enGene announces poster presentation containing interim Phase 1 clinical trial data at the 2023 American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium

Interim Phase 1 results from enGene's Phase 1/2 LEGEND study of intravesical EG-70 (detalimogene voraplasmid) demonstrate a 71% CR rate at three months in patients with high-grade non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) that is BCG-unresponsive

BOSTON, MA and MONTRÉAL, Feb. 14, 2023 /PRNewswire/ - enGene Inc., a clinical-stage biotechnology company pioneering non-viral gene therapies for local administration to mucosal tissues enabled by its proprietary DDX platform, today announced a poster presentation at the American Society of Clinical Oncology (ASCO) Genitourinary Cancers Symposium being held from February 16th to 18th, 2023. The poster will highlight positive pharmacodynamic urinary biomarker data, an encouraging safety profile across all tested doses, and strong preliminary efficacy data based on cytology, cystoscopy, and biopsy, including a j3-month complete response rate of 71%.

Presenter, Dr. Gary Steinberg MD, Professor at the Perlmutter Cancer Center and Department of Urology and Director of the Goldstein Urology Bladder Cancer Program of NYU Langone Health, said: "While the data are still early, EG-70's safety profile and efficacy are well on their way towards establishing a new benchmark for monotherapy treatment of high-risk NMIBC with BCG-unresponsive Carcinoma in situ (CIS)." He added, "If these trends continue into Phase II, I am optimistic that EG-70 will become an important, useful, and innovative tool in the fight against non-muscle invasive bladder cancer (NMIBC), especially given its non-viral nature and relative ease of handling and use."

"From the start, we designed EG-70 to be a safe, practical, and effective option for both patients and physicians that will integrate seamlessly into community urology clinics," said Jason Hanson, CEO of enGene. "It is deeply rewarding to see EG-70 continuing its best-in-class trajectory, and we look forward to the upcoming initiation of the pivotal Phase II portion of the LEGEND study."

Presentation highlights:

- 71% CR rate at 3 months and a rate of patients continuing past 3 months of 82%, both based on a total of 17 patients.
- A strong safety profile, with observed adverse events largely consistent with urinary tract instrumentation used to deliver EG-70.
- Dose-responsive induction of the IL-12 therapeutic transgene expression, as measured in urine.

Poster session details:

Title: Clinical results of a Phase 1 study of intravesical EG-70 in patients with BCG-unresponsive NMIBC
Abstract Number: 512
Session Information: Session B: Prostate Cancer and Urothelial Carcinoma
Date and Time: Friday, February 17, 2023, 3:30PM ET
Presenter: Gary Steinberg, M.D.

Additional meeting information and the published abstract are available on the ASCO GU website (https://conferences.asco.org/gu/attend).

About EG-70

Based on enGene's DDX platform, EG-70 is a novel non-viral gene therapy encoding two RIG-I agonists to stimulate

the innate immune system, and IL-12 to stimulate the adaptive immune system. By stimulating both arms of the immune system, intravesically administered EG-70 yields remarkable tumor regression in preclinical models of bladder cancer, with induction of effective immunological memory and minimal signs of toxicity.

About the LEGEND study

The LEGEND study, both first-in-human and first-in-class, is an open-label, monotherapy, multi-center, dose-escalation trial evaluating safety and tolerability, pharmacokinetics, pharmacodynamics, and efficacy of EG-70 administered by intravesical instillation. To learn more about the first-in-human clinical trial of EG-70 in BCG-unresponsive NMIBC, please visit ClinicalTrials.gov. For additional information about the LEGEND study, please visit thelegendstudy.com.

About enGene Inc.

enGene Inc. is a clinical-stage biotechnology company developing non-viral gene therapies based on localized delivery of nucleic acid payloads to mucosal tissues. The dually derived chitosan (DDX) platform has a high-degree of payload flexibility, including DNA and various forms of RNA with broad tissue and disease application. In preclinical models, enGene's DDX technology has been demonstrated to effectively induce expression of therapeutic genes following delivery to the lung, gastrointestinal tract and urinary tract. Engene has developed scalable GMP-compliant manufacturing of DDX products.
https://www.engene.com

Note regarding forward-looking statements

This press release contains certain "forward-looking statements" that reflect the Company's beliefs and assumptions based on currently available data and information. These forward-looking statements fall within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "positioned," "future," and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on enGene's current beliefs, expectations, and assumptions that by definition involve risks, uncertainties, that are difficult to predict and are subject to factors outside of management's control and that could cause actual results to differ substantially from statements made including but not limited to: risks associated with the success of preclinical studies, clinical trials, research and development programs, as well as regulatory approval processes. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. enGene has no approved drugs available for sale marketing at this time and may never have an approved drug. You are cautioned not to rely on enGene's forward-looking statements, which are only made as of the date hereof. The Company is under no obligation to update these statements.

SOURCE enGene

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