September 4, 2025
Company Name: AnGes Inc.
Presentative: Ei Yamada, President & CEO

Notice Regarding the Initiation of a New Clinical Study for the Jointly Developed Tie2 Receptor Agonist (AV-001)

We are pleased to announce the initiation of a new investigator-initiated clinical study involving the Tie2 receptor agonist Pegevongitide AV-001 (“AV-001”), which is being jointly developed with Vasomune Therapeutics, Inc. (“Vasomune”), a biopharmaceutical company based in Canada, led by COO Dr. Brian E. Jahns.

This study aims to evaluate whether AV-001 can mitigate cytotoxic cerebral edema caused by hemodialysis and help preserve white matter function in the brain. The trial will be conducted under the leadership of Dr. Christopher McIntyre, Professor of Medicine, Medical Biophysics, and Pediatrics at Western University, and Chair of the Robert Lindsay Dialysis Research and Innovation Program.

Hemodialysis, used by up to 90% of patients with end-stage renal disease, is associated with structural and functional changes in the brain, leading to symptoms such as confusion, delirium, and long-term cognitive decline. Among patients aged 55 and older, approximately 70% experience moderate to severe cognitive impairment, posing a significant clinical challenge.

This study is supported by the Heart and Stroke Foundation of Canada. Should the results prove favorable, a larger-scale clinical trial will be considered.

Although this matter does not fall under the timely disclosure requirements of the Tokyo Stock Exchange, we have chosen to voluntarily disclose it as we believe it constitutes valuable information.

This selection is not expected to have any impact on our consolidated earnings forecast for the fiscal year ending December 2025. Should any matters requiring disclosure arise in the future, we will promptly make an announcement.

For further details, please refer to the attached press release.

PRESS RELEASE

Health Canada Gives Green Light to New Study Investigating Novel Made-In-Canada Drug Candidate to Prevent Brain Injury in Hemodialysis Patients

Toronto, ON –September 3 — A groundbreaking clinical study has been approved by Health Canada to evaluate the safety and efficacy of a novel pharmacologic intervention aimed at preventing acute ischemic brain injury in patients undergoing routine hemodialysis. Pegevongitide (AV-001), a made-in-Canada drug candidate codeveloped by Vasomune Therapeutics Inc., and AnGes., Inc., will work to stabilize the cerebrovasculature, which undergoes significant circulatory stress during the hemodialysis procedure. Cerebrovascular destabilization is linked to vascular cognitive impairment in up to 70% of patients initiating routine hemodialysis.

The clinical study is led by Dr. Christopher McIntyre, Professor of Medicine, Medical Biophysics, and Paediatrics at Western University and holder of the Robert Lindsay Chair of Dialysis Research and Innovation. Dr. McIntyre also serves as Director of the Lilibeth Caberto Kidney Clinical Research Unit at London Health Sciences Centre, where he practices as a Clinical Nephrologist. A recognized leader in kidney research, Dr. McIntyre leads a multidisciplinary team investigating the pathophysiological impact of chronic kidney disease on cardiovascular, neurological, hepatic, and gastrointestinal systems. His research integrates multimodal imaging with clinical and translational studies to develop and evaluate novel therapeutic strategies. His recent work increasingly focuses on mitigating the adverse consequences of dialysis therapy itself, and he has recently published about dialysis and cognitive impairment in Nature Reviews Nephrology.

“Hemodialysis, used by up to 90% of patients with end-stage kidney disease, is often associated with structural and functional brain changes that cause symptoms like confusion, delirium, and possible long-term cognitive decline.”, reported Dr. McIntyre. Patients, particularly those over 55, face a high burden of moderate-to-severe cognitive impairment, affecting up to 70% of this age group.

Hemodialysis patients are uniquely vulnerable to recurrent ischemic brain injury caused by circulatory stress during treatment. “Pegevongitide (AV-001) offers a promising new approach by targeting the Tie2/Angiopoietin-1 signaling pathway to stabilize blood vessels, prevent vascular leakage and reduce vascular inflammation. With this approval from Health Canada and the initiation of this study, Vasomune now moves into a new and exciting opportunity to improve cerebrovascular health in patients.”, according to Dr. Harold Kim, Vice-President of Research at Vasomune Therapeutics Inc. Published data using Pegevongitide (AV-001) demonstrated that this mechanism can improve neurological health, reduce cognitive impairment, and reduce cerebrovascular leak.

The study will assess whether Pegevongitide (AV-001) can reduce hemodialysis-induced cytotoxic brain edema and preserve white matter integrity. Advanced neuroimaging techniques, cognitive assessments, and blood biomarkers will be used to evaluate outcomes.

Supported by a prestigious Heart and Stroke Foundation grant, this research has the potential to redefine how brain health is protected in hemodialysis patients. Positive findings will inform a larger confirmatory trial and could lead to improved quality-of-life and functionality for this high-risk population.

About Vasomune Therapeutics, Inc.

Vasomune Therapeutics, Inc. is a private clinical-stage biopharmaceutical company developing the next generation of medicines to boost the body's ability to defend against vascular leak. Founded in 2014, Vasomune has focused on vascular normalization strategies, and has progressed the lead candidate Pegevongitide (AV-001) from bench to bedside. Vascular dysfunction and vascular leak are associated with the pathology of several disease states, including bacterial and viral pneumonia and acute respiratory distress syndrome, sepsis, hemorrhagic shock, acute kidney injury, stroke, and vascular dementia. Vasomune's corporate headquarters and laboratories are in Toronto, Canada with US offices in Raleigh, NC. For more information about the company please visit http://www.vasomune.com.

About AnGes, Inc.

AnGes, Inc., a biopharmaceutical company founded in December 1999, focuses on the development of gene-based medicines. The company's flagship development product and genetic drug, HGF gene therapy products, received Breakthrough Therapy designation from the FDA in 2024. AnGes is currently working on the development of a Tie2 tyrosine kinase receptor agonist (AV-001) for viral and bacterial-associated pneumonia and an NF-κB decoy oligonucleotide for chronic discogenic lumbar back pain. Furthermore, AnGes acquired EmendoBio in December 2020 to expand its capabilities in genome-editing technologies. For more information, visit https://www.anges.co.jp/en/.

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