November 10, 2022

GT Biopharma Presents Two Posters at the Society for Immunotherapy of Cancer's (SITC) 37th Annual Meeting

- Poster #1: Tri-specific killer engagers target natural killer cells towards mesothelioma
- Poster #2: Enhancing NK cell function in the 'cold' tumor microenvironment of prostate cancer with a novel Tri-specific Killer Engager against prostate-specific membrane antigen (PSMA)

BRISBANE, CALIFORNIA, Nov. 10, 2022 (GLOBE NEWSWIRE) -- GT Biopharma, Inc. (the "Company" or "GTB") (NASDAQ: GTBP), a clinical stage immuno-oncology company focused on developing innovative therapeutics based on the Company's proprietary natural killer (NK) cell engager, TriKE® platform, will present two poster presentations at the Society for Immunotherapy of Cancer's 37th Annual Meeting (SITC 2022), to be held in Boston, Massachusetts and virtually on November 8-12, 2022. The two posters highlight tri-specific killer engagers for the treatment of mesothelioma and prostate cancer.

"We are pleased with the progress that has been made in assessing the broad applicability of our novel TriKE platform across solid tumors" said Michael Breen, Executive Chairman and Interim CEO of GT Biopharma. "Our TriKE structure consisting of an anti-CD16 nanobody which binds to NK cells and triggers antibody directed cell-mediated cytotoxicity (ADCC), IL-15 cross-linker that binds to NK cells inducing self-sustaining expansion and extended survival and an anti-tumor associated antigen which binds to well-known tumor antigens. The TriKE modular platform allows for targeting multiple tumor-associated antigens. As such, we remain excited in our progress to date while looking forward to submitting an Investigational New Drug (IND) application in 2023 for lead assets GTB-3650 targeting CD33 positive tumors and GTB-5550 targeting B7H3 positive tumors, respectively."

Presentation Highlights:

Abstract #1202: *Tri-specific killer engagers target natural killer cells towards mesothelioma*
Presenter: Martin Felices
Date: November 11, 2022
Location and time: Poster Hall from 9:00am – 8:30pm ET

- Mesothelioma is a rare cancer, most cases are of the cell lining of the lung as a result of asbestos exposure and in fewer cases, the lining of the abdomen wall. The study examined two novel TriKEs targeting mesothelin (cam1615SS1) commonly found on epithelioid mesothelioma, and a second TriKE targeting B7H3 (GTB-5550), a common tumor antigen.

- TriKEs cam1615SSS1 and GTB-5550 were tested across multiple mesothelioma cell lines in particular cell lines that were present in pleural and peritoneal lines.
- TriKEs targeting mesothelin or B7H3 induce NK cell degranulation and cytokine production and in the presence of cam1615SSS1 or GTB-5550, NK cells control peritoneal mesothelioma in three-dimensional spheroid cultures.

Conclusion: GTB-5550 drove NK cell responses towards all mesothelioma subtypes, while cam1615SS1 successfully targeted epithelial peritoneal mesothelioma. In future pre-clinical studies, a goal will be to combine a TriKE with immune checkpoint inhibitors to test their potential to drive innate immune responses in the context of currently approved therapies.

Abstract #1204: *Enhancing NK cell function in the 'cold' tumor microenvironment of prostate cancer with a novel Tri-specific Killer Engager against prostate-specific membrane antigen (PSMA)*
Presenter: Gwen Phung
Date: November 11, 2022
Location and time: Poster Hall from 9:00am – 8:30pm ET

- In cold tumor microenvironments (TME) of metastatic castration-resistant prostate cancers (mCRPC), the lethal form of prostate cancer, immuno-suppressive cells such as myeloid-derived suppressor cells (MDSC) found in the TME can play a role in impairing NK cell effector function.
- Designing a novel tri-specific killer engager cell (TriKE) consisting of a:
    - CD16 arm that activates receptors of NK cells and enhances delivery of IL-15,
    - An arm that binds to prostate-specific membrane antigen (PSMA) (highly and specifically expressed on mCRPC),
    - A linker IL-15 moiety ensures NK cell survival, proliferation, priming and motility; which improves NK cell anti-tumor responses against mCRPC in the TME.

- The novel “PSMA TriKE” induces specific NK cell activation against PSMA-expressing prostate cancer cell lines.
- The PSMA TriKE sustains NK cell cytolytic capacity even after long term incubation in hypoxia.
- PSMA TriKE maintains NK cell degranulation after co-culture with MDSC.

Conclusion: PSMA TriKE induces specific NK cell proliferation and activation against PSMA+ tumor cells. TriKE robustly relieves NK cells from suppression induced by hypoxia and MDSCs.

About GT Biopharma, Inc.
GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology therapeutic products based on our proprietary TriKE® NK cell engager platform. Our TriKE® platform is designed to harness and enhance the cancer killing abilities of a patient’s immune system’s natural killer cells. GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize therapies using TriKE® technology. For more information, please visit gtbiopharma.com.

Forward-Looking Statements
Certain statements in this press release may constitute "forward-looking statements"

regarding future events and our future results. All statements other than statements of historical facts are statements that could be deemed to be forward-looking statements. These statements are based on current expectations, estimates, forecasts, and projections about the markets in which we operate and the beliefs and assumptions of our management. Words such as "expects," "anticipates," "targets," "goals," "projects", "intends," "plans," "believes," "seeks," "estimates," "endeavors," "strives," "may," or variations of such words, and similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements are subject to a number of risks, uncertainties and assumptions that are difficult to predict, estimate or verify. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Such risks and uncertainties include those factors described in our most recent annual report on Form 10-K, as such may be amended or supplemented by subsequent quarterly reports on Form 10-Q, or other reports filed with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements are made only as of the date hereof, and we undertake no obligation to publicly release the result of any revisions to these forward-looking statements. For more information, please refer to our filings with the Securities and Exchange Commission.

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