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GT Biopharma Inc. Announces >50% Enrollment in Proof-Of-Concept Clinical Trial For Its Novel Treatment For Motion Sickness

WASHINGTON, March 29, 2018 /PRNewswire/ --

GT Biopharma Inc. (OTCQB: GTBP) (Euronext Paris: GTBP.PA) announced today that the Proof-of-Concept clinical trial with GTP-011, a novel treatment for the symptoms of motion sickness, that was initiated in late February 2018 is more than 50% enrolled. The study is a single-blind, placebo-controlled, cross-over study. The primary objective of the study will be to demonstrate the anti-motion sickness efficacy of transdermal GTP-011.

The cause of motion sickness is incompletely understood, but it has been suggested that motion sickness may involve a sensory conflict between the visual and the vestibular systems (Bestaven, 2016). The vestibular system is located in the brain stem and inner ear and helps control balance and eye movements. It is believed that more than 35% of US adults 40 years and older, or approximately 69 million people, experience vestibular dysfunction at some point in their lives and many of them go on to develop a chronic vestibular disorder (Vestibular Disorders Association).

The prevalence of motion sickness varies as a function of the type and severity of stimulus but is particularly common among passengers on cruise ships in rough seas. It is also experienced by individuals with air travel and when riding in automobiles. The prevalence is generally higher in females.

Common symptoms of motion sickness, and certain vestibular disorders, include vomiting preceded by nausea, malaise, drowsiness, headache and sweating, among others. Certain vestibular disorders such as vertigo are characterized by a feeling the person or world is moving when it is not.

Currently, the scopolamine patch (Transderm Scop® from Novartis) is viewed as a first-line medication for prevention of motion sickness (Gil et al., 2012; Brainard and Gresham, 2014). However, side effects can be of particular concern and include sedation (Spinks et al., 2004), reduced memory for new information, impaired attention, and lowered feelings of alertness (Parrott, 1989). Mental confusion or delirium can occur after application of scopolamine patch (Seo et al., 2009). Elderly people as well as people with undetected incipient dementia or mild cognitive impairment, or MCI, may be particularly prone to develop mental confusion after applying the scopolamine patch (Seo et al., 2009).

GTP-011 is a 72-hour, transdermal formulation that contains a muscarinic receptor antagonist. Unlike scopolamine, however, GTP-011's active ingredient has been reported not to affect memory and cognition and has a low incidence of sedation (Kay et al., 2012). GTP-011 may thus be a more favorable alternative, if approved for marketing, to the scopolamine patch for the treatment of motion sickness.

GTP-011 may also have utility in certain disorders of the vestibular system which GT Biopharma expects to evaluate assuming positive proof-of-concept data from the ongoing clinical trial. The trial is sponsored by Cognitive Research Corporation.

GT Biopharma's President of the Neurology Division, Dr. Kathleen Clarence-Smith, said "I am pleased that the first trial with GTP-011 for motion sickness has started. This drug could be particularly useful in elderly patients. In case of positive results, other vestibular disorders for which there is a major medical need, will also be considered."

About Cognitive Research Corporation (CRC)

CRC is a privately held clinical research organization known for expertise in evaluating the effects of medications, nutritional supplements, and foods on cognitive functioning. CRC offers a full range of services for Drug Development; Product Registration; and Scientific/Medical Affairs. CRC is recognized for being a leader in computer-based cognitive testing and use of driving simulators in clinical trials. Additional information about Cognitive Research Corporation can be found by visiting the company's website at http://www.cogres.com .

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.

Contact:
Westwicke Partners
John Woolford
+1(443)213-0506
john.woolford@westwicke.com

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