enGene Appoints Joan Connolly as Chief Technology Officer and Anthony Cheung, Ph.D., as Chief Scientific Officer

BOSTON & MONTREAL - enGene Holdings Inc. (Nasdaq: ENGN or "enGene" or the "Company"), a clinical-stage genetic medicines company whose non-viral lead investigational product detalimogene voraplasmid (also known as detalimogene, and previously EG-70) is in an ongoing pivotal study in patients with high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (Cis), today announced the appointment of Joan Connolly as Chief Technology Officer (CTO) and member of the corporate leadership team. In addition, enGene Co-Founder and former CTO, Anthony Cheung, Ph.D., will transition to the role of Chief Scientific Officer, succeeding James Sullivan, MSc, Ph.D.

Ms. Connolly's career spans more than 30 years, with experience across CMC development for large and small molecules, manufacturing management, regulatory filings, and product commercialization, as well as supply chain, logistics and sourcing, and procurement. Ms. Connolly has extensive experience filing submissions for regulatory approval and product launches. In her most recent role, Ms. Connolly served as Chief Technology Officer of Albireo Pharma, Inc., where she oversaw drug substance and product development, clinical supply distribution, commercial supply chain and quality. Prior to Albireo, she held senior roles at Stemline Therapeutics, Inc., ImClone Systems Inc., and Bristol-Myers Squibb.

"We are thrilled to welcome Joan to the enGene team. She brings significant experience in managing the technical operations required to drive a late-stage clinical asset through to commercialization, which will be critical as we complete the pivotal portion of the LEGEND study of detalimogene and anticipate filing our BLA in mid-2026," said Ron Cooper, Chief Executive Officer of enGene.

"I am excited to join enGene at this critical juncture. Detalimogene's highly differentiated, non-viral DDX formulation and easily scalable manufacturing process are designed to offer significant advantages over other therapies available and in development," said Ms. Connolly. "Recent preliminary data from LEGEND's pivotal arm underscore detalimogene's future potential as a foundational therapy for the many NMIBC patients in need of new therapeutic options."

Dr. Cheung is a co-founder of enGene and has served in various capacities since the Company's inception. He has been central to the discovery and development of the Company's novel and proprietary Dually Derivatized Oligochitosan (DDX) platform and in the creation of detalimogene. He has co-authored numerous book chapters, review articles and peer-reviewed journals, and is a named inventor on numerous patents in the areas of gene therapy and polymer chemistry.

"Having developed enGene's DDX technology from the ground up, Anthony is intimately familiar with the science and well-suited to drive future expansion of our DDX platform," said Ron Cooper. "We are grateful to Dr. Sullivan for his meaningful contributions in advancing detalimogene and wish him luck in his future endeavors."

About enGene

enGene is a clinical-stage biotechnology company mainstreaming genetic medicines 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, and previously EG-70) 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 study, which includes a pivotal cohort studying detalimogene in Bacillus Calmette-Guérin (BCG)-unresponsive patients with carcinoma in situ (Cis).

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. For more information, visit enGene.com.

Forward-Looking Statements

Some of the 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 regarding enGene's expectations, hopes, beliefs, intentions, goals, strategies, forecasts and projections. The words "anticipate", "appear", "approximate", "believe", "continue", "could", "estimate", "expect", "foresee", "intend", "may", "might", "plan", "possible", "potential", "predict", "project", "seek", "should", "would", and similar 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: our expectations regarding regulatory submissions, our beliefs as to the potential benefits of detalimogene, and our expectations regarding the potential broad adoption of detalimogene.

Many factors, risks, uncertainties and assumptions 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, that preliminary clinical data may not accurately reflect the complete results of a particular study and remain subject to audit and verification, and final data may differ materially from preliminary data; 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 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, 2023 and most recent Quarterly Report on Form 10-Q for the fiscal quarter ended July 31, 2024 (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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