enGene Focuses Board to Support Planned Upcoming Regulatory and Commercial Milestones

Michael Heffernan assumes the role of Chairman of the Board

Dr. Richard Glickman to step down

Pre-Biologics License Application (BLA) meeting with the FDA planned for 2H 2026

Initiation of BLA submission for detalimogene planned for 2H 2026

Potential FDA approval of detalimogene in 2027

BOSTON & MONTREAL - enGene Therapeutics Inc. (Nasdaq: ENGN, "enGene" or the "Company"), a clinical-stage, non-viral genetic medicines company, today announced changes to its Board of Directors as it plans for potential regulatory milestones and to support commercial readiness for detalimogene voraplasmid ("detalimogene") if approved. Detalimogene is being evaluated in the ongoing, open-label, multi-cohort, Phase 2 LEGEND trial to establish its safety and efficacy in high-risk non-muscle invasive bladder cancer (NMIBC). LEGEND's pivotal cohort (Cohort 1) consists of 125 patients with high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive NMIBC with carcinoma in situ (CIS).

"We are pleased that Michael Heffernan, who has served on our Board since July 2025, will assume the role of Chairman. With a strong track record of guiding companies through development and commercialization, Mike is well positioned to lead our Board as we plan for the potential approval and launch of detalimogene," said Ron Cooper, President and Chief Executive Officer, enGene. "It has been a pleasure to work alongside Dr. Glickman. As a longtime member of the Board, he has played an essential role in guiding enGene's evolution from a research organization to a late clinical-stage company."

Dr. Richard Glickman has served as enGene's Chairman for over 14 years. His expertise was instrumental in supporting the Company's scientific and medical leadership in the development of its unique Dually Derivatized Oligochitosan® (DDX) platform, enabling non-viral gene transfection. His experience in company formation, capital raising and capital markets was also critical in guiding enGene's transition from a seed-stage venture to a publicly listed company. Dr. Glickman continues to serve on the boards of several biotechnology companies.

"With a clinical-stage asset approaching both a key pivotal readout and planned BLA filing in the second half of this year, a potential approval in 2027 and in a strong capital position, enGene is well positioned for a period of meaningful growth," said Michael Heffernan, Chairman of enGene. "I'm excited to step into the role of Chairman and work closely with the Board and management team to advance detalimogene in NMIBC."

Michael Heffernan is a seasoned biopharmaceutical executive and entrepreneur with over 30 years of experience in the industry. He was the Founder of Collegium Pharmaceutical and has previously served as its President and Chief Executive Officer, as well as Chairman of the Board. Mr. Heffernan has built and led multiple companies through numerous financings and successful exits. He has also held leadership positions at Onset Dermatologics, Clinical Studies Ltd., and Eli Lilly and Company. Currently, Mr. Heffernan serves as Chairman of the Board at NMD Pharma, Avalo Therapeutics and AAVantgarde Bio, and is a board member at Biohaven, Trevi Therapeutics, and K36 Therapeutics. He holds a Bachelor of Science in Pharmacy from the University of Connecticut and is a registered pharmacist.

About Detalimogene Voraplasmid

Detalimogene is a novel, investigational, non-viral gene therapy for patients with high-risk, non-muscle invasive bladder

cancer (NMIBC), including Bacillus Calmette-Guérin (BCG)-unresponsive disease. It is designed to be instilled in the bladder and elicit a powerful yet localized anti-tumor immune response.

Detalimogene was developed using the Company's Dually Derivatized Oligochitosan® (DDX) platform, a technology designed to transform how gene therapies are accessed by patients and utilized by clinicians. Medicines developed with the DDX platform can potentially overcome the limitations of viral-based gene therapies, reduce complexities related to safe handling and cold storage, and streamline both manufacturing processes and administration paradigms.

Regenerative Medicine Advanced Therapy (RMAT) and Fast Track Designations

Detalimogene has received Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations from the U.S. Food and Drug Administration (FDA) based on its potential to address the high unmet medical need for patients with BCG-unresponsive NMIBC with carcinoma in situ (CIS) (with or without resected papillary tumors) who are unable to undergo cystectomy. These designations are intended to expedite the development and review of drugs to serious or life-threatening conditions and fill an unmet medical need. Detalimogene has also been selected for the FDA's Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP) program, designed to facilitate CMC development for therapies with compressed clinical development timeframes based on the anticipated clinical benefits of earlier patient access to the therapy.

