EnGeneIC Announces First Patients with Advanced-Stage Pancreatic Cancer Dosed in Phase 1/2a Clinical Study of Targeted Cytotoxic Immunotherapy

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EnGeneIC Limited →
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NEW YORK and SYDNEY, May 9, 2019 /PRNewswire/ -- EnGeneIC Limited, a clinical-stage biopharmaceutical company advancing its proprietary EDV™ nanocell platform for targeted cyto-immunotherapy in cancer, today announced that the first four patients have been dosed in a Phase 1/2a study using the Company's tumor-targeting, immunogenic EDVs™ to deliver a cytotoxic drug payload directly to tumors of patients who have exhausted curative treatment options. The study is enrolling patients with advanced pancreatic cancer and other EGFR-expressing solid tumors in a second cohort, which is currently underway at Frankston Private Hospital in Victoria, Australia, with Professor Vinod Ganju, MBBS, FRACP, as the Principal Investigator.

EnGeneIC's second-generation EDV™ nanocells deliver an extremely cytotoxic nemorubicin derivative (D682) directly to solid tumors via EGFR targeting on the tumor cell surface, keeping healthy tissue protected from damage. The novel therapy also includes EDVs™ carrying an immune-boosting adjuvant to further augment the anti-tumor immune response stimulated by the bacterially-derived EDVs™ and perpetuated by tumor cell destruction.

Jennifer MacDiarmid, Ph.D., and Himanshu Brahmbhatt, Ph.D., joint-CEOs and Directors of EnGeneIC, stated, "We developed our second-generation EDVs™ to address multi-drug resistance in patients who have failed multiple lines of chemotherapy and therefore have the highest unmet need. D682 is an extremely potent drug that is far too toxic to be delivered systemically, but has proven safe in patients when encapsulated in our EDVs™. We have named the study, the Carolyn Trial, after a close friend who had end-stage pancreatic cancer and was treated in a compassionate use case study. Carolyn was the first patient in the world to receive D682, and we observed highly encouraging results. Not only was survival extended, but quality of life improved considerably for the patient. Moreover, there was significant evidence of tumor regression coincident with a decrease in a key pancreatic cancer blood marker and a robust increase in anti-tumor $CD8^+$ T cells and other anti-tumor immune cells. We are now executing a more rigorous clinical trial, not only for pancreatic cancer patients, but also for other advanced-stage patients with drug-refractory tumors."

Professor Ganju commented "Novel therapies for these late stage patients with drug-resistant tumors are desperately needed. Four patients have been enrolled on the study and so far we have been impressed with the tolerability and safety of this therapy. We will be getting some efficacy data in coming months."

About the Phase 1/2a Study

The two-cohort study will enroll up to 40 evaluable patients per cohort: 1) patients with advanced pancreatic cancer and 2) patients with EGFR-expressing solid tumors who have failed first- and second-line therapy or for whom standard therapies are not appropriate. The test article is EnGeneIC's second-generation EGFR-targeted, D682-carrying EDV™ ($^{E}EDV_{D682}$) plus EDVs™ carrying an immune adjuvant (EDV_{adj}) which acts to augment the anti-tumor immunity. Study objectives include assessing the safety and tolerability of $^{E}EDV_{D682}$ plus EDV_{adj}, assessing anti-tumor response and overall survival. Exploratory objectives include biomarker assessment for immune response such as cellular immune response (CD8+ T cells, NK cells), and activated dendritic cells. In addition to the current clinical site, the study is expected to be opened in at

least one other major cancer center in Sydney, Australia. For more information visit https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=365258&isReview=true

About EnGeneIC and the EDV™ Nanocell Technology

EnGeneIC is a clinical stage biopharmaceutical company advancing its proprietary bacterially-derived EDV™ nanocells as a powerful nanoparticle drug, siRNA, or miRNA delivery platform designed to directly target and effectively kill tumor cells with minimal toxicity, while simultaneously stimulating the immune system's innate and adaptive anti-tumor response. First- and second-generation EDV™ nanocells have shown promising results in early clinical studies and EnGeneIC is currently planning to commence further clinical trials in several cancer indications in Australia and USA.

For more information, please visit www.engeneic.com.

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