

Acasti Announces Appointment of New Scientific Advisory Board Members

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LAVAL, QC, June 22, 2023 /PRNewswire/ -- Acasti Pharma Inc. ("Acasti" or the "Company") (Nasdaq: ACST), a late-stage, biopharma company advancing GTX-104, its novel formulation of nimodipine that addresses the high unmet medical needs for a rare disease, aneurysmal subarachnoid hemorrhage (aSAH), today announced the appointment of W. Taylor Kimberly, MD, PhD, Alejandro A. Rabinstein, MD and Sherry H-Y. Chou, MD to its Scientific Advisory Board.

"We are extremely pleased to add eminent physicians with a deep understanding of aSAH and neurocritical care to the Acasti Scientific Advisory Board," commented Prashant Kohli, CEO of Acasti. "As we continue to focus our efforts squarely on the advancement GTX-104, a critically important drug candidate for the thousands of patients who suffer from subarachnoid hemorrhage without effective treatment options, Drs. Kimberly, Rabinstein and Chou will offer unmatched insight into this indication."

Acasti announced in May 2023 the successful submission to the FDA of GTX-104's full protocol of its pivotal Phase 3 Safety Study for what it believes will be the final clinical step required to seek FDA approval under the 505(b)(2) regulatory pathway with expectation for first patient dosed in calendar Q4 2023.

Drs. Kimberly, Rabinstein and Chou join existing Scientific Advisory Board members, including Dr. Andrew Ducruet, MD, an endovascular neurosurgeon at Barrow Neurological Institute in Phoenix; Dr. Alex Choi, MD, Associate Professor of Neurology and Neurosurgery at UTHealth Houston/ McGovern Medical School as well as Director of Neurocritical Care at Memorial Hermann Hospital; and Dr. R. Loch Macdonald, MD, PhD, Acasti's recently appointed Chief Medical Officer, a respected physician-scientist in aSAH, as well as the former founder of a clinical-stage biotechnology company focused on aSAH.

"Acasti's Scientific Advisory Board now has a perfect blend of clinical expertise including neurosurgery and neurocritical care from the leading academic medical centers in the country," Kohli concluded.

About W. Taylor Kimberly, M.D., PhD

W. Taylor Kimberly, MD PhD is Chief of the Division of Neurocritical Care, and a stroke and

critical care neurologist in the Department of Neurology at Massachusetts General Hospital.

Clinically, he primarily cares for patients in the Neuroscience ICU as part of an integrated and multi-disciplinary team, coordinating care with Neurosurgery and Neuroendovascular specialists. He sees Neuro ICU patients in follow-up in outpatient clinic as part of the NeuroRecovery clinical team. He serves on several hospital-based and national committees that focus on clinical guideline development and care improvement.

Dr. Kimberly's research group is located in the Center for Genomic Medicine (Kimberly Lab), and studies metabolomic and neuroimaging biomarkers of subarachnoid hemorrhage, stroke and cerebral edema. The goal of his research is to identify novel pathways and candidate therapeutic targets for the treatment of acute brain injury. Dr. Kimberly has co-led multi-site, randomized, placebo-controlled trials in the prevention of brain edema, and currently co-leads an international phase 3 trial evaluating the safety and efficacy of intravenous glibenclamide for the prevention of brain edema after large hemispheric stroke.

About Alejandro A. Rabinstein, M.D.

Dr. Alejandro A. Rabinstein is Professor of Neurology at Mayo Clinic and a diplomate of the American Board of Psychiatry and Neurology (ABPN). Hs is also boarded in Vascular Neurology and Neurocritical Care. He currently serves as Chair of the Division of Neurocritical Care and Hospital Neurology at Mayo Clinic, Rochester. He is a fellow of the American Academy of Neurology (FAAN), the American Neurological Association (FANA), the American Heart Association (FAHA) and the Neurocritical Care Society (FNCS). He has authored over 700 papers, 12 books and multiple chapters on various topics related to Neurocritical Care and Stroke. He is currently Associate Editor of the journals JAMA Open and Neurocritical Care, Assistant Editor of Stroke, and section editor for UpToDate.

About Sherry H-Y. Chou MD. MSc.

Dr. Sherry H-Y Chou, MD MSc. is Chief of Neurocritical Care Division in the Department of Neurology and Associate Professor of Neurology (Neurocritical Care) at the Northwestern University Feinberg School of Medicine, and Medical Director of the Neuro/Spine ICU at Northwestern Memorial Hospital. Dr. Chou is a fellow of the Neurocritical Care Society (FNCS) and a fellow of critical care medicine (FCCM), and serves on the board of directors for the Neurocritical Care Society (NCS).

Dr. Chou is a physician-scientist with expertise in clinical neurology, neurocritical care and vascular neurology. Dr. Chou's research program focuses on the role of inflammation and immune response in vascular brain injuries and biomarker discovery, particularly in subarachnoid hemorrhage. Dr. Chou is an expert in clinical biomarker discovery and multicenter clinical trials in critically ill patient with SAH. Dr. Chou has led the biomarker section in large international collaboratives such as the National Institute of Neurological Disorders SAH common data element (CDE) in biospecimens and biomarkers.

About aneurysmal Subarachnoid Hemorrhage (aSAH)

aSAH 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. Approximately 70% of aSAH patients experience death or dependence, and a third die within one month after the hemorrhage (Becske, 2018). Approximately 50,000 patients are affected by aSAH per year, based on market research conducted by Fletcher Spaght.

About GTX-104

GTX-104 is a clinical stage, novel aqueous formulation of nimodipine being developed for IV infusion in aSAH patients to address significant unmet medical needs. GTX-104 provides a more convenient IV delivery of nimodipine in the ICU eliminating the need for nasogastric tube administration of the drug in unconscious or dysphagic patients. Due to IV delivery, GTX-104 also has the potential to lower food effects, drug-to-drug interactions, and eliminate potential dosing errors. Further, GTX-104 has the potential to better manage hypotension in aSAH patients. GTX-104 has been dosed in over 150 healthy subjects and was well tolerated with significantly lower inter and intra subject PK variability compared to the oral drug. The addressable market in the United States for GTX-104 is estimated to be about \$300 million, based on market research conducted by Fletcher Spaght.

About Acasti

Acasti is a late-stage biopharma company with 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. Acasti's lead clinical assets have each been granted Orphan Drug Designation by the FDA, which provides 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 asset, GTX-104, is an intravenous infusion targeting aneurysmal 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. For more information, please visit: <u>https://www.acasti.com</u>.

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 forwardlooking statements, which speak only as of the date of this press release. The forwardlooking statements in this press release, including on the Company's anticipated cash runway, 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; (ii) regulatory requirements or developments and the outcome and timing of the proposed IND application for GTX-104; (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. The NASDAQ does not accept responsibility for the adequacy or accuracy of this release.

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