March 5, 2025
Company Name: AnGes Inc.
Presentative: Ei Yamada, President & CEO

# Notice of Approval for Clinical Trial Application for the Jointly Developed Tie2 Receptor Agonist (AV-001) for Resuscitation Treatment in Patients with Severe Burns

We are pleased to announce that the U.S. Food and Drug Administration has approved the Investigational New Drug (IND) application for the Tie2 receptor agonist Pegevongitide (AV-001), which AnGes Inc.is jointly developing with Vasomune Therapeutics, Inc. (Headquarters: Canada; CEO: Dr. Brian E. Jahns), for use in the acute-phase resuscitation treatment of patients with severe burns.

This approval is not expected to have any impact on our consolidated financial results for the fiscal year ending December 2026. Should any matters requiring disclosure arise in the future, we will promptly provide an update.

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

**PRESS RELEASE**

# Vasomune Therapeutics Inc., and AnGes, Inc., Announce US FDA Clearance of Investigational New Drug (IND) Application for Pegevongitide (AV-001) Treatment in Resuscitation of Severely Burned Patients

*Toronto, ON –March 4*— Vasomune Therapeutics, Inc., ("Vasomune"), a clinical-stage biopharmaceutical company, today announced U.S. Food and Drug Administration (FDA) clearance of the Investigational New Drug (IND) application to develop Pegevongitide (AV-001) for use in the acute resuscitation of severely burned patients. Pegevongitide, an injectable Tie2 agonist that blocks vascular leak, is currently being researched for the prevention and treatment of acute respiratory distress syndrome (ARDS) (NCT05123755).

"Vascular leak reflects a loss of endothelial barrier integrity that allows fluid and proteins to escape the intravascular space into surrounding tissues. This disrupts oxygen delivery, organ perfusion, and destabilizes hemodynamics. By activating the pivotal target Tie2, Pegevongitide targets a root mechanism driving endothelial instability and leakage." said Harold Kim, Ph.D., Vice-President of Research at Vasomune.

This new IND clearance allows Vasomune to initiate a clinical program evaluating Pegevongitide safety and efficacy in the resuscitation of severely burned patients. Pegevongitide offers a promising new approach by targeting the Tie2/Angiopoietin-1 signaling pathway to stabilize blood vessels, prevent vascular leakage and reduce vascular inflammation. Published preclinical data using Pegevongitide supports that this mechanism can reduce vascular leak and improve hemodynamic function.

Dr. Ei Yamada, President & CEO of AnGes, said that "We are encouraged by the FDA decision to allow the expansion of our AV-001 development program. Our commitment to developing AV-001 will allow us to take a step forward in the treatment of serious pathologies driven by vascular leak."

## 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/.