September 11, 2017

GT Biopharma Announces Development Plan For Non-Opioid Neuropathic Pain Treatment "PainBrake"

LOS ANGELES, CA / ACCESSWIRE / September 11, 2017 /GT Biopharma Inc. announced today that it has made the required payment to license and develop PainBrake, a non-opioid pain medication, to Accu-Break Pharmaceuticals Inc.

The payment allows GT Biopharma (OTCQB: OXISD) to begin the clinical development process and the filing of a New Drug Application, the final step for a commercial license from the Food and Drug Administration. The company expects to submit an NDA for PainBrake within 18 months.

PainBrake will use a patented technology - and unique shape - that allows tablets to be easily broken into smaller, precise doses, for maximum dose flexibility and accuracy. The top layer contains the pain-killer and is pre-divided by deep scoring during the manufacturing process to provide exact doses. The bottom layer is drug-free and provides a stable breaking region when splitting the tablet.

PainBrake is a new formulation of a marketed drug for the treatment of neuropathic pain, a chronic condition associated with a variety of causes, including diabetic neuropathy, postherpetic neuralgia, trauma, certain forms of chemotherapy, and multiple sclerosis. In 2009 almost 16 million Americans suffered from chronic neuropathic pain, and the prevalence is expected to increase in the future due to the aging population.

Current drugs provide a useful degree of pain relief in only about half the patients. It is estimated that very few patients achieve complete pain relief, only one in four patients experiences over 50% pain relief, and 30% of patients have no or very little relief (Nightingale 2012).

In most patients, pain relief is obtained at the price of burdensome side effects, such as sedation, drowsiness, problems with balance, risk of addiction (Nightingale, 2012). Current treatments for neuropathic pain include narcotic analgesics, anticonvulsants, antidepressants, and cannabinoids. However, these therapies have safety and tolerability issues including, for some, tolerance, abuse and addiction liability. PainBrake is a new delivery system of a pain killer that is expected to decrease side effects and allow for

maximum pain relief to be achieved. It is not an opioid, and does not give rise to tolerance and does not have abuse potential.

Because PainBrake is a modified version of an existing drug, only a few short trials are expected. These trials are expected to begin in the third quarter of 2018.

GT Biopharma Chief Executive Officer Dr. Kathleen Clarence-Smith said, "I am looking forward to initiating the development of PainBreak as we anticipate that many patients with difficult to treat neuropathic pain could benefit from this product."

Dr. Elliot F.Hahn, the Executive Chairman of Accu-Break Pharmaceuticals, Inc. added, "We are delighted by the opportunity for our patented technology to provide a product that will treat such a critically important disease as neuropathic pain. We are pleased to assist GT Biopharma in the development of this very important product."

GT Biopharma obtained the rights to license PainBrake as part of its recent acquisition of Georgetown Translational Pharmaceuticals Inc.

GT Biopharma Executive Chairman Anthony J. Cataldo said, "We are thrilled to take this key step toward commercialization of PainBrake, a non-opioid pain reliever that we believe will fulfill a significant need in the treatment of neuropathic pain. PainBrake and the other assets in GTP's Central Nervous System pipeline were major reasons why we agreed to acquire GTP. They are exceptional additions to our company, which already has a rich pipeline of targeted immunotherapy BiKE and TriKE technologies."

GT Biopharma is collaborating with a New Jersey manufacturing facility that is equipped to produce these high technology tablets.

About GT Biopharma Inc.: GT Biopharma, Inc (formerly known as Oxis International Inc.) is an immuno-oncology focused company developing innovative drugs focused on the treatment of cancer and other unmet medical needs. Oxis' lead 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 diphtheria toxin as its cytotoxic drug payload. OXS-1550 targets and binds to cancer cells expressing the CD19 receptor or CD22 receptor or both receptors. When OXS-1550 binds to cancer cells, they internalize the drug and are killed due to the 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 NK cells to kill cancer cells while diminishing drug-related toxicity, and is anticipated to be to NK cells what CAR-T is to T-cells. Additionally, GT Biopharma 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 the products through the FDA approval process to the NDA. GTP products currently include treatment for neuropathic pain, refractory epilepsies, the symptoms of myasthenia gravis, and motion sickness.

Forward-Looking Statements: 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.

Media contact:

Stuart Pfeifer
Tel: (310) 788-2850
Email: spfeifer@sitrick.com