May 29, 2024
Company Name: AnGes Inc.
Presentative: Ei Yamada, President & CEO

**Tie2 receptor agonist (AV-001), co-development product,
received fast track designation from the U.S. FDA**

AnGes Inc. and Vasomune Therapeutics Inc. have received Fast Track*1 designation from the U.S. Food and Drug Administration (FDA) for Tie2 receptor agonist (AV-001) for the treatment of acute respiratory distress syndrome (ARDS), which includes viral and bacterial pneumonitis.

ARDS is a condition that results in severe respiratory failure caused by a variety of diseases, and there is currently no treatment for this condition. The Fast Track designation granted by the FDA for Tie2 receptor agonist (AV-001) indicates that it is a promising drug for the treatment of ARDS.

Although there is no change in our consolidated earnings forecast for the current fiscal year as a result of the Fast Track acquisition, we believe that this designation will accelerate the development of Tie2 receptor agonist (AV-001), which will contribute to the enhancement of our corporate value in the medium term.

For details, please refer to the attached press release.

# Vasomune Therapeutics Inc., receives US FDA Fast Track Designation for novel investigational medicine AV-001

*Fast Track Designation underscores the high unmet medical need for treatment and prevention of acute respiratory distress syndrome (ARDS)*

Vasomune Therapeutics Inc., has announced today that the US Food and Drug Administration (FDA) has granted Fast Track designation for AV-001 for the prevention or treatment of moderate-to-severe ARDS in patients hospitalized with viral and/or bacterial respiratory infections. AV-001 is a first-in-class fully synthetic PEGylated peptide targeting the Tie2 receptor which plays a critical role in vascular stability, barrier integrity and endothelial quiescence, particularly within the pulmonary space.

Fast track designation represents a significant regulatory milestone and has been granted based on the potential for AV-001 to address an unmet medical need in ARDS, a global disease characterized by extremely high mortality rates, reaching up to 46% in patients with severe cases. Data from the Phase 1 study demonstrated safety and a pharmacokinetic profile amenable to once-daily dosing, and the Tie2 activation results demonstrate strong on-target activity. AV-001 is currently in a Phase 2a clinical trial for patients hospitalized with pneumonia due to viral or other respiratory infections.

“Vasomune is focused on the persisting unmet needs of people grappling with ARDS and other diseases driven by vascular endothelial instability" said Dr. Brian Jahns, President and Chief Operating Officer. “Vasomune is indebted to the United States Department of Defense Congressionally Directed Medical Research Programs award #PR191212 for support to advance AV-001 to the clinic and award #PR203503 for support to research AV-001 in Phase 2a. Vasomune is also grateful to the National Research Council Canada for grant #IRAP-965762 which supported the Phase 1 study”.

Ei Yamada, President & CEO of AnGes, said that “The FDA’s support of accelerate development marks another important milestone in our endeavor to change the treatment paradigm with AV-001. We look forward to future success with the Phase 2a study, AV001-004.”

## About AV-001

Originally discovered and designed at Sunnybrook Research Institute at Sunnybrook Hospital in Toronto, AV-001 is being developed by Vasomune Therapeutics, Inc. under a co-development agreement with AnGes, Inc. [TYO: 4563]. AV-001 is a novel investigational medicine that targets the Tie2 receptor, a transmembrane protein most highly expressed on the surface of endothelial cells in the vasculature. AV-001 activates the nonredundant Tie2-Angiopoietin signaling axis, and through stimulation of multiple downstream pathways normalizes the vasculature by enhancing endothelial cell stability, restoring normal barrier defense, and blocking vascular leak. Vascular dysfunction contributes to the underlying disease pathophysiology in patients with bacterial and viral acute respiratory distress syndrome, sepsis, hemorrhagic shock, acute kidney injury, stroke, and vascular dementia. Importantly, in multiple pre-clinical studies AV-001 tightened endothelial cell-cell junctions and promoted endothelial cell survival, which reduced pulmonary edema, and improved lung function compared to untreated controls translating into significantly improved survival.

## About Vasomune Inc.

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

## About AnGes, Inc.

AnGes, Inc., a biopharmaceutical company founded in December 1999, focuses on the development of gene-based medicines. In March 2019, AnGes obtained conditional and time-limited approval for its lead product, Collategene® (Hepatocyte Growth Factor; HGF—plasmid gene therapy), for the treatment of lower limb ischemic ulcers. In September 2019, AnGes commenced commercialization in Japan of Collategene®, the world's first marketed drug using plasmid DNA. AnGes is currently working on the development of a Tie2 tyrosine kinase receptor agonist (AV-001) for COVID-19, 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/.