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GT Biopharma, Inc. Announces Additional Positive Data From Its Phase 1 Clinical Trial For Myasthenia Gravis and Potential for Acceleration of the Start of Its Phase 2 Trial

WASHINGTON, March 26, 2018 /PRNewswire/ -- GT Biopharma Inc. (OTCQB "GTBP" and Euronext Paris "GTBP.PA") today announced that it has completed the analysis of pharmacokinetic data from its Phase 1 clinical trial for GTP-004, its promising treatment for the symptoms of myasthenia gravis. Based on these and additional data from the Phase 1 clinical trial, GP Biopharma expects to potentially accelerate the start of its Phase 2 trial in MG patients to the third quarter of 2018 from the second half of 2018.

GTP-004 combines pyridostigmine with ondansetron and is designed to attenuate the gastro-intestinal (GI) side effects of pyridostigmine alone, providing the potential for a fully efficacious dose of pyridostigmine to be safely used. The objective of the Phase 1 clinical trial was to demonstrate that GI side effects can be safely reduced with GTP-004.

Five healthy volunteers were enrolled in the Phase 1 study. Following enrollment, subjects received single increasing oral doses of pyridostigmine (ranging from 30 to 120mg) administered once daily in the morning. Once subjects reached First Intolerable Dose (FID) as defined by protocol criteria, upward dose escalation of pyridostigmine was discontinued and subjects stopped taking pyridostigmine for 2 to 7 days (wash out period). Following this wash-out period, subjects that reached FID received daily increasing doses of pyridostigmine in combination with ondansetron.

Three subjects (2 males, one female; aged 34 to 43) reached First Intolerable Dose (FID) with pyridostigmine alone. The dose-limiting gastro-intestinal adverse event occurred at 60 mg for 2 subjects, and 90 mg for the third subject. When these three subjects received GTP-0004 (pyridostigmine + ondansetron), gastro-intestinal adverse events were substantially reduced, if not eliminated, and all subjects tolerated doses as high as 120 mg, the maximum allowed dose allowed by the protocol.

To study the possibility that the reduction in GI side effects was due to a decrease in the blood concentrations of pyridostigmine in the pyridostigmine + ondansetron (GTP-004) dosing, the blood concentrations of GTP-004 and pyridostigmine were measured in the three subjects who reached FID. Blood concentrations showed that for each subject there was nearly identical blood levels of pyridostigmine during Period 1 (pyridostigmine alone) and Period 2 (GTP-004). Thus, the substantial reduction, if not elimination, of GI side effects

was due to GTP-004 (pyridostigmine + ondansetron) and not due to a decrease in the absorption and therefore blood levels of pyridostigmine.

GT Biopharma owns the worldwide rights to commercialize GTP-004 and intellectual property protection including composition of matter patents on the combination.

GT Biopharma Chief Executive Officer, Shawn Cross said: "These results provide additional evidence of the ability of GTP-004 to avoid the GI side effects of administering pyridostigmine alone and offer hope to all those suffering from myasthenic syndromes. We are working diligently to accelerate this program and be in a position to begin a Phase 2 clinical trial in patients in the third quarter of 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.

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 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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