enGene Appoints Hussein Sweiti, M.D., MSc, as Chief Medical Officer

Bladder cancer development leader who helped drive recent FDA product approval in NMIBC joins to lead research and development strategy

Appointment strengthens enGene's clinical development and regulatory capabilities ahead of planned 2H 2026 BLA submission for detalimogene

BOSTON & MONTREAL - enGene Holdings Inc. (Nasdaq: ENGN, "enGene" or the "Company"), a clinical-stage, non-viral genetic medicine company, today announced that Hussein Sweiti, M.D., MSc, was appointed Chief Medical Officer, effective September 29, 2025.

Dr. Sweiti is a surgical oncologist and physician-scientist with more than 15 years of experience spanning clinical practice, oncology clinical research, global drug development, regulatory submissions, and medical affairs. He most recently served as Global Medical Head, Oncology Clinical Development at Johnson & Johnson (J&J), where he led end-to-end clinical strategy and execution for the company's bladder cancer portfolio. He was intimately involved in U.S. Food and Drug Administration (FDA) interactions that culminated in J&J's FDA approval in high-risk, BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) earlier this month.

Dr. Sweiti received his medical degree from the University of Heidelberg and a Master of Science in Public Health from the University of Düsseldorf. He is board certified in surgical oncology and holds a Certification in Medical Oncology from the European Society for Medical Oncology (ESMO). He has authored over 70 peer-reviewed publications.

"After reaching target enrollment in detalimogene's pivotal NMIBC clinical trial, Hussein is exactly the right fit for enGene as we transition our focus to regulatory filing and commercialization," said Ron Cooper, Chief Executive Officer of enGene. "We're thrilled to welcome a leader with recent filing success in this space, deep knowledge of urologic oncology and bladder cancer trials, and strong credibility across the urology community."

"Joining enGene at this moment is energizing, as the non-viral DDX platform is unique and the science is compelling," said Dr. Sweiti. "Urologists who treat NMIBC are looking for new options that have a unique mode of action. Detalimogene has the potential to fulfill a major clinical and physician practice need."

As Chief Medical Officer, Dr. Sweiti will oversee enGene's global clinical development strategy for detalimogene, as well as any future clinical development programs. His appointment reflects the Company's next stage of growth as it advances its lead investigational candidate in NMIBC, detalimogene voraplasmid, and builds the capabilities required for potential commercialization.

About Non-Muscle Invasive Bladder Cancer (NMIBC)

Non-muscle invasive bladder cancer (NMIBC) is a disease that poses a significant burden on both patients and clinics and has a massive economic impact on our healthcare system. NMIBC occurs when cancer cells grow in the tissues that line the interior of the bladder, but the cancer has not yet penetrated the muscle of the bladder wall. NMIBC can present as papillary outgrowths from the bladder wall, which are typically resected, or as carcinoma in situ (CIS), which consists of flat, multifocal lesions that cannot be resected. The two forms can also co-occur. About 75-80% of new bladder cancer diagnoses are NMIBC. Patients suffering from high-risk NMIBC who are unresponsive to the standard of care, Bacillus Calmette-Guérin (BCG), face high rates of disease recurrence (50-70%) and are potentially subject to full removal of the bladder (cystectomy) as a curative but life-altering next step.

About Detalimogene Voraplasmid

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 genetic medicines are accessed by patients and utilized by clinicians. Medicines developed with the DDX platform can potentially overcome the limitations of viral-based genetic medicines, including gene therapies, reduce complexities related to safe handling and cold storage, and streamline both manufacturing processes and administration paradigms.

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 carcinoma in situ (CIS) NMIBC with or without resected papillary tumors who are unable to undergo cystectomy. The RMAT program is intended to expedite the development and review of regenerative medicine therapies for serious or life-threatening conditions, where preliminary clinical evidence suggests potential to address unmet medical needs. Similarly, 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 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 approximately 100 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 three 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); and BCG-unresponsive high-risk NMIBC patients with papillary-only disease (Cohort 3). The LEGEND trial is actively enrolling patients with sites participating in the USA, Canada, Europe, and the Asia-Pacific region.

About enGene

enGene is a clinical-stage biotechnology company mainstreaming 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, 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 trial, which includes a pivotal cohort studying detalimogene in high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive 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 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: the growth and business strategy of enGene, the Company's future outlook, the expected contributions of the new Chief Medical Officer, the Company's plans regarding the timing of its planned BLA submission to the Food and Drug Administration, the Company's plans regarding potential commercialization, the Company's expectations as to the timing and anticipated results of the LEGEND study, 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.

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