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GT Biopharma Announces Approved FDA IND Transfer of Its First TriKE (OXS-3550)

WASHINGTON, DC / ACCESSWIRE / October 24, 2017 /GT Biopharma Inc. (OTCQB: GTBP and Euronext Paris GTBP.PA) announced today the FDA has accepted the transfer of IND 136205 Change of Sponsor from the University of Minnesota to GT Biopharma for a commercial IND of OXS-3550 (anti-CD16-IL-15-anti-CD33); a first of its kind, single-chain, tri-specific NK cell engager (TriKE).

OXS-3550 TriKE technology was developed by researchers at the University of Minnesota Masonic Cancer Center. As demonstrated in non-clinical models, this targeted immunotherapy directs immune cells to kill cancer cells while diminishing drug-related toxicity.

Several months ago, the GT Biopharma TriKE platform technology received funding from the University of Minnesota's National Institution of Health (NIH) REACH award. This award is given by the NIH to support technology that is promising for commercial success.

The TriKE platform technology can be viewed as a protein version of CAR-T. However, unlike traditional CAR-T platforms like Kite Pharma (KITE) and Juno Therapeutics (JUNO), TriKEs are not an expensive cell therapy currently only available to treat liquid tumors. It is anticipated that TriKEs will be a therapeutic option for a much larger portion of the cancer population at a fraction of the cost. TriKEs are an antibody platform that can be tailored to treat any form of cancer, liquid or solid tumors.

The TriKE platform focuses on Natural Killer (NK) cells, a type of white blood cell, which plays a major role in the rejection of tumor and virally infected cells. NK cells are an important component of the innate immune system and are critical in killing cancer cells.

The TriKE IND (OXS 3550) will focus on AML, the most common form of adult leukemia with 21,000 new cases expected in 2017 alone (American Cancer Society). These patients will require frontline therapy, usually chemotherapy including cytarabine and an anthracycline, a therapy that has not changed in over 40 years. Also, about half will have relapses and require alternative therapies. In addition, about 13,000 new cases of myelodysplastic syndrome (MDS) are diagnosed each year and there are minimal treatment options (Siegel et al, 2014). At a minimum, OXS-3550 can be expected to serve as a relatively safe, inexpensive, and easy to use therapy for resistant/relapsing AML. From a biologic standpoint, it could also be combined with chemotherapy as frontline therapy.

The University of Minnesota's Deputy Director of the Masonic Cancer Center, Dr. Jeff Miller said, "We have focused on NK cell therapy for the past 20 years at the University of Minnesota Masonic Cancer Center. While promising, limitations of NK cell therapy include

their lack of specificity and the fact that they may be suppressed by the tumor microenvironment. The design of the TriKE is intended to overcome both limitations by making NK cells antigen specific and providing IL-15 as an important activation co-stimulus."

GT Biopharma Chief Medical officer (CMO) Dr. Raymond Urbanski said, "Cancer treatment continues to move towards immunotherapy and the TriKE platform is a powerful new approach. It is the protein version of CAR-T without the excessive resource demands, expense and risk. Our current TriKE, OXS-3550, can be given as a convenient IV infusion. The commercial IND allows us to establish the safety of the TriKE which can then be administered on an outpatient basis."

GT Biopharma Chief Executive Officer (CEO) Dr. Kathleen Clarence-Smith said, "TriKEs hold great promise in treating a number of liquid and possibly solid tumors; the IND transfer to GT Biopharma will allow for faster development and earlier delivery to patients who are in great need of better therapies."

GT Biopharma Executive Chairman Anthony J. Cataldo said, "During 2017 we have continued to accomplish our goals. This is another major milestone for our shareholders. We are continuing with our stated efforts to up-list to NASDAQ."

About the TriKE: TriKE CD16/IL15/CD33 focuses on NK cell cancer-killing activity which is expected to be increased by bringing the NK cells in close proximity to the cancer cells. This is achieved by "engagers" (linkers) that bind to CD16 on the surface of NK cells and bind specific proteins (such as CD33) on the surface of cancer cells, thus linking the NK cell to the cancer cell. The inclusion of a modified Interleukin-15 (IL-15), a peptide that activates NK cells, in the "engager" further increases NK cancer-cell killing capabilities and improves their function in the tumor microenvironment (Vallera et al,2016). The TriKE platform consists of "engagers" to which a modified IL-15 has been added.

About GT Biopharma, Inc.: GT Biopharma, Inc. is a biotechnology company focused on innovative drugs for the treatment of cancer and nervous system diseases (Neurology and Pain) along with other unmet medical needs. GT's lead oncology drug candidate, OXS-1550 (DT2219ARL) is a novel bispecific scFv recombinant fusion protein-drug conjugate composed of the variable regions of the heavy and light chains of anti-CD19 and anti-CD22 antibodies and a modified form of diphtheria toxin as its cytotoxic drug payload. OXS-1550 targets cancer cells expressing the CD19 receptor or the CD22 receptor or both receptors. When OXS-1550 binds to cancer cells, the cancer cells internalize the drug and are killed due to the action of cytotoxic payload. OXS-1550 has demonstrated success in early human clinical trials in patients with relapsed/refractory B-cell lymphoma or leukemia. In addition, GT Biopharma's TriKE platform will address a number of cancer types. GT's nervous system platform is focused on acquiring or discovering and patenting late-stage, de-risked, and close-to-market improved treatments for nervous system diseases (Neurology and Pain) and shepherding them through the approval process to the NDA. GT Biopharma's neurology products currently include PainBrake, as well as treatments for the symptoms of myasthenia gravis, and motion sickness.

Except for historical information contained herein, the statements in this release are forward-looking and made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are inherently unreliable and actual results may differ materially. Examples of forward-looking statements in this news release include

statements regarding the payment of dividends, marketing and distribution plans, development activities and anticipated operating results. Factors which could cause actual results to differ materially from these forward-looking statements include such factors as the Company's ability to accomplish its business initiatives, significant fluctuations in marketing expenses and ability to achieve and expand significant levels of revenues, or recognize net income, from the sale of its products and services, as well as the introduction of competing products, or management's ability to attract and maintain qualified personnel necessary for the development and commercialization of its planned products, and other information that may be detailed from time to time in the Company's filings with the United States Securities and Exchange Commission. The Company undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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