July 27, 2022

Acasti Pharma Announces Initiation of Pharmacokinetic Study for GTX-101, the Company's Drug Candidate for the Treatment of Postherpetic Neuralgia

LAVAL, Quebec, July 27, 2022 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("Acasti" or the "Company") (Nasdaq: ACST and TSX-V: ACST), today announces the initiation of its planned pharmacokinetic (PK) bridging study to evaluate the relative bioavailability of GTX-101 compared to the reference listed drug bupivacaine in 48 healthy subjects. Feedback from FDA was obtained on the study protocol, and the non-objection letter was received on July 12th from Health Canada. The First-Subject, First-Dose was administered on July 26th. The PK study is the next step in the proposed 505(b)(2) regulatory pathway for GTX-101. This study is expected to be completed by the end of calendar 2022 as planned and will provide important information on the dose and dosing frequency in humans.

GTX-101 is a novel formulation of bupivacaine hydrochloride (HCl) for topical administration via a bio-adhesive, film-forming polymer, for relief of pain associated with Postherpetic Neuralgia (PHN), a persistent and often debilitating neuropathic pain caused by nerve damage from the varicella zoster virus (shingles), which may persist for months and even years.

Jan D'Alvise, Chief Executive Officer of Acasti, stated, "The initiation of this PK study for GTX-101 is yet another accomplishment achieved in 2022 for Acasti. We now have multiple drugs in the clinic that are progressing towards important key milestones that leverage Acasti's novel drug delivery technologies and have the potential to improve the performance of currently marketed drugs by achieving faster onset of action, enhanced efficacy, reduced side effects, and more convenient drug delivery. We anticipate the completion of the PK study for GTX-101 later this year as we look to bring this exciting new treatment alternative to patients who suffer from PHN."

Based on market research with more than 250 physicians, the Company believes that a significant unmet need exists for treating these patients with PHN. Approximately 40% of patients that are prescribed the standard of care, which includes oral gabapentin and lidocaine patches, experience insufficient pain relief. Market research has shown that gabapentin does not work well for this indication, it can cause unpleasant side effects, and was recently added to the controlled substance list in several states due to a tendency for abuse. The lidocaine patches are difficult to use as they fall off and can cause skin sensitivity and irritation, especially in older individuals, and depending on their placement, are inconvenient, uncomfortable and unattractive. Additionally, our market research noted that it could take up to 2 weeks for the lidocaine patch to work, and they can only be worn for 12 hours and then must be removed for another 12 hours, so break-through pain is common.

Given these issues with the oral and patch alternatives, many PHN patients end up being prescribed opioids, which given the abuse potential, physicians would prefer to avoid.

The potential benefits of GTX-101 could include faster onset of action and a longer duration of pain relief which are inherent benefits with the active ingredient bupivacaine vs. lidocaine. GTX-101 can be conveniently sprayed on the skin wherever the pain is located, and based on the PK profile of bupivacaine, the Company believes that GTX-101 may have to be applied only once or twice a day to the affected area for 24 hour pain relief, although this dosing schedule will need to be confirmed in the Company's clinical trials. Based on this product profile, and assuming a successful development program, the Company believes GTX-101 has the potential to be a game-changer as a non-opioid analgesic for PHN patients who suffer from this debilitating pain.

The PK study is a Phase 1, Randomized, Single-Dose, 4-Cohort, Parallel study to evaluate the pharmacokinetics, dose proportionality, safety and tolerability of GTX-101 (bupivacaine hydrochloride metered dose spray) and subcutaneous injectable bupivacaine in healthy subjects. The primary objective is to assess the pharmacokinetics (PK) of 3 dose levels of GTX-101 (50, 100, and 200 mg) given as a single-dose topical application (metered spray). The study will enroll up to 48 subjects (12 subjects per cohort) to evaluate the PK of GTX-101 compared to subcutaneous injection of bupivacaine in healthy male and female adult subjects. Subjects in Cohorts 1, 2, and 3 will receive GTX-101 as either 5, 10, or 20 sprays (50, 100, or 200 mg, respectively). Subjects in Cohort 4 will receive a single 10 mg subcutaneous injection of the active control.

In addition, a pharmacodynamic assessment measuring skin sensitivity, will be performed to collect early information on efficacy, and to guide important further decisions for advancing GTX-101 development, such as phase 2 dosing and dose frequency.

