NEWS RELEASE

enGene to Initiate a BLA Submission for Detalimogene by Year End and Reports New Data from LEGEND Trial Pivotal Cohort 1 in BCG-Unresponsive NMIBC

2026-11-11

Improvements reported across all efficacy endpoints for pivotal cohort over April 2026 data analysis

Primary endpoint of complete response (CR) at any time improved to 56% from 54%

Preliminary Kaplan-Meier estimate of duration of response (DoR) ≥ 12-months, a key secondary endpoint, improved to 43% from 25%

Preliminary median duration of response improved to 10.1 months from 8.6 months

Landmark 12-month CR rate improved to 24% from 13%

Detalimogene continues to demonstrate a favorable tolerability profile, with just 2% of patients experiencing a serious treatment-related adverse event (TRAE)

Positive pre-BLA meeting with FDA resulting in alignment on efficacy evaluable population

If approved, detalimogene would be the first and only non-viral plasmid gene therapy suitable for integration into any urology practice setting

Webcast and conference call scheduled for November 11, 2026 at 4:30 p.m. ET

BOSTON & MONTREAL--(BUSINESS WIRE)-- enGene Therapeutics Inc. (Nasdaq: ENGN, “enGene” or the “Company”), a clinical-stage, non-viral genetic medicines company, today announced updated results from the pivotal Cohort 1 of its ongoing, Phase 2 LEGEND trial of detalimogene voraplasmid (also known as detalimogene). Data from Cohort 1, which enrolled 125 patients with high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without concomitant papillary disease, are expected to form the basis for a Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA).

“For patients with high-risk BCG-unresponsive NMIBC, we need therapies that provide meaningful and durable disease control while minimizing treatment-related toxicity and burden,” said Ashish M. Kamat, MD, Professor of Urologic Oncology at The University of Texas MD Anderson Cancer Center and Primary Investigator of the LEGEND trial. “The updated LEGEND data are encouraging, demonstrating clinically meaningful antitumor activity with a favorable tolerability profile. Combined with its straightforward administration and handling requirements, detalimogene has the potential to become a valuable addition to our bladder-preserving treatment options, particularly in community urology practices where ease of administration and practical considerations can influence treatment selection.”

“The updated results from Cohort 1 demonstrate encouraging improvements across all key efficacy measures as the data have matured, bringing detalimogene’s efficacy profile to date within range of approved products for this indication,” said Ron Cooper, President and Chief Executive Officer, enGene. “Importantly, our recent interactions with the FDA provide a clear path to initiate a BLA submission before year-end 2026, representing a significant step toward bringing detalimogene to patients, with potential approval in 2027.”

Mr. Cooper continued, “In parallel, we are preparing for commercialization, with a focus on positioning detalimogene for broad adoption across community urology practices, where more than 75% of high-risk, BCG-unresponsive NMIBC patients receive care. We believe detalimogene’s differentiated ease of use and handling could facilitate integration into existing treatment settings, helping expand access to a new bladder-preserving treatment option for patients.”

LEGEND Pivotal Cohort Update

The following efficacy data are based on 120 efficacy-evaluable patients enrolled in Cohort 1 as of the data cutoff date, October 29, 2026.

Efficacy Overview:

- CR at any time of 56% (CI:47%, 65%) (n=120)
- Landmark 12-month CR rate is 24% (CI: 16%, 33%) (n=110)
    - 1 patient is pending the 12-month landmark disease assessment
- Median follow-up for responders increased to 12.0 months from 9.2 months since April 2026 data analysis
- Preliminary Kaplan-Meier Estimate of DoR ≥12 months is 43% (CI: 30%, 55%)
- 9 patients are pending the DoR ≥12 months disease assessment
    - 8 patients currently in maintenance are pending a durability assessment
    - 1 patient is pending the 12-month landmark disease assessment
- 100% of patients who entered maintenance and had been assessed for durability have recorded durable responses
- Median duration of complete response is 10.1 months (CI: 7.5, Not Estimable)
- 97% of all efficacy evaluable patients were free from progression to muscle-invasive or metastatic bladder cancer, defined as T2 or greater disease
- 100% of responders were free from progression to T2 or greater disease in the bladder
- 86% of all efficacy evaluable patients remain free from cystectomy
- 96% of responders remain free from cystectomy

