February 14, 2023

Acasti Pharma Reports Third Quarter 2023 Operational Results

Company to Host Conference Call Today at 1:00pm ET

LAVAL, Québec, Feb. 14, 2023 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. (“Acasti” or the “Company”) (Nasdaq: ACST and TSX-V: ACST), a late-stage, specialty pharma company advancing three clinical stage drug candidates addressing rare and orphan diseases, today announced financial and operational results for the third quarter ended December 31, 2022

Recent Highlights

- The Company anticipates receiving clarifying guidance from the Food and Drug Administration (FDA) on its proposed phase 3 study design for GTX-104 through a written Type C meeting in the first calendar quarter of 2023. The Company expects that favorable FDA guidance would allow Acasti to initiate the Phase 3 safety study and begin recruiting clinical sites and enrolling patients. The Company expects the study to take about 18 months to complete once the first patient is enrolled, and if the trial is successful, the Company expects that it will be the final clinical step required to seek FDA approval under the 505(b)(2) regulatory pathway.
- Preliminary topline results of the pharmacokinetic (PK) bridging study for GTX-102 announced in December 2022 met all primary outcome measures. The objectives of the study were to evaluate the bioavailability, pharmacokinetics, and safety of GTX-102, a novel, concentrated oral-mucosal metered spray of betamethasone in healthy volunteers, and to compare the PK profile to an intramuscular injection of betamethasone, the reference drug, which is approved in the U.S. Acasti’s new and patented formulation of betamethasone is intended to improve the neurological symptoms of Ataxia Telangiectasia (A-T) in a pediatric population for which there are currently no FDA-approved therapies. The Company expects that the next step in the proposed 505(b)(2) regulatory pathway for GTX-102 will be a Phase 3 safety and efficacy study in children with A-T, which could be initiated following a Type B meeting with the FDA.
- Preliminary topline results announced in December 2022 for the Company’s single-dose PK study to evaluate the relative bioavailability of GTX-101 compared to the reference listed drug in the U.S., bupivacaine subcutaneous injectable, met all primary outcome measures for the study. The Company anticipates receiving the final clinical study report in the first half of calendar 2023. This PK study was the next step in the Company’s proposed 505(b)(2) regulatory pathway for GTX-101 and it provided important information on the dose and dosing frequency in humans for future clinical studies.
- The Company finished the second fiscal quarter ended December 31, 2022, with $31.3 million in cash, cash equivalents and short-term investments. Management continues

to believe that based on current projections, the Company has sufficient capital to fund operations into calendar Q2 of 2024 allowing for the advancement of GTX-104 well into Phase 3 and advancing GTX-102 and GTX-101 to additional important milestones.

Management Discussion

Jan D'Alvise, Chief Executive Officer of Acasti, said "Significant progress was made over the past few months on all three of our clinical programs. We ended calendar 2022 in a very strong fashion with the completion of two successful clinical trials, and we announced important pharmacokinetic study results for both GTX-101 and GTX-102 in late December. In both cases, the preliminary topline results met all outcome measures. These positive results allow us to advance both programs to the next stage of clinical development in 2023. We expect 2023 to be very exciting for Acasti with two of our drug candidates ready to enter Phase 3. We look forward to receiving clarifying guidance from the FDA in calendar Q1 2023 on the Phase 3 study design for our lead program, GTX-104, a novel formulation of nimodipine for continuous IV infusion in patients suffering from subarachnoid hemorrhage. We are hopeful that this FDA feedback will confirm our 505(b)(2) regulatory strategy and allow us to finalize the study protocol, paving the way for the initiation of our Phase 3 safety study later this year."

Program Updates

GTX-104: GTX-104 is a clinical stage, novel formulation of nimodipine to be administered via continuous IV infusion for treating aSAH patients. Subarachnoid hemorrhage (SAH) is bleeding over the surface of the brain in the subarachnoid space between the brain and the skull, which contains blood vessels that supply the brain. A primary cause of such bleeding is rupture of an aneurysm (aSAH). The Company anticipates receiving clarifying guidance from the FDA on its proposed phase 3 study design for GTX-104 in the form of a written Type C meeting in the first calendar quarter of 2023. The Company expects that favorable FDA guidance would allow the Company to initiate the Phase 3 safety study and begin recruiting clinical sites and enrolling patients. Once the first patient is enrolled, the Company expects the study to take about 18 months to complete, and if the trial is successful, the Company expects that it will be the final clinical step required to seek FDA approval under the 505(b)(2) regulatory pathway.

GTX-102: GTX-102 is a novel, concentrated oral-mucosal spray of betamethasone intended to improve the neurological symptoms of A-T, for which there are currently no FDA-approved therapies. GTX-102 is comprised of a proprietary formulation of the gluco-corticosteroid betamethasone that can be sprayed conveniently over the tongue of the A-T patient.

The Company initiated its PK bridging study as planned in fiscal Q2 2022 to evaluate the comparative bioavailability, pharmacokinetics, and safety of GTX-102, compared to an intramuscular injection (IM) of betamethasone and to an oral solution of betamethasone, in 48 healthy subjects. On December 28, 2022, the Company reported that the topline results of this study met all primary outcome measures.

