May 7, 2021

Acasti Announces Definitive Agreement to Acquire Grace Therapeutics, Inc.

Grace provides Acasti with a pipeline of rare and orphan disease programs, including 3 clinical stage assets that have received Orphan Drug Designation from the FDA

Expects lead asset to complete PK Bridging Study in early 2022, with potential to advance directly into a Phase 3 clinical safety trial for Subarachnoid Hemorrhage

Combination creates a unique rare disease company with innovative drug delivery technologies, and is expected to have ~$64M in cash at closing to advance lead clinical assets

LAVAL, Québec, May 07, 2021 (GLOBE NEWSWIRE) -- Acasti Pharma Inc. ("**Acasti**" or the "**Company**") (Nasdaq: ACST and TSX-V: ACST) announces it has entered into a definitive agreement to acquire Grace Therapeutics, Inc. ("**Grace**"), a privately held emerging biopharmaceutical company focused on developing innovative drug delivery technologies for the treatment of rare and orphan diseases (the "**Proposed Transaction**"). Subject to the completion of the Proposed Transaction, Acasti will acquire Grace's pipeline of drug candidates addressing critical unmet medical needs with the potential to deliver significant value to patients and providers. It is anticipated that the cash at closing of about $64 million will be principally used to pursue the clinical development of the first two assets through Phase 3, and further advance earlier pipeline assets into the clinic. The Proposed Transaction has been approved by the boards of directors of both companies and is supported by Grace shareholders through voting and lock-up agreements with the Company. The transaction remains subject to approval of Acasti stockholders, as well as applicable stock exchanges.

The Company has posted a presentation summarizing key highlights of the transaction, which is available on both the Acasti and Grace websites. Acasti plans to file the required Form S-4 proxy statement with the U.S. Securities & Exchange Commission (SEC), which will include detailed disclosures regarding the transaction. Following the filing of the required Form S-4, Acasti and Grace management plan to host an investor conference call to further discuss the anticipated benefits of the acquisition and answer investor questions. Acasti will call a shareholder meeting to approve the transaction following the public filing of the Form S-4 proxy statement. As the Proposed Transaction moves forward, Acasti continues to evaluate strategic options for value creation from its existing assets.

In connection with the Proposed Transaction, Acasti will acquire Grace's entire therapeutic pipeline consisting of three unique clinical stage and multiple pre-clinical stage assets supported by an intellectual property portfolio consisting of more than 40 granted and pending patents in various jurisdictions worldwide. Grace's product candidates aim to improve clinical outcomes by applying proprietary formulation and drug delivery technologies to existing pharmaceutical compounds to achieve improvements over the current standard

of care or provide treatment for diseases with no currently approved therapy. Grace's three lead programs have all received Orphan Drug Designation[1] from the U.S. Food & Drug Administration (FDA), which could provide up to seven years of marketing exclusivity in the United States upon FDA's approval of the New Drug Application (NDA), provided that certain conditions are met.

Grace's Leading Drug Assets:

- **GTX-104: Subarachnoid Hemorrhage (SAH) – Intravenous Infusion**
    - *Clinical stage:* PK Bridging study results expected Q1'22; Phase 3 Safety Study expected to start enrollment Q3'22.
    - *Product Description:* Novel aqueous nanoparticle formulation of water insoluble nimodipine, that enables a continuous peripheral IV infusion for rapid and enhanced bioavailability. Acasti and Grace believe GTX-104 can potentially improve the management of hypotension and vasospasm in SAH patients, thereby improving patient outcomes and potentially preventing death and/or reduce long-term disability.
    - *Disease Target:* SAH is 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. A primary cause of such hemorrhage is rupture of an aneurysm or ballooning of a weakened blood vessel wall. Notably, 10-15% of SAH patients currently die before reaching hospital and 20% of admitted patients die in hospital[2].
    - *Target Market:* SAH affects approximately 50,000 patients per year in the U.S.[3] with an estimated addressable market of over $300 million[4]. Nimodipine, the current standard of care for SAH, is only available as an oral capsule and liquid solution in the U.S., making drug delivery very difficult particularly when a patient is unconscious. Oral nimodipine also has suboptimal absorption when administered through the gut[5].

- **GTX-102: Ataxia-telangiectasia (A-T) - Oral Mucosal Spray**
    - *Clinical stage:* PK Study results expected 2H'22; start of Phase 3 expected 1H'23.
    - *Product Description:* A novel and convenient oral mucosal spray formulation of betamethasone intended to significantly improve neurological symptoms of A-T, including improving clinical assessments of posture and gait disturbance, and kinetic speech and oculomotor functions. Currently, there are no FDA approved pharmacotherapies for A-T. Acasti and Grace also believe that GTX-102 could ease drug administration for patients experiencing A-T given its application as a more convenient, concentrated and metered betamethasone liquid spray onto the tongue, as these A-T patients typically have difficulty swallowing[6].
    - *Disease Target:* A-T is a progressive, neurodegenerative genetic disease that primarily impacts children causing severe disability, for which no treatment currently exists. A-T affects many parts of the body, including areas of the brain, causing difficulty with motor function and motion. The disease is also associated with weakening of the immune system predisposing patients to infection, and with

faulty repair of damaged DNA that may increase the risk of cancer[7].

