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GT

Biopharma, Inc.

## **GT Biopharma Announces Update to OXS-3550 IND Filing, Its Most Advanced Tri-specific Killer Engager**

LOS ANGELES, May 16, 2018 /PRNewswire/ -- GT Biopharma Inc. (OTCQB: GTBP and Euronext Paris "GTBP.PA" or the "Company"), an immuno-oncology biotechnology company focused on innovative treatments based on the Company's proprietary platforms, has reported that it expects to file the Investigational New Drug Application ("IND") for OXS-3550, the Company's most advanced Tri-specific Killer Engager ("TriKE") product candidate, in mid-2018.

GT Biopharma is working in collaboration with the Masonic Cancer Center at the University of Minnesota under a program led by Dr. Jeffrey Miller, Deputy Director. Dr. Miller is a recognized leader in the field of Natural Killer ("NK") cell and IL-15 biology and their therapeutic potential.

"The expected filing of the IND for our first TriKE product candidate in mid-2018 is representative of the overall progress we are making as a company," said Shawn M. Cross, Chairman and Chief Executive Officer of GT Biopharma. "We look forward to updating our shareholders on our progress throughout 2018 as we continue to execute on our objectives."

The IND for OXS-3550 was filed in June 2017 by the University of Minnesota. Before the IND was transferred to the Company in October 2017, the FDA requested that additional preclinical toxicology be conducted prior to initiating clinical trials. The FDA also requested additional information and clarifications on the manufacturing (CMC) and clinical packages. The Company has reported that the requested additional information and clarifications have been completed and are being incorporated into the IND in eCTD format and that it expects to file the IND in mid-2018.

### **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 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 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 NDA. GT Biopharma's neurology products currently include PainBrake, as well as treatments for the symptoms of myasthenia gravis, and motion sickness.

### **Safe Harbor Statement**

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 effectiveness of the Company's products, the potential outcome of clinical studies, the potential outcome of the FDA regulatory approval process, the future success of development activities and the future growth and operating and financial performance of the Company. 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, obtain regulatory approval and protect its intellectual property; significant fluctuations in marketing expenses and ability to achieve or grow revenue, 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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