Safety Overview:

The overall tolerability profile associated with detalimogene has been favorable. Of the 125 patients assessed for safety in Cohort 1, 59% experienced at least one TRAE, which were mainly Grade 1/2 in severity. The most common TRAEs were fatigue (21%), dysuria (16%), pollakiuria (16%), and bladder spasm (13%), micturition urgency (13%), and urinary tract infection (10%). Only 4% of patients experienced Grade 3 TRAE, with just 2% of patients experiencing a serious TRAE. No Grade 4 or Grade 5 TRAEs were reported. TRAEs leading to dose discontinuation (1%) or dose interruption (4%) were rare.

Regulatory Update and Anticipated Milestones:

Following the Company's pre-BLA meeting with the FDA, enGene reached alignment on key components of the planned BLA for detalimogene, including the efficacy evaluable patient population. The Company expects to initiate the submission by year-end 2026 and plans to complete the BLA submission in the first half of 2027, with potential FDA approval in 2027. In addition, the Company expects to provide an update on the detalimogene plus surfactant bladder rinse cohort mid- 2027.

Conference Call and Webcast

enGene will host a conference call and webcast on November 11, 2026, at 4:30 p.m. Eastern Time to discuss the updated LEGEND data and provide an overview of the regulatory path for detalimogene. Details for the conference call and webcast are included below.

Conference Call Dial-in Numbers:

North America Toll-Free: +1 833-461-5787
International Toll: +1 585-542-9983
Additional International Dial-Ins can be found **here**

Meeting ID: 485 327 198

Webcast Link: **https://events.q4inc.com/attendee/485327198**

A link to the webcast will also be available on the Investors section of enGene's website. A replay of the webcast will be available at this same link within two hours of the event's conclusion.

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 the 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 generally 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 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 carcinoma in situ (CIS) NMIBC with or without resected papillary tumors who are unable or refuse to undergo cystectomy. These designations are intended to expedite the development and review of drugs intended to treat 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 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, 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 “forecast”, “intend”, “develop”, “expect”, “anticipate”, “appear”, “approximate”, “believe”, “continue”, “could”, “estimate”, “expect”, “foresee”, “goal”, “intends”, “may”, “might”, “plan”, “possible”, “potential”, “predict”, “project”, “seek”, “should”, “strategy”, “future”, “potential”, “opportunity”, “target”, “term”, “will”, “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, the potential benefits of detalimogene, plans regarding regulatory interactions and the potential BLA submission and potential approval of detalimogene, plans regarding updates on the LEGEND study or on the detalimogene plus surfactant bladder rinse cohort, including clinical data and engagement with the FDA, our current views and market research on the non-muscle invasive bladder cancer market, the depth, breadth and quality of our market research, our conclusions, implications or take-aways from the results of our market research, estimates, projections or forecasts of payer coverage of therapies, projected revenues for detalimogene at pricing parity with new therapies, the size of the addressable BCG unresponsive population, our expectations regarding the frequency or manner in which healthcare providers may use detalimogene, potential growth of the potential patient population, sequencing of products, the potential benefits of combining a surfactant bladder rinse with detalimogene, including the potential for increased efficacy and durability, estimates and forecasts of financial and performance metrics, projections of market opportunity and market share, the anticipated market acceptance of detalimogene, expectations and timing related to regulatory submissions and commercial product launches and the prospects for regulatory approval of 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.

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 Quarterly Report on Form 10-Q for the third quarter ended July 31, 2026 (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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