About PHN

Postherpetic neuralgia (PHN) is neuropathic pain caused due to damage by the varicella zoster virus. After a primary varicella infection (chickenpox), the varicella zoster virus can remain persistent but clinically latent in the sensory nerve ganglia for many years before being reactivated and becoming manifest clinically as herpes zoster. This pain may persist for months or even years and this PHN is the most common and debilitating complication of herpes zoster.

Postherpetic neuralgia is associated with significant loss of function and reduced quality of life, particularly in the elderly, and is highly resistant to treatment. Since PHN is often resistant to pharmacologic treatments, a multimodal analgesic treatment strategy is often used to balance the efficacy and tolerability of the medication regimen, the side effects of which can be limiting and can themselves compromise quality of life and patient compliance. Postherpetic neuralgia occurs most commonly in the elderly, in whom a large number of drugs are often prescribed, and so the use of a long-acting topical analgesic with minimal risk of systemic toxicity, would be advantageous.

Current treatment of PHN most often consists of oral gabapentin (first line) and prescription lidocaine patches (second line), and refractory cases may be prescribed opioids to address persistent pain. Gabapentin and opioid abuse have continued to proliferate, and lidocaine patches are suboptimal for many reasons. Prescription lidocaine patches are only approved

for PHN, and the market is currently made up of both branded and generic offerings. It is estimated that PHN affects approximately 120,000 patients per year in the United States. According to the third-party report commissioned by Acasti, the total addressable market for GTX-101 could be as large as $2.5 billion, consisting of approximately $200 million for PHN pain and $2.3 billion for non-PHN pain.

About Acasti

Acasti is a late-stage specialty pharma company with drug delivery technologies and drug candidates addressing rare and orphan diseases. Acasti's novel drug delivery technologies have the potential to improve the performance of currently marketed drugs by achieving faster onset of action, enhanced efficacy, reduced side effects, and more convenient drug delivery—all which could help to increase treatment compliance and improve patient outcomes. Acasti's three lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provide the assets with seven years of marketing exclusivity post-launch in the United States, and additional intellectual property protection with over 40 granted and pending patents. Acasti's lead clinical assets target underserved orphan diseases: (i) GTX-104, an intravenous infusion targeting Subarachnoid Hemorrhage (SAH), a rare and lifethreatening medical emergency in which bleeding occurs over the surface of the brain in the subarachnoid space between the brain and skull; (ii) GTX-102, an oral mucosal spray targeting Ataxia-telangiectasia (A-T), a progressive, neurodegenerative genetic disease that primarily affects children, causing severe disability, and for which no treatment currently exists; and (iii) GTX-101, a topical spray targeting PHN.

For more information, please visit: https://www.acastipharma.com/en.

Forward-Looking Statements

Statements in this press release that are not statements of historical or current fact constitute "forward-looking information" within the meaning of Canadian securities laws and "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (collectively, "forwardlooking statements"). Such forward looking statements involve known and unknown risks, uncertainties, and other unknown factors that could cause the actual results of Acasti to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. In addition to statements which explicitly describe such risks and uncertainties, readers are urged to consider statements containing the terms "believes," "belief," "expects," "intends," "anticipates," "potential," "should," "may," "will," "plans," "continue", "targeted" or other similar expressions to be uncertain and forward-looking. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this press release.

The forward-looking statements in this press release are based upon Acasti's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, including, without limitation: (i) the success and timing of regulatory submissions of the PK bridging study for GTX-104 and Acasti's other pre-clinical and clinical trials; (ii) regulatory requirements or developments; (iii) changes to clinical trial designs and regulatory pathways;

(iv) legislative, regulatory, political and economic developments, and (v) the effects of COVID-19 on clinical programs and business operations. The foregoing list of important factors that could cause actual events to differ from expectations should not be construed as exhaustive and should be read in conjunction with statements that are included herein and elsewhere, including the risk factors detailed in documents that have been and may be filed by Acasti from time to time with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Acasti undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by applicable securities laws. Neither NASDAQ, the TSXV nor its Regulation Services Provider (as that term is defined in the policies of the TSXV) accepts responsibility for the adequacy or accuracy of this release.

Acasti Contact:

Jan D'Alvise
Chief Executive Officer
Tel: 450-686-4555
Email:info@acastipharma.com
www.acastipharma.com

Investor Relations:
Robert Blum
Lytham Partners, LLC
602-889-9700
ACST@lythampartners.com

Source: Acasti Pharma, Inc.