

DeltaRex-G Tumor-targeted Gene Therapy for Chemotherapy- Induced Leukemia

Harvard and Mayo Clinic Investigators report a new clinical indication for DeltaRex-G genetic medicine.

LOS ANGELES, CALIFORNIA, USA, April 27, 2020 /EINPresswire.com/ -- The Aveni Foundation is proud to announce the publication of a novel treatment for chemotherapy-induced leukemia with an off-the-shelf injectable gene therapy, DeltaRex-G (Haematologica, Volume 105; doi:10.3324/haematol.2020.246744; Impact Factor: 7.57). Harvard and Mayo Clinic investigators led by Dr. Sheng Xiao reported a novel genetic mutation, IGH-CCNG1 gene rearrangement, that was found in a patient with chemotherapyinduced acute myeloid leukemia (AML). This specific mutation could serve as a target for therapeutic DeltaRex-G, a tumor-targeted gene therapy encoding a CCNG1 inhibitor.

According to Dr. Xiao:

"Clinical trials with a dominant-negative CCNG1 retroviral expression vector (DeltaRex-G) showed impressive results, including several metastatic tumors being cancer-free ten years after DeltaRex-G



The Aveni Foundation mission is to expedite development of gene-targeted technologies for cancer and other unmet medical needs.

monotherapy.... It will be interesting to evaluate how frequent the CCNG1 is overexpressed in myeloid tumors, and whether an anti-CCNG1 strategy such as DeltaRex-G is effective in treating myeloid tumors, a group of diseases typically with very poor prognosis."

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"Clinical trials with a dominant-negative CCNG1 retrovector (DeltaRex-G) showed impressive results, including several metastatic tumors being cancer-free ten years after DeltaRex-G monotherapy." Sheng Xiao, MD PhD Consistent with these findings, Dr. Gordon and co-workers have shown that CCNG1 is highly expressed in many cancer types, and they are developing a companion diagnostic assay for this novel biomarker to identify patients who are likely to benefit from DeltaRex-G (AACR Annual Meetings, March 2019, Atlanta GA; J Clin Oncol 36, 2018, suppl; abstr e24315).

DeltaRex-G is a tumor-seeking gene therapy that targets the signature (SIG) proteins in the microenvironment of invading tumors. DeltaRex-G has been successfully tested in five U.S. based clinical trials, that resulted in long term

survival/sustained remissions (11-12 years) of patients with hard-to-treat Stage 4 cancers

including pancreatic cancer, bone and soft tissue sarcoma, breast cancer and B-cell lymphoma (ASCGT Annual Meetings, April, 2019).

In February 2020, the FDA approved Expanded Access for DeltaRex-G for advanced pancreatic cancer and sarcoma to serve a larger size population (NCT04091295). According to Dr. Erlinda Gordon, President of the Aveni Foundation, "To gain this type of approval, the FDA requires an investigational drug to have demonstrated safety and efficacy in early phase clinical trials".

Dr. Gordon predicts that while DeltaRex-G has never been used for the treatment of leukemias, this recent discovery is likely to extend the use of DeltaRex-G to cancers of the blood and bone marrow.

For further information, please visit our websites: <u>www.avenifoundation.org</u>, <u>www.sarcomaoncology.com</u> or contact Dr. Gordon at egordon@avenifoundation.org or egordon@sarcomaoncology.com.

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Graphic illustration of DeltaRex-G vector. The DeltaRex-G vector displaying a Sig targeting peptide (A), for binding to Signature (Sig) Proteins in the tumor microenvironment [TME] (B), and encodes a dominant negative human cyclin G1 inhibitor gene (C).



Left Panel: Cyclin G1 Functional Domains. Cyclin G1 physically binds to the ser/thr protein phosphatase subunit designated 2A (PP2A) to activate a key regulatory oncoprotein, Mdm2.

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