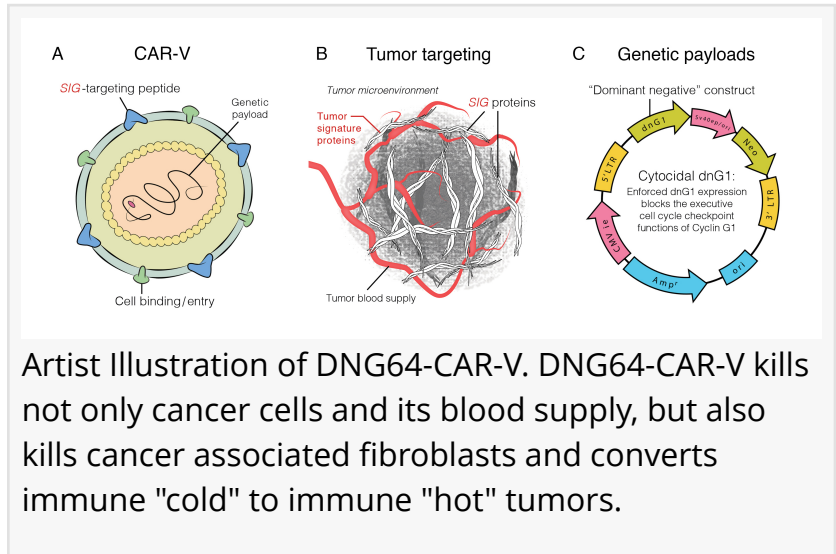


FDA Authorizes Injection of Tumor Targeted Gene Therapy Directly into Cerebrospinal Fluid for Leptomeningeal Disease

DNG64-CAR-V (DeltaRex-G), A Novel Off-The-Shelf Intraventricular Gene Therapy for Brain Tumors, Leukemia, Lymphoma and Cancers That Have Spread to the Brain

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Aveni Foundation is proud to announce that FDA CBER has authorized the injection of DNG64-CAR-V (DeltaRex-G) directly into cerebrospinal fluid (CSF) via an Ommaya reservoir for a patient with refractory glioblastoma that has spread to the cerebrospinal fluid and the delicate membranes covering the brain and spinal cord ([leptomeningeal disease](#); [IND#32087]).



“

This is a tribute to Will Roberts from Ralph, Alabama, a brave young man with osteosarcoma that had spread to his brain, whose plea for access to DeltaRex-G resonated worldwide.”

James H. Flint, MD and Erlinda M. Gordon, MD

According to Dr. Santosh Kesari, neuro-oncologist and Director of AsthraHealth Clinic in Santa Monica CA, and investigator at The Lundquist Institute for Biomedical Innovation at Harbor-UCLA Medical Center (TLI): “DNG64-CAR-V is the first tumor targeted gene therapy product to be authorized by FDA CBER for direct delivery into the CSF and represents an innovation that millions of patients suffering from brain cancer and leptomeningeal disease could benefit from”.

Dr. Sant P. Chawla, Director of the Sarcoma Oncology Center in Santa Monica CA, echoed the importance of this emergency use authorization for DNG64-CAR-V that could

help many patients whose cancers have spread to the brain including osteosarcoma and other sarcomas, melanoma, lung cancer, breast cancer, leukemia and lymphoma.

Dr. James H. Flint, Orthopedic Oncologist and Associate Professor of Surgery at Uniformed Services University, San Diego CA and Dr. Erlinda M. Gordon, Director of Gene and Cell Therapy at Sarcoma Oncology Center emphasized that “This is a tribute to Will Roberts from Ralph, Alabama, a brave young man with osteosarcoma that had spread to his brain, whose plea for access to DeltaRex-G resonated worldwide.”

DNG64-CAR-V (DeltaRex-G) is a targeted gene delivery system created and reduced to practice by Drs. Erlinda Maria Gordon and Frederick L. Hall at USC Keck School of Medicine, Los Angeles CA. An off-the-shelf, injectable replication-incompetent chimeric (tumor-targeted) amphotropic RNA vector encoding a Cyclin G1/CCNG1 inhibitor construct, DNG64-CAR-V not only kills cancer cells and neoangiogenic cells, but also kills growth-promoting, stroma-producing cancer-associated fibroblasts (CAFs) in the tumor microenvironment (TME). By reducing stroma which serves as an impermeable fortress for cancer cells, DNG64-CAR-V enables entry of chemo/immunotherapy drugs for enhanced drug concentration in the TME. Intravenously administered DNG64-CAR-V has been used successfully in phase I/II studies for sarcoma, pancreatic, and breast cancer, and in a phase II clinical trial for osteosarcoma that had failed standard chemotherapy (Chawla et al., Mol Ther 2009 doi.org/10.1038/mt.2009.126; Chawla et al., Mol Ther Oncol 2019, doi:10.1038/mt2009.228; Bruckner et al., Frontiers Mol Med, 2023, doi: 10.3389/fmmed.2023.1105680), with long term (10-18 years) survivors and no delayed adverse events reported (Al Shihabi et al., Mol Ther Oncol 2018, doi: 10.1016/j.omto.2018.11; Liu et al., Clin Oncol 2021, <http://clinicsinoncology.com/>).

DNG64-CAR-V is available in an expanded access program sponsored by Aveni Foundation (NCT04091295; www.clinicaltrials.gov). For further information, please go to the following websites: www.avenifoundation.org, www.sarcomaoncology.com, or contact Dr. Gordon at egordon@avenifoundation.org or egordon@sarcomaoncology.com. To make a donation, please visit www.avenifoundation.org and click on the “donate” button for credit card donations. Wire transfer information may be provided upon request.

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AVENI FOUNDATION

The Aveni Foundation mission is to expedite development of gene-targeted technologies for osteosarcoma, leptomeningeal disease and other cancers.

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