EnGeneIC Receives FDA Orphan Drug Designation for Targeted EDV™ Nanocells to Treat Glioblastoma Multiforme

New York, NY, and Sydney, Australia, March 2, 2017 — EnGeneIC Ltd., a clinical stage biopharmaceutical company focused on developing its proprietary EDV™ nanocell platform for targeted cyto-immunotherapy in cancer, announced that U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation to EGFR-targeted, doxorubicin-loaded EDV nanocells for the treatment of glioblastoma multiforme (GBM).

Jennifer MacDiarmid, Ph.D., joint-CEO and Director of EnGeneIC, commented, "We are pleased that the FDA has granted Orphan Drug Designation to our targeted EDV nanocells for the treatment of GBM, a difficult-to-treat cancer indication with an especially poor prognosis. This is not only an important U.S. regulatory milestone, but an exciting step towards our U.S. clinical advancement."

Orphan Drug Designation is granted by the FDA Office of Orphan Products Development (OOPD) to novel drugs or biologics that treat a rare disease or condition affecting fewer than 200,000 patients in the U.S. The designation provides the drug developer with a seven-year period of U.S. marketing exclusivity, as well as tax credits for clinical research costs, the ability to apply for annual grant funding, clinical research trial design assistance and waiver of Prescription Drug User Fee Act (PDUFA) filing fees.

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 anti-tumor response. Intravenously injected EDV™ nanocells exit the leaky vascular system only found within tumors and attach to cancer cells via a specially designed, targeted bi-specific antibody. Once attached, the nanocell is able to enter the tumor cell and deliver a drug, siRNA, or miRNA payload at high concentrations, intracellularly. The 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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