Augustine Therapeutics announces first patient dosed in Phase I clinical trial evaluating lead candidate AGT-100216 for the treatment of Charcot-Marie-Tooth disease

- *AGT-100216 is the first HDAC6 inhibitor from Augustine's pipeline to enter clinical trials*

LEUVEN, Belgium – [27 May 2025] – Augustine Therapeutics NV ("Augustine" or "the Company"), a biotechnology company focused on developing new therapies for neuromuscular, neurodegenerative and cardio-metabolic diseases through the inhibition of the cytosolic Histone DeACetylase 6 (HDAC6) enzyme, today announces it has dosed the first patient in its Phase I clinical trial evaluating lead candidate AGT-100216, the first peripherally-restricted, selective HDAC6 inhibitor (HDAC6i) for the treatment of Charcot-Marie-Tooth disease (CMT).

The Phase I trial is a randomized, double-blind, placebo-controlled, first-in-human trial, designed to evaluate the safety, tolerability, pharmacokinetics and exploratory pharmacodynamics of oral AGT-100216 in healthy adult volunteers. The trial is a combined two-part study evaluating single ascending and multiple ascending doses of AGT-100216.

Gerhard Koenig, PhD, CEO of Augustine, said: "The initiation of our first clinical trial is a major milestone for Augustine. Decades of research have validated the therapeutic potential of HDAC6 as a target but efforts to drug it to date have been sub-optimal. Augustine is developing a new generation of HDAC6 inhibitors, like AGT-100216, with a unique mechanism of action shown to be selective, safe and effective in pre-clinical trials. Having recently raised EUR 78 million / USD 85 million in an oversubscribed Series A financing round, and with a strengthened management team, the Company is entering a new stage of growth. We are well positioned to progress AGT-100216 through clinical development for CMT and to also advance our pipeline of next-generation HDAC6 inhibitors in significant cardio-metabolic and neurodegenerative diseases."

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About Augustine Therapeutics

Augustine Therapeutics is a biotechnology company focused on the treatment of neuromuscular, neurodegenerative and cardio-metabolic diseases through its next-generation approach to selectively inhibit HDAC6. Augustine's HDAC6 inhibitors have been purposefully designed to selectively inhibit HDAC6 while preserving its beneficial non-catalytic functions. Augustine's lead program, AGT-100216, is the first selective HDAC6 inhibitor for long-term treatment of Charcot-Marie-Tooth (CMT) disease. With its novel non-hydroxamate, non-hydrazide producing chemotype, Augustine's HDAC6 approach is selective, avoids the limitations of other chemotypes, and built for chronic diseases. With this novel approach, the Company will also be targeting diseases beyond CMT, including neurodegenerative and cardio-metabolic diseases. Augustine Therapeutics was founded on the ground-breaking research of Prof. Ludo Van Den Bosch from the VIB-KU Leuven in Belgium. The Company raised an oversubscribed EUR 78 million / USD 85 million Series A financing round in March 2025, led by Novo Holdings and Jeito Capital and supported by Asabys Partners, Eli Lilly and Company, AdBio partners, V-Bio Ventures, PMV, VIB, Gemma Frisius Fund, the US-based Charcot-Marie-Tooth (CMT) Research Foundation and Newton Biocapital. For more information visit www.augustinetx.com

About Charcot-Marie-Tooth (CMT) disease

Charcot-Marie-Tooth (CMT) disease is a genetically heterogeneous group of hereditary peripheral neuropathies characterized by progressive distal nerve damage, primarily affecting the feet, legs, hands, and arms. The disorder damages peripheral nerves, causing muscle weakness, loss of sensation and other disabling symptoms. CMT is the most common inherited neuromuscular disorder with an estimated frequency of 1 in 2,500 people worldwide and there are currently no approved cures available.