

October 10, 2017



## **GT Biopharma Announces Completion of First Four Patients in FDA Phase 2 Trial of Cancer Drug OXS-1550**

**WASHINGTON, DC / ACCESSWIRE / October 10, 2017** /GT Biopharma Inc. (OTCQB: GTBP) (Euronext Paris: GTBP.PA) announced today that the first four patients have completed treatment in their Food and Drug Administration-approved (FDA) Phase 2 clinical trial of its promising cancer therapy, OXS-1550. Additional patient enrollment is ongoing.

GT Biopharma owns the worldwide rights to commercialize OXS-1550. The targeted immuno-oncology company is focused on novel antibody constructs that provide alternative treatments to cancer patients for whom existing therapies have failed.

The Phase 2 clinical trial is being conducted with GT Biopharma's partner, the University of Minnesota's Masonic Cancer Center. Earlier this year, researchers at the University of Minnesota completed a Phase 1 trial of OXS-1550 to determine the safe highest tolerated dose of the drug. A seamless Phase 2 trial followed and began in April. Topline results of the Phase 2 trial are expected to be released in the first quarter of 2018.

Anthony Cataldo, Executive Chairman of GT Biopharma said, "We are pleased with the progress of our four patients in the Phase 2 trial as we continue to move forward with this promising technology."

Dr. Kathleen Clarence-Smith said, "The product performed well in Phase 1 studies of blood cancers, enrollment in the Phase II study is advancing rapidly, and we look forward to providing a targeted immunotherapy product that has the capability of treating a number of different liquid tumors."

OXS-1550 is an ADC (Antibody Drug Conjugate) drug. ADCs, such as ADCETRIS® (brentuximab vedotin) from Seattle Genetics (SGEN), a first-in-class FDA approved antibody-drug conjugate, have paved the way for this type of next-generation platform drug.

OXS-1550 uses a proprietary immunoconjugate platform technology as a treatment for leukemia and other blood-borne cancers. What sets OXS-1550 (DT2219ARL) apart from other treatments, such as chemotherapy, is that it is designed to specifically target and kill cancer cells while minimizing damage to normal tissues.

Dr. Daniel Vallera, director of the section on Molecular Cancer Therapeutics at the University of Minnesota Masonic Cancer Center, helped develop OXS-1550.

"The initiation of Phase 2 patient treatment is a key opportunity to demonstrate the effectiveness of this promising cancer therapy," Dr. Vallera said.

The clinical progress for OXS-1550 brings the company closer to an important alternative to toxic and poorly tolerated chemotherapies and to costly cell therapies, such as those from Kite Pharma, Inc. (KITE), and from Juno Therapeutics (JUNO), for cancer patients.

The news about OXS-1550 follows another major corporate development about GT Biopharma, Inc. with the announcement that it had completed its merger with GTP (Georgetown Translational Pharmaceuticals, Inc.), a move that brought in new management and a class of close-to-market Central Nervous Systems (CNS) products to GT Biopharma.

The inclusion of products and new management can be accessed thru the company's website ([gtbiopharma.com](http://gtbiopharma.com)) which highlights several benefits of the acquisition for its shareholders.

**About GT Biopharma, Inc.:** GT Biopharma, Inc. is a biotechnology company focused on innovative drugs for the treatment of cancer and CNS 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. 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. GT's CNS platform is focused on acquiring or discovering and patenting late-stage, de-risked, and close-to-market improved treatments for CNS disease (Neurology and Pain) and shepherding the products through the FDA approval process to the NDA. The current CNS pipeline products currently include treatment for neuropathic pain, the symptoms of myasthenia gravis, and motion sickness.

### **Forward-Looking Statements:**

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.

**Company website:**

[www.gtbiopharma.com](http://www.gtbiopharma.com)

**Media contact:**

Stuart Pfeifer, Sitrick & Co.  
(310) 788-2850, or [spfeifer@sitrick.com](mailto:spfeifer@sitrick.com)