# enGene to Present Details of its Pivotal Phase 1/2 LEGEND Study of EG-70 in BCG-Unresponsive Non-Muscle Invasive Bladder Cancer with Carcinoma in situ at the American Urology Association 2024 Annual Meeting

*Oral presentation highlights rational design of EG-70 to address challenges faced by other intravesical treatment options, including preparation, handling, and safety considerations*

BOSTON and MONTREAL, May 2, 2024 /CNW/ - enGene Holdings Inc. (Nasdaq: ENGN) or ("enGene" or the "Company"), a clinical-stage genetic medicines company whose non-viral lead program EG-70 is in a pivotal study for BCG-unresponsive non-muscle invasive bladder cancer (NMIBC), today announced an oral presentation at the American Urology Association (AUA) 2024 Annual Meeting being held May 3-6, 2024 in San Antonio, Texas.

The presentation, "LEGEND: a Phase 1/2 study of EG-70 (detalimogene voraplasmid), a novel, non-viral intravesical gene therapy for patients with BCG-unresponsive non-muscle invasive bladder cancer with carcinoma in situ (CIS)," will be given by Dr. Gordon Brown, Director of the Center for Advanced Therapeutics and Urologic Oncology, Summit Health-South, at 10:30 a.m. CT on Friday, May 3rd during the Paradigm-shifting, Practice-changing Clinical Trials in Urology Plenary Session. The complete dataset from the 12-month follow-up of all patients in the Phase 1 portion of LEGEND will be reported at a future meeting or within a peer-reviewed publication.

"I am pleased to present a detailed overview of EG-70 and the pivotal Phase 1/2 LEGEND study. EG-70 is designed to be a practice-changing product that does not require a change in practice for urologists, offering attributes that render it practical for use in community-based and high-volume clinics." said Dr. Brown.

Dr. Richard Bryce, enGene's Chief Medical Officer, added: "The promising initial efficacy and safety data from LEGEND's Phase 1 cohort in high-risk, BCG-unresponsive NMIBC patients with CIS, combined with its ease of handling, simplicity of administration, minimal storage requirements, and lack of post-procedural patient restrictions, demonstrate EG-70's potential to unlock the power of genetic medicine for any and all urologists."

"EG-70 was rationally designed to be easy to use and meet the needs of patients and urologists alike. As a non-viral, non-infectious, locally delivered genetic medicine, EG-70 is designed to synergistically activate both the innate and adaptive immune responses, be easily reconstituted in water, and require only a short procedural time," said Jason Hanson, Chief Executive Officer of enGene. "Within the subgroup of patients in LEGEND's Phase 1 who received our optimized Phase 2 dose, we saw complete response rates of 70% and 60% at three months and six months, respectively, which speak to EG-70's potential to drive durable remissions. The encouraging safety data from the Phase 1 study also suggest that this efficacy was achieved without significant impairment to the patients' quality of life. We look forward to providing additional updates on the broader EG-70 program as we look to expand its potential use across bladder cancer."

## 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 EG-70 for patients with non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (Cis) who are unresponsive or naïve to treatment with Bacillus Calmette-Guérin (BCG) - a disease with a high clinical burden. EG-70 is being evaluated in an ongoing Phase 2 pivotal study. EG-70 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 EG-70.

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, 2023 and most recent Quarterly Report on Form 10-Q (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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