



EnGeneIC Doses First Patient in U.S. Phase 1 Clinical Study of Targeted EDV™ Nanocells in Recurrent Glioblastoma Multiforme

New York, NY, and Sydney, Australia, March 21, 2017 — [EnGeneIC Limited](#), today announced that it has begun dosing patients in a USA-based open-label Phase 1 clinical trial evaluating its proprietary EDV™ nanocells to treat recurrent glioblastoma multiforme (GBM) in adults.

GBM is the most common primary malignant brain tumor in adults in the United States, accounting for approximately 16% of all primary brain tumors. These patients almost invariably relapse and there are few treatment options available for recurrent GBM.

Himanshu Brahmabhatt, Ph.D., joint-CEO and Director of EnGeneIC, stated, “The Cerebral EDV study is a very exciting trial since for several decades the blood brain barrier (BBB) has been thought to be the limiting factor in allowing anti-tumor drugs to safely get to brain tumor cells. The EDV nanocells bypass the BBB, get into the brain tumor via the tumor associated leaky blood vessels and then deliver the toxic payload in therapeutically significant concentrations inside the cancer cells. This allows us to send potent drugs directly into brain cancer cells and in previous trials we have witnessed minimal to no toxicity in patients. We call our EDV platform a cyto-immuno-therapeutic since it not only directly targets and kills cancer cells but also stimulates the patient’s immune system to ‘wake up’ and fight the tumor.”

The open-label Phase 1 Cerebral EDV study is a two-part clinical trial in approximately 20 adults diagnosed with recurrent GBM who have already received first-line chemotherapy. The first part of the study, which will be a dose exploration study, will assess the safety of multiple doses of (EGFR)-EDV-doxorubicin at two dose levels, administered once a week for 7 weeks. The second part of the study will provide guidance on the recommended Phase 2 dose of (EGFR)-EDV-doxorubicin. The primary objective of the study is to assess the safety of the therapy, while secondary endpoints include assessing anti-tumor response rates and overall survival, as well as to identify the recommended Phase 2 dose. In addition, the study will assess biomarkers associated with immunotherapy aspects of (EGFR)-EDV-doxorubicin.

More information regarding the Cerebral EDV trial can be found by visiting <https://clinicaltrials.gov/ct2/show/NCT02766699?term=Cerebral+EDV&rank=1>

About Glioblastoma Multiforme

Glioblastoma multiforme (GBM) is the most common primary malignant brain tumor in adults in the United States, accounting for approximately 16% of all primary brain tumors. More than 11,000 new cases of GBM are projected for 2017 in the USA. Despite an aggressive multimodal approach of surgery and chemotherapy and/or radiation, relapse is almost inevitable for patients with GBM (approximately 90% recurrence rate). Outcomes for patients with GBM are poor despite best management and median overall survival for recurrent glioma is less than four months.

About EnGeneIC and the EDV™ Nanocell Technology

EnGeneIC is a clinical stage biopharmaceutical company focused on developing 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 natural and adaptive anti-tumor response. The

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EDV™ nanocell platform has 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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