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GT Biopharma Begins Manufacturing of "Non-Opioid" Pain-Brake Drug to Compete in Multi-Billion Dollar Chronic Pain Market

WASHINGTON, DC / ACCESSWIRE / October 17, 2017 /GT Biopharma Inc. (OTCQB: GTBP and Euronext Paris GTBP.PA) announced today that it has initiated manufacturing of PainBrake, a non-opioid medication for chronic pain. PainBrake is an innovative new formulation of an approved drug for the treatment of neuropathic pain, which utilizes a patented technology that was in-licensed from Accu-Break Pharmaceuticals Inc. This technology allows tablets to be easily separated into smaller, precise doses thus allowing maximum ease of dose titration, as well as dosing flexibility and accuracy. The top layer of this non-opioid drug contains the active medication (pain killer) pre-divided by deep scoring during the manufacturing process to provide exact doses. The bottom layer is drug-free and provides a stable foundation for separating the doses when splitting the tablet.

PainBrake is targeted for chronic conditions associated with a variety of causes, including diabetic neuropathy, post-herpetic neuralgia, trauma, certain forms of chemotherapy, and multiple sclerosis. In 2009 almost 16 million Americans suffered from chronic neuropathic pain, which prevalence is expected to increase in the future due to the aging population.

Existing drugs provide a degree of pain relief. In most cases, pain relief is obtained at the price of burdensome side effects, most notably addiction. Other side effects such as sedation, drowsiness, problems with balance, along with the risk of addiction (Nightingale, 2012) play a role in the lifestyle of the patients. PainBrake is a new delivery system of a non-opioid painkiller. The new formulation is expected to help decrease side effects and thus allow for maximum pain relief to be achieved. It is not an opioid, and does not give rise to tolerance and abuse potential. Because PainBrake is a modified version of an approved drug, only a few clinical trials of short duration are expected. These trials are expected to begin in the third quarter of 2018. Subsequently, GT Biopharma believes it will be able to file with the FDA a 505(B)2 New Drug Application (NDA) by the second quarter of 2019.

PainBrake manufacturing has been contracted out to CMIC, a contract manufacturing organization (CMO), with modern manufacturing facilities in Cranbury, New Jersey. With state-of-the-art-processing equipment, CMIC CMO specializes in formulation development and commercial manufacturing of oral solid dosage products. CMIC New Jersey owns specialized equipment that is needed for the manufacturing of PainBrake and will provide GT Biopharma with services for pre-formulation, pilot batches, clinical trials batches, and commercial batches. Sources for the Active Pharmaceutical Ingredient (API) and for the excipients have been identified, and all manufacturing activities have started.

GT Biopharma Chief Executive Officer Dr. Kathleen Clarence-Smith said, "I am pleased that CMIC CMO has accepted to partner with us on this project. Their expertise will allow us to manufacture a high-quality product, and will facilitate rapid development. This partnership is expected to help us stay on track with our timeline to NDA filing."

GT Biopharma Executive Chairman Anthony J. Cataldo said, "The beginning of manufacturing is a major milestone achievement that will advance our ability to take this drug through FDA approval to compete in the multi-billion dollar pain marketplace."

GT Biopharma CMO Dr. Raymond Urbanski said, "The recent attention to current therapies for chronic pain, including neuropathic pain, certainly highlight the problems with pain management: relatively ineffective drugs that have a very high abuse potential and possible life-threatening side effects. Pain Break addresses many of all of these issues thus affording patients a better, more tolerable treatment option."

About GT Biopharma, Inc.: GT Biopharma, Inc. is a biotechnology company focused on innovative drugs for the treatment of cancer and nervous system diseases (Neurology and Pain) along with other unmet medical needs. 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 success 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. 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 payment of dividends, marketing and distribution plans, development activities and anticipated operating results. 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, 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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