

TUMOR MARKERS FOR DELTAREX-G GENE THERAPY, THE SAFER CHECKPOINT INHIBITOR FOR SARCOMA

A BEACON IN OUR CAMPAIGN AGAINST SARCOMA

LOS ANGELES, CA, UNITED STATES, November 11, 2020 /EINPresswire.com/ -- The Aveni Foundation and the Sarcoma Oncology Center / Cancer Center of Southern California, Santa Monica, CA, USA, are proud to announce the pre-meeting publication of an important study for presentation at the Connective Tissue Oncology Society virtual meeting to be held on November 19-21, 2020. Abstract # 152: BIOMARKERS FOR DELTAREX-G, THE SAFER CHECKPOINT INHIBITOR FOR SARCOMA: A SINGLE CENTER EXPERIENCE. Authors: Paul Stendahl Dy, Kelly Wang, Ted T. Kim, Don A. Brigham, Sant P. Chawla, Sheng Xiao, Frederick L. Hall, and Erlinda M. Gordon, Sarcoma Oncology Center, Santa Monica CA, USA, and Brigham and Women's Hospital, Harvard University, Boston MA, USA (www.ctos.org).

Metastatic cancer is, hitherto, associated with an invariable fatal outcome. DeltaRex-G (a tumortargeted gene vector displaying a Signature (SIG)-binding peptide and encoding a CCNG1 inhibitor gene) has induced long-term (>12 years) survival in

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patients with hard-to-treat cancers including Stage 4 sarcoma, lymphoma, cancer of the pancreas and breast, with minimal, if any, side effects (Molecular Therapy Vol 27 No 4S1 April 2019, abs 275). Two patients had available molecular profiles, which included mutations along the CCNG1 pathway: TP53, PIK3CA, and MAP kinase.

The Objectives of the study are: (1)To evaluate the frequency of genetic mutations along the CCNG1 pathway in patients with sarcoma, and (2) To identify patients who are likely to benefit most from DeltaRex-G tumor-targeted gene therapy. Methods: The molecular profile of archived tumors of four hundred fifty-one (451) patients who were treated at the Cancer Center from

October 2019 to April 2020 were examined. Results: CCNG1 pathway mutations were found in 62 of 157 (39.5%) patients, with 22 (36%) patients having leiomyosarcoma (LMS). The tumors of three patients were tested for CCNG1 expression and all 3 tumors showed enhanced expression (80-90% cancer cells) of the CCNG1 protooncogene. The authors conclude that (1) Genetic mutations along the CCNG1 pathway in sarcoma are not uncommon; (2) These mutations may serve as novel biomarkers for genetargeted therapy, specifically with DeltaRex-G, to prolong survival and potentially, elicit a cure, and (3) A Phase 2 study using DeltaRex-G is warranted to correlate treatment outcome parameters in patients with genetic mutations along the CCNG1 pathway.

The Aveni Foundation is actively raising funds for this Phase 2 study. According to Dr. Erlinda M. Gordon, Director of Biological and Immunological Therapies at the Sarcoma Oncology Center: "The results of this Phase 2

A Retroviral vector B Tumor targeting C Genetic payloads

SIG-targeting peptide

Genetic payload

Tumor microenvironment

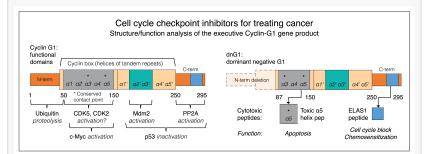
SIG proteins

"Dominant negative" construct

Cytocidal dnG1:
Enforced dnG1 expression blocks the executive cell cycle checkpoint functions of Cyclin G1

Tumor blood supply

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).



Structure/Function analysis of the executive Cyclin G1 gene product. 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. The M

study is hypothesis generating and will be used in planning a Phase 3 clinical trial to determine if augmented CCNG1 gene expression and/or genetic mutations along the CCNG1 pathway are definitive biomarkers that would predict a favorable response to DeltaRex-G gene therapy".

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"The results of this Phase 2 study will be used in planning a Phase 3 clinical trial to prove that enhanced CCNG1 gene expression in tumors predicts a favorable response to DeltaRex-G gene therapy"."

Erlinda M. Gordon, M.D.

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