case control population.
- Increased 90-day survival in a subgroup of patients on respiratory bypass (ECMO) of 75% compared to 30% in a comparative cohort with median survival of 119.5 vs 47 days.
- agenT-797 demonstrates a favorable safety profile. Only 1 grade ≥3 treatment related adverse event and no CRS was observed.
- agenT-797 treatment was associated with a reduction in secondary infections, including reduced incidence of pneumonia at the highest dose level, a driver of ICU mortality.

MiNK’s FAP-CAR-iNKT therapeutic candidate, MiNK-215, demonstrates robust efficacy in non small cell lung cancer (NSCLC) preclinical

models, promoting curative responses, eliminating tumor burden in the lungs, and enhancing tumor specific CD8+ T cell infiltration through tumor stroma.

- FAP-CAR-iNKT demonstrates a drastic increase of CD8+ T cells infiltrating the tumor and significantly increased tumor killing compared to T cells in murine models.
- MiNK-215 shows robust preclinical efficacy towards tumor expressing FAP (FAP+ cancer model), underscoring potential to target FAP+ tumors.

MiNK-413 is a differentiated allogeneic IL-15-armored-BCMA-CAR-iNKT therapeutic candidate, a next generation approach designed to overcome the limitations of current autologous cell therapies.

- MiNK-413 demonstrates superior tumor clearance in a systemic multiple myeloma models, compared to control BCMA-CAR.
- Armoring MiNK-413 with soluble IL-15 enables prolonged persistence, which may translate to increased durability in patients.
- MiNK-413 has the potential to target a broader population of patients with multiple myeloma.
- MiNK's proprietary CARDIS platform enables high-throughput rapid selection and optimization of functional CARs, like MiNK-413 (IL-15-armored-BCMA-CAR-iNKT) and MiNK-215 (FAP-CAR-iNKT).

Allo-iNKTs (agenT-797) reinvigorate partially exhausted T cells and improve effector functions within the tumor microenvironment; critical mechanisms in rescuing PD-1 refractory tumors.

- In addition to their direct anti-tumor activity, allogeneic iNKT cells (agenT-797) improve immune effector function of immune cells in the tumor microenvironment.
- agenT-797 restores the cytotoxic capacity, activation, and cytokine production of partially exhausted T cells.
- agenT-797 preferentially kills tumor-promoting M2 macrophages while preserving pro-inflammatory M1 macrophages associated with anti-tumor responses.
- agenT-797 activates dendritic cells, which can promote activation of T cells through enhanced antigen presentation.

The full poster presentations can be accessed on the publication section of MiNK's website at https://minktherapeutics.com/publications/.

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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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Forward Looking Statements

This press release contains forward-looking statements that are made pursuant to the safe harbor provisions of the federal securities laws, including statements regarding the therapeutic and curative potential of agenT-797 and iNKT cells (native and modified), the mechanism of action, potency and safety of agenT-797 and iNKT cells (native and modified), interim or top-line data, including statements regarding an upcoming presentation at SITC on MiNK's clinical data of agenT-797 alone and in combination with anti-PD-1, the anticipated benefits of agenT-797 and clinical development plans and timelines as well as data related to the mechanism of action of agent-797 and CAR_INKT candidates, and the potential benefit of therapeutic candidates MiNK-413 and MiNK-215 an armored BCMA-CAR-INKT and FAP-CAR-INKT respectively. These forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially. These forward-looking statements are subject to risks and uncertainties, including the factors described under the Risk Factors section of the most recent Form 10-K, Form 10-Q and the S-1 Registration Statement filed with the SEC. MiNK cautions investors not to place considerable reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this press release, and MiNK undertakes no obligation to update or revise the statements, other than to the extent required by law. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

Source: MiNK Therapeutics