- *Target market:* A-T affects approximately 4,300 patients per year in the U.S.[8] with an estimated addressable market of approximately $150 million[4].

- **GTX-101: Post Herpetic Neuralgia (PHN) - Topical Spray**

  - ***Clinical Stage:*** Phase 1 results expected 2H'22; start of Phase 2 expected 2H'22.
  - ***Product Description:*** A novel, topical bio-adhesive film-forming spray of bupivacaine for the treatment of PHN, which could provide significant benefits over the standard of care, including greater convenience, and faster onset and longer action. GTX-101's metered-dose of bupivacaine spray forms a thin bio-adhesive topical film on the surface of the patient's skin, which enables a touch-free, non-greasy application. No skin sensitivity was reported in its Phase 1 study.
  - ***Disease Target:*** PHN is a persistent and often debilitating neuropathic pain caused by nerve damage from the varicella zoster virus (shingles). PHN pain varies from mild to excruciating in severity, and may persist for months and even years, adversely impacting quality of life and leading to social withdrawal and depression. As a result, PHN is often cited as the leading cause of suicide in chronic pain patients over the age of 70[9].
  - ***Target market:*** PHN affects approximately 150,000 patients per year in the U.S.[10] with an estimated addressable market of approximately $400 million[4]. Current treatment of PHN most often consists of oral gabapentin and lidocaine patches, and refractory cases may be prescribed opioids to address persistent pain. Current lidocaine patches used for PHN are suboptimal, as these patches are difficult to use; 40% of patients experience insufficient pain relief, the analgesic effect could take up to 2 weeks, and many patients suffer from skin sensitivity and irritation[4]. Unlike oral gabapentin and lidocaine patches, Acasti and Grace believe that the biphasic delivery mechanism of GTX-101 has the potential for rapid onset and continuous pain relief for up to eight hours[11].

Roddy Carter, chairman of Acasti, commented on the transaction, "We have diligently pursued a thorough strategic process to evaluate a range of value-creating alternatives. We believe that combining Grace's innovative research programs and scientific talent with Acasti's financial resources and drug development and commercialization expertise position us to build a portfolio of innovative therapeutics that will address unmet medical needs. The Acasti and Grace boards have approved this transaction, which is also supported by Grace shareholders, and we highly recommend that our shareholders also approve it."

Jan D'Alvise, chief executive officer of Acasti, stated, "We believe that Grace's assets represent a transformative opportunity for Acasti, as their novel drug delivery technologies used to develop new therapies could improve upon existing compounds with known safety profiles and provide an attractive path to drug development and commercialization. We believe Grace's product portfolio has the potential to provide better patient solutions with enhanced efficacy, faster onset of action, reduced side effects, convenient delivery, and increased patient compliance. For these and other reasons, we are very excited about the therapeutic potential of Grace's pipeline, and we believe there could be significant

international licensing and marketing opportunities for these assets."

Vimal Kavuru, co-founder and chairman of Grace, noted, "Merging with Acasti is a significant opportunity for Grace, as it allows us to partner with an experienced team, well-versed in drug development and commercialization, with a strong commitment to the highest standards of corporate governance. As a result of the merger, we anticipate the combined company will have the financial resources to fund our lead programs to critical value inflection points. Our board of directors have approved the proposed transaction with Acasti, which is also supported by Grace's shareholders."

"We believe our dedication to bringing new, safe and effective medicines to patient populations where there is significant unmet medical need is shared by the management and board of Acasti. We look forward to a successful future together and driving value for our combined shareholders," noted S. George Kottayil, Ph.D., co-founder and chief executive officer of Grace.

Management and Operations
Upon shareholder approval of the Proposed Transaction, the combined companies will be led by Jan D'Alvise as president and chief executive officer, and the corporation will continue to maintain its corporate headquarters in Laval, Quebec, Canada. All Grace employees will transition to Acasti and they will continue to maintain an R&D laboratory and commercial presence in North Brunswick, New Jersey. The new Board of Directors will be composed of 4 representatives from Acasti and 3 from Grace, with more details to be provided in the proxy statement.

