Detalimogene Demonstrates 71% Complete Response Rate at Any Time in Preliminary Analysis of LEGEND Pivotal Cohort

Data from pivotal cohort demonstrate compelling clinical activity, consistent with Phase 1 results

Favorable tolerability profile with no drug-related discontinuations

Detalimogene's profile to date supports its potential as a foundational therapy for NMIBC

enGene to host a conference call to discuss preliminary data today at 8:00 a.m. ET

BOSTON & MONTREAL - enGene Holdings Inc. (Nasdaq: ENGN or "enGene" or the "Company"), is 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, the Company announced preliminary data from 21 patients assessed at three months, including 17 patients who were also assessed at six months, in the ongoing pivotal cohort of the LEGEND study. The Complete Response (CR) rate at any time was 71%, the CR rate at three months was 67% and the CR rate at six months was 47%. Detalimogene was generally well-tolerated by patients and no patients discontinued due to treatment-related adverse events.

"We are pleased with this preliminary dataset, which clearly demonstrates that detalimogene is highly active and generally well tolerated. The data are consistent with what was observed in Phase 1 and give us increased confidence in the emerging profile," said Raj Pruthi, M.D., Chief Medical Officer of enGene. "We are also planning protocol refinements in LEGEND, which we believe will provide patients with additional clinical benefit."

"The promising initial efficacy and safety data observed in LEGEND's pivotal cohort, combined with detalimogene's ease of handling, administration, minimal storage requirements, and lack of post-procedural patient restrictions underscore its potential to become a broadly utilized treatment option for NMIBC patients, especially in the community practice setting," remarked Suzanne Merrill, M.D., a urologist specializing in bladder cancer with the United Urology Group in Colorado.

Bladder cancer is a top 10 cancer by incidence in the US with high annual treatment cost. NMIBC represents more than 75% of bladder cancer diagnosis and over 70% of urologists practice in the community setting where the majority of these patients are treated.

"Detalimogene was designed to be the most practical therapy for urologists to manage NMIBC," said Ron Cooper, Chief Executive Officer of enGene. "The early results from our pivotal LEGEND study clearly demonstrate that detalimogene has the potential to offer a highly differentiated profile by striking an optimal balance between efficacy, tolerability, and ease of use."

Safety Information

The overall tolerability profile associated with detalimogene was favorable, and there have been no drug-related discontinuations in the study. Of the 42 patients assessed for safety, inclusive of all Phase 2 cohorts, 20 patients (48%) experienced at least one treatment-related adverse event (TRAE), which were mainly Grade 1/2 in severity, except for two Grade 3 TRAEs (peripheral edema and urosepsis). The most common TRAEs (10%) were dysuria, bladder spasm, pollakiuria and fatigue. There were no Grade 4 or Grade 5 TRAEs reported.

About LEGEND

The LEGEND study is a multi-cohort study to establish efficacy of detalimogene in high-risk NMIBC patients with Cis,

as well as those with papillary-only NMIBC. The pivotal cohort is an approximately 100 patient, open-label study evaluating detalimogene in BCG-unresponsive NMIBC patients with Cis. Patients receive 800µg/mL of detalimogene intravesically at weeks one, two, five, and six during a 12-week cycle, for up to four cycles, with assessments at three, six, nine, and 12 months. The study's primary efficacy endpoint is the percentage of patients with a complete response at 12 months, based on cystoscopy, urine cytology and biopsy.

In addition to LEGEND's pivotal cohort, the Company plans to initiate enrollment of three additional cohorts in the LEGEND study: (i) high-risk BCG-exposed patients with Cis and BCG-naïve patients with Cis in cohorts 2a and 2b, respectively, and (ii) high-risk BCG-unresponsive NMIBC patients with papillary-only disease in cohort 3. Enrollment for cohorts 2a, 2b, and 3 is expected to begin in the fourth quarter of 2024. The Company remains on track to file a Biologics License Application (BLA) for detalimogene in its pivotal cohort in mid-2026.

Investor Conference Call

enGene will host a conference call and live webcast at 8:00 a.m. ET today, September 26, 2024. Individuals interested in listening to the conference call may do so by using the webcast link available at the "Investors" section of the Company's website at www.engene.com/investors. Following the live webcast, an archived version of the call will also be available on the website.

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 beliefs as to the potential benefits of detalimogene, our plans to amend the LEGEND protocol, our plans regarding expansion and modification of the LEGEND study for potential additional bladder cancer indications for detalimogene, our expectations regarding timing of the enrollment of patients in the additional cohorts of the LEGEND study, and our expectations regarding regulatory submissions.

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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