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GT Biopharma, Inc. Starts FDA Phase 1 Clinical Trial for Myasthenia Gravis Autoimmune Muscular Disease

WASHINGTON, DC / ACCESSWIRE / December 6, 2017 /GT Biopharma Inc. (OTCQB: GTBP and Euronext Paris "GTBP.PA") announced today that it has initiated the Proof of Concept Phase I clinical trial with GTP-004, a novel treatment for the symptoms of myasthenia gravis, a rare autoimmune muscular disease caused by antibodies that attack certain components of muscles leading to varying degrees of weakness and fatigue. The prevalence of myasthenia gravis in the United States is estimated at 14 to 20 per 100,000 population, approximately 36,000 to 60,000 cases in the U.S. (Howard, 2015). The hallmark of the disease is muscle weakness that increases during periods of activity and improves after periods of rest. Muscular weakness can be generalized or localized to certain muscle groups, and involvement of the bulbar and respiratory muscles can be life-threatening (Phillips and Vincent, 2016). The disease occurs in all ethnic groups and both genders. Onset commonly occurs in young adult women (under 40 years) and older men (over 60 years), but it can occur at any age (NINDS, 2017). Rarely, children may show signs of congenital myasthenia or congenital myasthenic syndrome (CMS). These are not autoimmune disorders but are caused by defective genes that produce abnormal proteins instead of those that normally are involved in the cholinergic transmission.

The treatment of myasthenia gravis involves treatment of the muscular weakness by acetylcholinesterase inhibitors that do not cross the blood-brain barrier and by immunotherapy to slow disease progression (Gotterer and Li, 2016).

Only two drugs - pyridostigmine and neostigmine - are approved for the treatment of the symptoms of myasthenia gravis. Both inhibit an enzyme called acetylcholine esterase. These drugs cause considerable improvement in muscular strength in some patients and little to none in others (Howard, 2015). Strength rarely returns to normal. Both drugs carry the risk of gastro-intestinal side effects, limiting their achievable efficacy. In the U.S., pyridosgimine is the drug most often prescribed. GTP-004 combines pyridostigmine with another approved treatment. The goal is to reduce gastro-intestinal side effects to allow for the fully efficacious dose of pyridostigmine to be safely used. The objective of the Phase I clinical trial is to demonstrate that with GTP-004 gastro-intestinal side effects are safely reduced.

GT Biopharma Chief Executive Officer, Dr. Kathleen Clarence-Smith, said, "I am very pleased that GT Biopharma's first clinical trial in patients with myasthenia gravis has started and I have high hopes that the GTP-004 drug will bring substantial help to patients. The start of this trial underscores our commitment to patients with neurological disease."

GT Biopharma Executive Chairman Anthony J. Cataldo said, "We continue to move our product portfolio forward with major milestones. The start of our clinical trial of GTP-004 (for Myasthenia Gravis) represents another biotech asset that we believe could bring significant value to our shareholders."

GT Biopharma CMO, Dr. Raymond Urbanski said, "This represents not only another significant step for GT Biopharma but also for the thousands of patients that suffer with this often debilitating disease."

About GT Biopharma, Inc.: GT Biopharma, Inc. is a clinical-stage biopharmaceutical company focused on the development and commercialization of novel cancer immunotherapy products as well as central nervous system treatments. 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 encouraging results 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 them through the approval process to the NDA. The Company'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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