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GT Biopharma (OXIS) Announces Enrollment of Fourth Patient in FDA Phase 2 Trial of Cancer Drug OXS-1550

LOS ANGELES, CA / ACCESSWIRE / August 2, 2017 /GT Biopharma Inc. (OTCQB: OXIS and Euronext Paris OXI.PA) announced today that four patients have been enrolled in the company's Food and Drug Administration-approved (FDA) Phase 2 clinical trial of its promising cancer therapy, OXS-1550.

Oxis Biotech, a wholly owned subsidiary of 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 Oxis' 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 and effective dose of the drug. The Phase 2 portion of the trial began in April and a total of 12 patients are expected to participate. 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 the enrollment of four patients in the Phase 2 trial is a key step for the company and a milestone for the promising technology.

"The product performed well in Phase 1 studies of blood cancers and we look forward to providing a targeted immunotherapy product that has the capability of treating a number of different liquid tumors," Mr. Cataldo said.

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-born 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 invasive chemotherapies and costly cell therapies, Kite Pharma, Inc. (KITE), Juno Therapeutics (JUNO), for cancer patients.

The news about OXS-1550 follows another major corporate development about GT Biopharma, Inc./Oxis. On June 26, Oxis announced that it had executed a binding LOI agreement to acquire GTP (Georgetown Translational Pharmaceuticals, Inc.), a move that will deliver new management and a class of close-to-market Central Nervous Systems (CNS) products to Oxis.

The products of GTP can be accessed thru the company's web site which highlights several benefits of the acquisition for Oxis and its shareholders.

As part of the acquisition, GT Biopharma (OXIS) brings in a new management team to Oxis. GTP co-founder Dr. Kathleen Clarence-Smith, a respected and experienced leader in the pharmaceutical industry, will become CEO of the combined companies. Additionally, a Chief Medical Officer will also join Oxis under the deal.

Prior to founding GTP, Dr. Clarence-Smith co-founded Chase Pharmaceuticals Corporation in Washington D.C. and served as Chairman of the company's Board from 2008 to 2014. Chase Pharmaceuticals was acquired by Allergan, PLC (AGN) in 2016 in a deal that, with milestones, could reach $1 billion.

Dr. Clarence-Smith also held executive management positions with Sanofi, Roche, Otsuka Pharmaceutical and Prestwick Scientific Capital. She is co-founder and a managing member of KM Pharmaceutical Consulting in Washington, D.C.

Additionally, GT Biopharma, Inc's management team will be joined by a new Chief Medical Officer (CMO) formerly Vice President and Chief Medical Officer and Medical Director of Oncology Clinical R&D of Pfizer, Inc. (PFE). Name to be disclosed upon completion of the merger acquisition.

About Oxis Biotech, Inc.:

Oxis Biotech is an immuno-oncology focused company developing innovative drugs focused on the treatment of cancer and other unmet medical needs. OXIS' lead 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 CD22 receptor or both receptors. OXS-2175 is a small molecule therapeutic candidate targeting the treatment of triple-negative breast cancer (TNBC). In in vitro and in vivo models of TNBC, OXS-2175 demonstrated the ability to inhibit metastasis.

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.

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