enGene Names Amy Pott as Chief Global Commercialization Officer

BOSTON & MONTREAL - enGene Holdings Inc. (Nasdaq: ENGN or "enGene" or the "Company"), a clinical-stage, non-viral genetic medicines company, today announced the appointment of Amy Pott as Chief Global Commercialization Officer. In this role, Ms. Pott will serve as the Company's first dedicated executive for commercialization planning and execution, reporting to enGene's Chief Executive Officer, Ron Cooper.

This appointment marks a significant milestone, as the Company expects to file a Biologics License Application (BLA) with the FDA in mid-2026 for detalimogene voraplasmid, its lead investigational agent in Bacillus Calmette-Guérin (BCG)-unresponsive, non-muscle invasive bladder cancer (NMIBC), following the completion of the pivotal cohort of the LEGEND trial.

"Amy brings a unique combination of P&L, full commercialization, gene therapy, deep analytics, and global experience to enGene," said enGene CEO, Ron Cooper. "We are thrilled to welcome Amy as our Chief Global Commercialization Officer and believe her leadership and track record of success will be a tremendous asset in preparing and executing the planned launch of detalimogene."

Ms. Pott joins enGene from Astellas Pharma, where she most recently served as Senior Vice President (SVP), Strategic Brand Marketing, Ophthalmics and Rare Diseases, and previously as Head of Commercial, Gene Therapies. Prior to Astellas, she was President, North America for Swedish Orphan Biovitrum, and Global Vice President (GVP) U.S. Franchise Head for Internal Medicine and Oncology, as well as GVP, U.S. Commercial Operations at Shire. Before joining Shire, Ms. Pott was Vice President, Strategy, Planning and Analytics at Baxalta, Inc.

Ms. Pott holds a Master of Science in European Studies from the London School of Economics and a Bachelor of Arts in History from the University of Bristol.

"I am excited to join enGene at such a pivotal moment in its journey," said Ms. Pott. "I look forward to working with this talented team to advance the mission to help transform the treatment landscape for bladder cancer patients with our innovative genetic medicine."

About Detalimogene

Detalimogene is a novel, investigational, non-viral genetic medicine 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, simplify safe handling and cold storage complexities, and streamline both manufacturing processes and administration paradigms.

Detalimogene has received Fast Track designation 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 carcinoma in situ (CIS) NMIBC with or without resected papillary tumors who are unable to undergo cystectomy. Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need.

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.

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 regarding enGene's management teams' expectations, hopes, beliefs, intentions, goals, or strategies regarding the future. 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", "intends", "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: our plans regarding the timing of our planned BLA submission to the Food and Drug Administration and our expectations as to the timing and anticipated results of the LEGEND study, the future growth of enGene, the potential benefits of detalimogene, and the potential benefits of medicines developed with the DDX platform.

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, 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, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20250528119361/en/

For media contact:
media@engene.com

For investor contact:

investors@engene.com

5/28/2025 7:30:00 AM