About the Proposed Transaction
Pending approval by Acasti shareholders as well as applicable stock exchange approvals, Grace will merge with a new wholly owned subsidiary of Acasti. Grace stockholders will receive newly issued Acasti common shares pursuant to an exchange ratio formula set forth in the definitive agreement. Under the terms of the definitive agreement, immediately following the consummation of the Proposed Transaction, Acasti's securityholders on a pro forma basis would own approximately 55% of the combined company's common shares, and Grace's securityholders would own approximately 45% of the combined company's common shares, in each case calculated on a fully-diluted basis, subject to upward adjustments in favor of Acasti based on each company's capitalization and net cash balance as set forth in the definitive agreement, with more details to be provided in the proxy statement. For illustrative purposes, assuming no adjustments for each company's capitalization and net cash balance, and based on 208,375,549 common shares of Acasti currently issued and outstanding, an aggregate of 170,489,086 common shares of Acasti would be issued to Grace stockholders as consideration for the Proposed Transaction.

In connection with the entering into the definitive agreement, Grace stockholders representing substantially all of the outstanding shares of Grace have entered into voting and lock-up agreements with the Company pursuant to which they have agreed, amongst other things to (i) vote their shares of Grace in favor of the Proposed Transaction, (ii) be subject to lock-up provisions for a period of 12 months (subject to certain exceptions), and (iii) support the election of board nominees through to the 2023 annual general meeting of shareholders.

The Proposed Transaction is expected to close in calendar Q3 of 2021, immediately

following approval by Acasti shareholders, subject to any applicable SEC review and stock exchange approvals, as well as satisfaction of other closing conditions by each company specified in the definitive agreement.

Acasti will take steps to regain compliance with Nasdaq's minimum bid price requirements in connection with the Proposed Transaction, and if required, would implement a share consolidation.

Oppenheimer & Co. is acting as Acasti's financial advisor for the Proposed Transaction and Osler, Hoskin & Harcourt, LLP is serving as its legal counsel. William Blair & Company, LLC is serving as financial advisor to Grace, with Reed Smith, LLP serving as its legal counsel.

The Proposed Transaction is an arm's length transaction in accordance with the policies of the TSX Venture Exchange.

Selected Financial Information of Grace

Selected financial information of Grace from its most recent audited annual financial statements is provided below:

	Year Ended December 31, 2020 (audited)	**Year Ended December 31, 2019 (audited)**
Assets	$1,198,921	$2,699,476
Liabilities*	$13,725,563	$12,753,123
Revenues	Nil	Nil
Net Loss	$(2,506,228)	$(3,666,329)

*Grace liabilities will be converted into Grace shares prior to the closing of the transaction, and are already accounted for in the conversion formula and the net cash adjustment.

About Acasti
Acasti is a biopharmaceutical innovator that has historically focused on the research, development and commercialization of prescription drugs using OM3 fatty acids delivered both as free fatty acids and bound-to-phospholipid esters, derived from krill oil. OM3 fatty acids have extensive clinical evidence of safety and efficacy in lowering triglycerides in patients with hypertriglyceridemia, or HTG. CaPre, an OM3 phospholipid therapeutic, was being developed for patients with severe HTG.

About Grace
Grace Therapeutics is an emerging biopharmaceutical company focused on rare and orphan diseases with high unmet medical needs. Grace's strategy is to improve clinical outcomes using novel drug delivery technologies to approved pharmaceutical compounds and achieve enhanced efficacy, faster onset of action, reduced side effects, convenient delivery, and increased patient compliance. Grace has a therapeutic pipeline of three unique clinical stage programs, several preclinical assets, and a robust intellectual property portfolio of over 40 granted and pending patent applications.

Important Additional Information Will be Filed with the SEC
This press release does not constitute an offer to sell or the solicitation of an offer to buy any

securities or a solicitation of any vote or approval. The Proposed Transaction will be submitted to the shareholders of Acasti for their consideration. Acasti will also prepare and file a Registration Statement on Form S-4 that will include a prospectus/proxy statement for Acasti's shareholders. Acasti plans to mail its shareholders a proxy statement in connection with the proposed transaction. Acasti may also file other documents with the Securities and Exchange Commission (the "SEC") regarding the proposed transaction. INVESTORS AND SECURITYHOLDERS ARE URGED TO READ THE PROSPECTUS/PROXY STATEMENT AND ANY OTHER RELEVANT DOCUMENTS THAT WILL BE FILED WITH THE SEC CAREFULLY AND IN THEIR ENTIRETY WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION.

Investors and securityholders may obtain free copies of the prospectus/proxy statement and other documents containing important information about Acasti, Grace and the Proposed Transaction once such documents are filed with the SEC through the website maintained by the SEC at www.sec.gov. Copies of the documents filed with the SEC by Acasti will be available free of charge on Acasti's website at http://www.acastipharma.com/ under the tab "Investor Relations" or by contacting Acasti by e-mail at ACST@crescendo-ir.com, or by phone at (450) 686-4555.

