

PRESS RELEASE



The Aveni Foundation and The Cancer Center of Southern California
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DeltaRex-G generates significant interest in a Commentary published in Molecular Therapy Family of Journals, the Official Organ of the American Society of Gene and Cell Therapy (ASGCT).

The Aveni Foundation and The Cancer Center of Southern California, Santa Monica CA, are proud to announce that the Molecular Therapy Oncolytics Journal has published a Commentary on a novel approach to cancer gene therapy/cancer therapy which focuses on "a pivotal and therapeutically accessible locus of executive Cell Cycle Checkpoint Control the human Cyclin G1 protein (CCNG1 proto-oncogene product) and the associated oncogenic drivers arrayed along the aberrant biochemical pathways that (i) promote and (ii) ensure uncontrolled cell proliferation, resulting in the development of cancer (carcinogenesis), its tendency to spread aggressively to other organs (metastasis), and its refractoriness to standard chemotherapies and other targeted therapies". The Commentary is authored by Drs. Ahmad Al-Shihabi, Sant P. Chawla, Frederick L. Hall, and Erlinda Maria Gordon (Corresponding Author). According to peer reviewers of the article, (1) "This is a high quality, timely, well written review article/commentary", and (2) "This is a well written comment about the Cyclin G1 and the related molecular drivers for cell cycle control. The information would explain why DeltaRex-G should be combined with other molecular targets along the CCNG1 pathway such as CDK2/5, PP2A, p53, c-Myc as a new promising cancer therapy" (https://doi.org/10.1016/j.omto.2018.11.002).

DeltaRex-G is a gene therapy vector that targets the signature of invading tumors, because the nanoparticles display a Signature (SIG^{TM}) binding peptide on its surface that follows the tumor back to the tumor microenvironment, possibly obviating the need of resecting the tumor. In other words, the SIG^{TM} binding peptide guides the medicine and delivers it (think auto-pilot) into the tumor microenvironment regardless of location. This is for known and unknown tumors detected by CT scan or MRI imaging. DeltaRex-G does not differentiate between primary and metastasized tumors.

DeltaRex-G has been successfully tested in five U.S. based clinical trials, that resulted in sustained remissions without further cancer therapy (9-12 years) of certain patients with hard-to-treat Stage IV cancers including pancreatic cancer, and bone and soft tissue sarcoma. Dr. Gordon and co-workers have shown that CCNG1 protein is highly expressed in many cancer types, and are developing a companion diagnostic assay for this novel biomarker, CCNG1. The presence of this CCNG1 biomarker in tumors or circulating DNA is likely to identify those patients who will benefit most from DeltaRex-G gene therapy (J Clin Oncol 36, 2018, suppl; abstr e24315).

The Aveni Foundation and The Cancer Center of Southern California, are continuing its further clinical development, as monotherapy and in combination regimens with other inhibitors of the CCNG1 pathway and/or with immune checkpoint inhibitors. Dr. Gordon, Chair of the Aveni Foundation, and Director of Biological and Immunological Therapies of the Cancer Center of Southern California, predicts that DeltaRex-G will be the first affordable cancer gene therapy product, once approved, as DeltaRex-G can simply be taken off the shelf and injected intravenously over 5-10 minutes, without causing the side effects of chemotherapy and immunotherapy agents. The reason for this is that DeltaRex-G nanoparticles target only the tumor microenvironment with its own built-in delivery system, without collateral damage to neighbouring normal cells and organs, as no serious toxicity has been experienced, so far, by patients who received DeltaRex-G gene therapy.

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. *Dr. Brigham is Business Development Advisor and member of the Fund Raising Committee of Aveni Foundation.