Results showed that GTX-102 betamethasone blood concentrations were highly predictable and consistent based on AUC and Cmax, indicating good linearity and dose-proportionality. GTX-102 betamethasone blood concentrations were within the same range of exposure as IM betamethasone, based on AUC. Acasti is proposing that this IM formulation will serve as

a bridge for GTX-102 for the 505(b)(2) regulatory pathway. GTX-102 betamethasone blood concentrations were also within the same range of exposure as the oral solution (OS), based on AUC. This OS formulation is not available in the US and was used in a published clinical trial conducted in Europe (Zannolli, et.al.), and may serve as a comparator for further clinical development. Furthermore, statistically there was no significant difference ($p>0.05$) between GTX-102 administered at a fast rate (each spray immediately following the preceding one) vs. a slow rate (1 spray/minute), as indicated by Cmax and AUC. The Company believes this finding is important because being able to use the fast or the slow rate of administration may provide greater flexibility for patients and caregivers. The Cmax of GTX-102 was within the same range of exposure as the OS, but the Cmax for the IM formulation was lower than both GTX-102 and the OS, as well as what has been reported previously for the IM in the literature. It is important to note that achieving bioequivalence with the IM was not an objective of this study, nor was it expected. Finally, no serious adverse events (AE) were reported, and the most frequent drug-related AE was mild headache (4 cases).

Based on this data, Acasti will work with its clinical experts and the FDA to determine the optimal final dosing regimen for GTX-102 to incorporate into its Phase 3 study design. Based on previous discussions with the FDA, the Company plans to conduct a confirmatory Phase 3 safety and efficacy trial in A-T patients, and plan to seek clarifying guidance from the FDA on the study design at a Type B meeting. The Company expects the Phase 3 study to be initiated following the Type B meeting. If both studies meet their primary endpoints, a Pre-NDA meeting with the FDA and an NDA filing under Section 505(b)(2) would follow.

GTX-101: GTX-101 is a non-narcotic, topical bio-adhesive film-forming bupivacaine spray designed to treat postherpetic neuralgia (PHN), the severe and often debilitating nerve pain that can persist following a shingles infection. The data from a single dose Phase 1 clinical trial for GTX-101 along with regulatory guidance from the FDA's Division of Anesthesiology has informed the design of additional preclinical toxicology studies and a proposed clinical and regulatory pathway to approval.

On July 26, 2022, the Company initiated its single dose PK study to evaluate the relative bioavailability of GTX-101 compared to the reference listed drug, bupivacaine, in 48 healthy subjects. Topline results from this study were reported on December 23, 2022, and the results met all primary outcome measures.

The median Tmax of bupivacaine in plasma following GTX-101 single-dose topical applications ranged between 18 to 24 hours depending on dose, while the median Tmax following the subcutaneous injection of 10 mg of bupivacaine was only 23 minutes. This result suggests that bupivacaine delivered by GTX-101 remains in the skin for a long period of time, potentially inducing a prolonged analgesic effect in the sprayed area. The exposure to bupivacaine based on Cmax and AUC following GTX-101 topical application as a single-dose increased with increasing dose.

The systemic exposure to bupivacaine following a 200mg dose of GTX-101 was approximately 29-fold less than a single subcutaneous dose of 10mg of bupivacaine based on Cmax and approximately 6-fold less than a single subcutaneous dose of 10mg of bupivacaine based on AUC. The Company expects these results will correspond to an increased safety margin for GTX-101 with regards to toxicity risk. Mean half-life (T half) following GTX-101 single-dose topical applications ranged between 24 to 37 hours depending on dose, suggesting a slow elimination and potentially long duration of effect,

while mean Tmax following the subcutaneous injection of 10 mg of bupivacaine was only 8 hours.

There were only two AEs determined to be related to the study drug by the investigator for each of GTX-101 and the bupivacaine subcutaneous injection. Following GTX-101 topical application, headache (1 event = 3%) and numbness (1 event = 3%) at the sprayed area; following bupivacaine subcutaneous injection, dizziness (1 event = 8%) and nausea (1 event = 8%).

The Company plans to follow this successful PK study with a multiple ascending dose study in 2023. Results from these non-clinical and clinical studies are required before the initiation of the Company's Phase 2 program in PHN patients.

Q3 2023 Financial Results

The Company's consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America and are presented in U.S. dollars.

Research and development expenses, net of government assistance for the three months ended December 31, 2022, totaled $2.5 million compared to $2.2 million for the three months ended December 31, 2021. Our research and development during the quarter ended December 31, 2022, was focused primarily on our clinical development programs for our GTX-104, GTX-102, and GTX-101 drug candidates.

General and administrative expenses for the three months ended December 31, 2022 were $1.6 million compared to $1.8 million for the three months ended December 31, 2021. This decrease was a result of decreased legal, tax, accounting and other professional fees that had been incurred in connection with our acquisition of Grace Therapeutics Inc. in August 2021.

Loss from operating activities for the three months ended December 31, 2022 was $4.2 million compared to a loss of $4.5 million for the three months ended December 31, 2021.

