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GT

Biopharma, Inc.

## **GT Biopharma Announces Preliminary Clinical Results From Interim Review of Phase 1/2 Clinical Trial of OXS-1550, its Bi-Specific Antibody Drug Conjugate**

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- Clinical benefit observed in more than 50% of patients that met evaluation criteria
- Efficacy signal most pronounced in relapsed/refractory acute lymphocytic leukemia patients (ALL) with clinical benefit in 75% (three of four) of evaluable patients
- Adverse events mostly grade 1 or 2 and reversible
- Expect additional ALL patients enroll in this trial

GT Biopharma, Inc. (GTBP) and (Euronext Paris: GTBP.PA) (the "Company"), an immunology biotechnology company focused on innovative treatments based on the Company's proprietary platforms, today announced preliminary clinical data taken from an interim review, or snapshot, of the OXS-1550 Phase 1/2 trial following a Bi-Specific Antibody Drug Conjugate (ADC) Advisory Board meeting and follow up discussions. OXS-1550 is a bi-specific 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, its cytotoxic drug payload. OXS-1550 targets cancer cells expressing the CD19 receptor, the CD22 receptor or both receptors.

OXS-1550 is being evaluated in an open-label, two-stage, investigator-led, Phase 1/2 trial at the Masonic Cancer Center, University of Minnesota. The trial has two arms including patients diagnosed with relapsed/refractory B-cell lymphomas (NHL) and leukemias (ALL). Eighteen patients have been enrolled to date, including 12 NHL and six ALL patients. At the time of the interim review, 13 patients met the evaluation criteria, including nine NHL and four ALL patients.

At the interim review more than 50% of patients (seven of 13) exhibited a clinical benefit, defined as stable disease plus partial response or complete remission at Day 29. Of the seven patients, one demonstrated a complete remission (CR), one demonstrated a partial response (PR) and five demonstrated stable disease (SD).

The efficacy signal was most prominent in ALL patients with 75% (three of four) exhibiting clinical benefit including one CR, one PR and one SD. In the NHL population, four of nine patients exhibited SD. Adverse events were mostly grade 1 and 2 and reversible. One patient had a grade 4 low platelet count, two patients had a grade 3 increase in liver function tests, or LFTs, and one patient had a grade 3 capillary leak.

GT Biopharma's President and Chief Medical Officer (CMO) Dr. Raymond Urbanski said: "In light of these data and discussions with the Bi-Specific ADC Advisory Board, I am increasingly encouraged by OXS-1550 and its potential to have a significant role in an oncologist's armamentarium. I also remain convinced that the bi-specific ADC platform has the potential to generate additional attractive product candidates. I look forward to continuing to work closely with the University of Minnesota team and other members of the Bi-Specific ADC Advisory Board with the goal of optimizing next steps for this program and the broader bi-specific ADC platform."

The Bi-Specific ADC Advisory Board has recommended that additional ALL patients be enrolled in the trial followed by another interim data review. The Company currently expects final data for this trial to be available in the fourth quarter of 2018 or the first quarter of 2019.

The Bi-Specific ADC Advisory Board is composed of distinguished clinicians, academics and researchers from several well-known institutions. Members include Dr. Jeffrey Miller, Deputy Director at the Masonic Cancer Center, University of Minnesota and Chair of GT Biopharma's Scientific Advisory Board. Dr. Veronika Bachanova, hematologist/oncologist and the principal investigator of the Phase 1/2 study and Dr. Daniel Vallera, lead researcher for the bispecific ADC program, both at the Masonic Cancer Center. Also included are Drs. Mark Litzow and Arthur Frankel. Mark R. Litzow, M.D., is Professor of Medicine in the Division of Hematology at Mayo Clinic. Arthur E. Frankel, M.D., is the inaugural holder of the Arlene and Mayer Mitchell Endowed Chair in Medical Oncology, Chief of Medical Oncology at Mitchell Cancer Institute (USA-MCI), Interim Associate Director for Basic & Translational Sciences and Professor of Oncological Sciences.

### **About GT Biopharma, Inc.:**

GT Biopharma, Inc. is an immuno-oncology biotechnology company focused on innovative treatments based on the Company's proprietary Tri and Tetra-specific Natural Killer Cell Engagers (TriKEs™ and TetraKEs) and bispecific antibody-drug conjugate (ADC) platforms. GT's lead oncology drug candidate, OXS-1550 (DT2219) is a 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 has demonstrated success in early human clinical trials in patients with relapsed/refractory B-cell lymphoma or leukemia. In addition, GT'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 Food and Drug Administration's New Drug Application. 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 progress and outcome of the Company's clinical trials and the likelihood of regulatory approval and commercialization of the Company's products. Factors which could cause actual results to differ materially from these forward-looking statements include such factors as the Company's ability to successfully complete its clinical trials and obtain regulatory approval and 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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