About the LEGEND Trial

Detalimogene is being evaluated in the ongoing, open-label, multi-cohort, Phase 2 LEGEND trial to establish its safety and efficacy in high-risk NMIBC. LEGEND's pivotal cohort (Cohort 1) consists of 125 patients with high-risk, BCG-unresponsive NMIBC with CIS (with or without papillary disease) and is designed to serve as the basis of the Company's planned Biologics License Application (BLA) filing. In addition to this pivotal cohort, LEGEND includes four additional cohorts, including NMIBC patients with CIS who are naïve to treatment with BCG (Cohort 2a); NMIBC patients with CIS who have been exposed to BCG but have not received adequate BCG treatment (Cohort 2b); BCG-unresponsive high-risk NMIBC patients with papillary-only disease (Cohort 3); and BCG-unresponsive high-risk NMIBC patients with CIS who receive polidocanol plus detalimogene.

About enGene

enGene Therapeutics Inc. is a clinical-stage biotechnology company mainstreaming non-viral genetic medicine through the delivery of therapeutics to mucosal tissues and other organs, with the goal of creating new ways to address diseases with high clinical needs. enGene's lead program is detalimogene voraplasmid (also known as detalimogene) for patients with non-muscle invasive bladder cancer (NMIBC), a disease with a high clinical burden. Detalimogene is being evaluated in the ongoing multi-cohort LEGEND Phase 2 trial, which includes a pivotal cohort studying detalimogene in high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive NMIBC patients with carcinoma in situ (CIS) with or without concomitant papillary disease.

Detalimogene was developed using enGene's proprietary Dually Derivatized Oligochitosan (DDX) platform, which enables penetration of mucosal tissues and delivery of a wide range of sizes and types of cargo, including DNA and various forms of RNA.

To learn more, please visit enGene.com and follow us on LinkedIn, X and BlueSky.

Forward-Looking Statements

Certain statements contained in this press release may constitute "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, and "forward-looking information" within the meaning of Canadian securities laws (collectively, "forward-looking statements"). enGene's forward-looking statements include, but are not limited to, statements relating to the Company's future plans, expectations, intentions,

strategies and objectives. In addition, any statements that refer to projections, forecasts or other characterizations of future events or circumstances, including any underlying assumptions, are forward-looking statements. The words "anticipate", "appear", "approximate", "believe", "continue", "could", "estimate", "expect", "foresee", "goal", "intend", "may", "might", "plan", "possible", "potential", "predict", "project", "seek", "should", "would", and similar expressions (or the negative version of such words or expressions) may identify forward-looking statements, but the absence of these words does not mean that a statement is not forward-looking. Forward-looking statements may include, for example, statements about: detalimogene's potential efficacy, durability, safety, tolerability and ease of use profile, the development of detalimogene, enGene's estimates regarding expenses, debt obligations and capital requirements necessary to fund its current operating plan, the expected period over which enGene estimates its cash and marketable securities will be sufficient to fund its current operating plan, the intended objectives and benefits of the reduction in force, including any estimated cost savings, the potential benefits of detalimogene, plans regarding regulatory interactions and a potential BLA submission for detalimogene, plans regarding updates on the LEGEND study, including clinical data and engagement with the FDA, the potential benefits of combining a surfactant bladder rinse with detalimogene, plans for the additional cohorts of the LEGEND study, and the potential benefits of medicines developed with the DDX platform. Such statements are subject to numerous important factors, risks and uncertainties, many of which are beyond enGene's control, that may cause actual events or results to differ materially from enGene's current expectations. For example, there can be no guarantee that detalimogene will successfully complete necessary clinical development phases, including achieving positive results in the pivotal cohort of the LEGEND study, or that those results or any feedback from regulatory authorities will ultimately lead to BLA submission for, and the approval of, detalimogene.

Management's expectations and, therefore, any forward-looking statements in this press release could also be affected by risks, uncertainties and assumptions relating to a number of other factors, which could cause the Company's actual results, performance or achievements to differ materially from those expressed or implied by the forward-looking statements, including, without limitation, the inability of preliminary clinical data to predict the final results of the trial, changes in the results from enGene's clinical trials, including due to new data collected from the ongoing LEGEND study or future studies, subsequent analysis of existing data, and audit and verification procedures; the content and timing of decisions made by the FDA and other regulatory authorities; the Company's ability to recruit and retain qualified scientific and management personnel, establish clinical trial sites and enroll patients in its clinical trials, execute on the Company's clinical development plans; and its ability to secure regulatory approval on anticipated timelines, and other risks and uncertainties detailed in filings with Canadian securities regulators on SEDAR+ and with the U.S. Securities and Exchange Commission ("SEC") on EDGAR, including those described in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the fiscal year ended October 31, 2025 (copies of which may be obtained at www.sedarplus.ca or www.sec.gov).

You should not place undue reliance on any forward-looking statements, which speak only as of the date on which they are made. enGene anticipates that subsequent events and developments will cause enGene's assessments to change. While enGene may elect to update these forward-looking statements at some point in the future, enGene specifically disclaims any obligation to do so, unless required by applicable law. Nothing in this press release should be regarded as a representation by any person that the forward-looking statements set forth herein will be achieved or that any of the contemplated results of such forward-looking statements will be achieved.

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