For the three months ended December 31, 2022 a financial gain of $0.8 million resulted mostly due to the decrease in the fair value of the derivative warrant liabilities.

Net loss and total comprehensive loss for the three months ended December 31, 2022 was $(3.9) million, or $(0.09) loss per share, compared to a net loss of $(3.8) million, or $(0.09) income per share, for the three months ended December 31, 2021.

Cash, cash equivalents and short-term investments totaled $31.3 million as of December 31, 2022, compared to $34.9 million in cash, cash equivalents and short-term investments as of September 30, 2022. Based on management's current projections, current cash, cash equivalents and short-term investments are expected to continue to fund our lead asset GTX-104 well into Phase 3, and GTX-102 and GTX-101 to additional important milestones.

Conference Call Details

Acasti will host a conference call on Tuesday, February 14, 2023, at 1:00 PM Eastern Time to discuss the Company's corporate progress and other developments, as well as financial

results for its quarter ended December 31, 2022.

The conference call will be available via telephone by dialing toll free 844-836-8745 for U.S. callers or +1 412-317-6797 for international callers. A webcast of the call may be accessed at https://app.webinar.net/E7mea0O2qxk or on the Company's Investor Relations section of its website: https://www.acastipharma.com/investors/.

A webcast replay will be available on the Investors News/Events section of the Company's website (https://www.acastipharma.com/investors/). A telephone replay of the call will be available approximately one hour following the call, through February 21, 2023, and can be accessed by dialing 877-344-7529 for U.S. callers or +1 412-317-0088 for international callers and entering replay access code: 9403168.

About Acasti

Acasti is a 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 provides the assets with seven years of marketing exclusivity post-launch in the United States, and have 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 (aSAH), a rare and life-threatening medical emergency in which bleeding occurs over the surface of the brain in the subarachnoid space between the brain and skull caused by a ruptured aneurysm; (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 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. 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 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, and "forward-looking information" within the meaning of Canadian securities laws (collectively, "forward-looking statements"). Such forward looking statements involve known and unknown risks, uncertainties, and other 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," "estimates", "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 planned Phase 3 safety study for GTX-104 and Acasti's other pre-clinical and clinical trials for GTX-102 and GTX-101; (ii) regulatory requirements or developments and the outcome and timing of meetings with the FDA; (iii) changes to clinical trial designs and regulatory pathways; (iv) legislative, regulatory, political and economic developments; and (v) actual costs associated with Acasti's clinical trials as compared to management's current expectations. 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 are filed by Acasti from time to time with the Securities and Exchange Commission and Canadian securities regulators. 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.

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ACASTI PHARMA INC.
Condensed Consolidated Interim Balance Sheet
(Unaudited)

(Expressed in thousands of U.S. dollars except share data)	December 31, 2022 $	March 31, 2022 $
Assets		

Current assets:		
Cash and cash equivalents	26,241	30,339
Short-term investments	5,015	13,322
Receivables	778	548
Assets held for sale	352	352
Prepaid expenses	1,042	720
Total current assets	33,428	45,281
Right of use asset	487	315
Equipment	112	250
Intangible assets	69,810	69,810
Goodwill	12,964	12,964
Total assets	116,801	128,620
Liabilities and shareholders' equity		
Current liabilities:		
Trade and other payables	3,360	3,156
Lease liability	73	104
Total current liabilities	3,433	3,260
Derivative warrant liabilities	-	10
Lease liability	430	191
Deferred tax liability	16,218	16,889
Total liabilities	20,081	20,350
Shareholders' equity:		
Common shares	258,294	257,990
Additional paid-in capital	13,643	12,154
Accumulated other comprehensive loss	(6,038)	(6,037)
Accumulated deficit	(169,179)	(155,837)
Total shareholder's equity	96,720	108,270
Commitments and contingencies		
Total liabilities and shareholders' equity	116,801	128,620

ACASTI PHARMA INC.
Condensed Consolidated Interim Statements of Loss and Comprehensive Loss
(Unaudited)

	Three months ended	Nine months ended

(Expressed in thousands of U.S dollars, except per share data)	December 31, 2022 $	December 31, 2021 $	December 31, 2022 $	December 31, 2021 $
Operating expenses				
Research and development expenses, net of government assistance	(2,450)	(2,179)	(8,332)	(3,233)
General and administrative expenses	(1,589)	(1,808)	(5,187)	(7,441)
Sales and marketing expenses	(206)	(238)	(563)	(263)
Impairment of Other asset and prepaid	-	(249)	-	(249)
Loss from operating activities	(4,245)	(4,474)	(14,082)	(11,186)
Financial income (expenses)	82	696	69	5,271
Loss before income tax recovery	(4,163)	(3,778)	(14,013)	(5,915)
Income tax recovery	274	-	671	-
Loss and total comprehensive loss)	(3,889)	(3,778)	(13,342)	(5,915)
Basic and diluted loss per share	(0.09)	(0.09)	(0.30)	(0.23)
Weighted average number of shares outstanding	44,612,831	44,288,183	44,497,907	25,785,579

Source: Acasti Pharma, Inc.