Participants in the Solicitation

Acasti and Grace and certain of their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from the shareholders of Acasti in connection with the Proposed Transaction. Information about the directors and executive officers of Acasti is set forth in Acasti's definitive proxy statement for Acasti's 2020 annual meeting of shareholders filed with the SEC on September 9, 2020. That document can be obtained free of charge from the sources indicated above. Additional information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the prospectus/proxy statement and other relevant materials to be filed with the SEC when they become available.

References:

1. *The Orphan Drug Designation program provides orphan status to drugs and biologics which are defined as those intended for the treatment, prevention or diagnosis of a rare disease or condition, which is one that affects less than 200,000 persons in the United States or meets cost recovery provisions of the Orphan Drug Act. The status helps incentivize the development of therapies to treat unmet medical needs by providing a company with seven years of exclusivity rights once a drug reaches market.*
2. *Rinkel G. 2016*
3. *Becske T. et al 2018*
4. *Fletcher Spaght Inc., Market Research Report*
5. *Soppi V. et al 2007*
6. *Lefton-Greif 2000*
7. *U.S. National Cancer Institute, Ataxia-Telangiectasia (2015)*
8. *National Organization for Rare Disorders, Ataxia-Telangiectasia (2015)*
9. *Hess et al 1990*
10. *CDC Morbidity and Mortality Weekly Report (2008)*

11. *Grace GTX-101 Phase 1 Study Report*

Cautionary Statement Regarding 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 U.S. federal securities laws (collectively, "forward-looking statements"). Such forward-looking statements involve known and unknown risks, uncertainties, and other unknown factors that could cause the actual results of Acasti, Grace and the combined company 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 labeled with 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. Forward-looking statements in this press release include, but are not limited to, the expected timetable for completing the Proposed Transaction and benefits of the Proposed Transaction; future product development plans and projected timelines for the initiation and completion of preclinical and clinical trials; the potential for the results of ongoing preclinical or clinical trials and the efficacy of drug candidates; the potential market opportunities and value of drug candidates; other statements regarding future product development and regulatory strategies, including with respect to specific indications; the combined company's plans, objectives, future opportunities for the combined company; future financial performance and operating results; sufficiency of capital resources to fund operating requirements; and any other statements regarding Acasti's and Grace's future expectations, beliefs, plans, objectives, financial conditions, assumptions or future events or performance.*

These statements are subject to numerous risks and uncertainties, many of which are beyond Acasti's or Grace's control, which could cause actual results to differ materially from the results expressed or implied by the statements. These risks and uncertainties include, but are not limited to: failure to obtain the required votes or approvals of Acasti's and/or Grace's shareholders; failure to obtain any applicable stock exchange approvals; the timing to consummate the proposed transaction; conditions to closing of the proposed transaction may not be satisfied or that the closing of the proposed transaction otherwise does not occur; the risk that as a result of adjustments to the exchange ratio, Grace stockholders could own less of the combined company than is currently anticipated; the risk that a regulatory approval that may be required for the proposed transaction is not obtained or is obtained subject to conditions that are not anticipated; the diversion of management time on transaction-related issues; the ultimate timing, outcome and results of integrating the operations of Acasti and Grace; the effects of the business combination of Acasti and Grace following the consummation of the proposed transaction, including the combined company's future financial condition, results of operations, strategy and plans; the combined company's need for, and the availability of, substantial capital in the future to fund its operations and research and development activities; the combined company's ability to continue to successfully progress research and development efforts and to create effective, commercially-viable products; the success of the combined company's product candidates in completing pre-clinical or clinical testing and being granted regulatory approval to be sold and marketed in the United States or elsewhere; results of any litigation, settlements and investigations; actions by third parties, including governmental agencies; global economic

conditions; ability to effectively identify and enter new markets; governmental regulations; and ability to retain management and field personnel.

Additional information concerning factors that could cause actual results to differ materially from those in the forward-looking statements is contained from time to time in Acasti's SEC filings. Acasti's filings may be obtained by contacting Acasti or the SEC or through Acasti's web site at http://www.acastipharma.com or through the SEC's Electronic Data Gathering and Analysis Retrieval System (EDGAR) at http://www.sec.gov. The foregoing list of risk factors is not exhaustive. These risks, as well as other risks associated with the proposed transaction will be more fully discussed in the prospectus/proxy statement that will be included in the Registration Statement on Form S-4 that will be filed with the SEC in connection with the proposed transaction. Each of Acasti and Grace does not undertake any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

Neither NASDAQ, the TSX Venture Exchange nor its Regulation Services Provider (as that term is defined in the policies of the TSX Venture Exchange) accepts responsibility for the adequacy or accuracy of this release.

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