



USFDA GRANTS EXPANDED ACCESS FOR DELTAREX-G, A PRECISION TUMOR TARGETED GENETIC MEDICINE FOR METASTATIC CANCER(S)

"Expanded Access for DeltaRex-G and Right to Try law will give individuals with different types of cancer a chance to benefit from this innovative treatment."

SANTA MONICA, CA, UNITED STATES, August 19, 2019 /EINPresswire.com/ -- The Aveni Foundation and the Cancer Center of Southern California, Santa Monica CA, are proud to announce that the United States Food and Drug Administration has granted Expanded Access for DeltaRex-G. This regulatory approval is based on Phase 1/2 studies demonstrating safety and efficacy for pancreatic cancer, sarcoma, and breast cancer, and long term (>10-year) survival data presented at the American Society of Gene and Cell Therapy Annual Meeting in Washington DC (Reporting long term survival following precision tumor-targeted gene delivery to advanced chemotherapy-resistant malignancies: an academic milestone. Liu et al., Molecular Therapy Vol 27 No 4S1 April 2019, abs 275). In this article, the authors reviewed long-term data of patients with advanced chemotherapy-resistant malignancies, who were treated with one or two targeted gene therapy vectors: (1) encoding a tumor-killing cell cycle inhibitor (DeltaRex-G), and (2) a GM-CSF vaccine (DeltaVax). Ninety-nine patients received >5,000 intravenous infusions of DeltaRex-G; another 16 patients received 288 intravenous infusions of DeltaRex-G plus 96 infusions of DeltaVax. No therapy-related bone marrow suppression, organ dysfunction, or delayed treatment-related adverse events were observed. Survival analysis 10 years after treatments showed a 5.0% overall survival rate in patients treated with DeltaRex-G alone, and 18.8% with the combination of DeltaRex-G and DeltaVax.

Dr. Erlinda Maria Gordon, President of the Aveni Foundation, and Director of Biological and Immunological Therapies at the Cancer Center of Southern California, stated that "Expanded Access for DeltaRex-G and the recently-enacted Right to Try law will give individuals with different types of cancer a chance to benefit from this innovative treatment. DeltaRex-G is a targeted gene therapy vector that seeks the biochemical signatures (SIG) of all invading cancers. Because the demonstrated anti-cancer activity of DeltaRex-G is broad spectrum, and the targeted nanoparticles display a unique (SIG)-hunting peptide, which recognizes and effectively seeks-out the tumor microenvironment, DeltaRex-G can be taken 'off the shelf' clinically – and injected intravenously over 15 minutes, without causing the side effects of chemotherapy and ungoverned immunotherapy agents."

The Aveni Foundation's Research & Development division is further engaged in (1) identifying individuals who are likely to benefit from DeltaRex-G therapy, using a novel biomarker, [CCNG1](#), which is abnormally found in over 50% of all cancer types, and (2) developing improved versions of DeltaRex-G and other [inhibitors along the CCNG1 pathway](#), including Mdm2 and c-myc.

For further information, please go to our websites: www.avenifoundation.org, www.sarcomaoncology.com or contact Dr. Gordon at egordon@avenifoundation.org or egordon@sarcomaoncology.com. To make a donation, please make checks payable to: Aveni Foundation, 2811 Wilshire Blvd., Suite 777, Santa Monica CA 90403, or click the "donate" button at www.avenifoundation.org for credit card donations.

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