DELTAREX-G GAINS FDA AUTHORIZATION AS FIRST-LINE THERAPY FOR EARLY-STAGE TRIPLE RECEPTOR POSITIVE BREAST CANCER

PREVENTING RECURRENCE WITH TUMOR-TARGETED GENE THERAPY: A LITMUS TEST

LOS ANGELES, CA, UNITED STATES, January 4, 2021 /EINPresswire.com/ -- The Aveni Foundation (www.avenifoundation.org), and the Cancer Center of Southern California (www.cancercentersocal.com) are proud to announce that the USFDA has granted authorization for DeltaRex-G in combination with trastuzumab and letrozole as first-line therapy of a patient with early stage hormone receptor positive and HER2/neu amplified invasive ductal carcinoma of breast. Triple receptor positive breast cancer is relatively rare and occurs in only 10% of patients with invasive ductal carcinoma of breast, which occurs in 1 out of 8 women in the United States.

AVENI FOUNDATION

The Aveni Foundation mission is to expedite development of gene-targeted technologies for cancer and COVID-19, an unmet medical need.

In a Phase 1/2 study using DeltaRex-G for chemotherapy-resistant Stage 4 breast cancer, DeltaRex-G induced 17.6% response rate by PET/Choi criteria, 76% tumor control rate and 83% one-year survival rate, with minimal, if any, systemic toxicity, and with 2 patients still alive >10 years after DeltaRex-G treatment initiation (Bruckner et al., Molecular Therapy Vol 27 No 4S1, abstract #273). According to Dr. Sant Chawla, principal investigator at the Cancer Center of Southern California, “These data suggest that (1) DeltaRex-G is uniquely safe and exhibits antitumor activity, (2) PET/ Choi are more sensitive indicators of early tumor response to DeltaRex-G and should be used to evaluate efficacy, (3) DeltaRex-G induced long term (>10 years) survival in 2 patients with pure bone metastases who subsequently received DeltaVax immunotherapy, (4) DeltaRex-G may prove to be a biochemical and/or antigen modulator when combined with other cancer therapy/ immunotherapy, and finally (5) DeltaRex-G is a viable alternative treatment for patients who choose not to receive standard toxic chemotherapy that may predispose them to secondary malignancies, debilitating

peripheral neuropathy and other untoward side effects that impair quality of life while undergoing treatment for breast cancer.

DeltaRex-G is a tumor-targeted gene therapy that (a) displays a Signature (SIG)-binding peptide on its surface for targeting the tumor microenvironment, and (b) encodes a designer killer gene for eradicating cancer cells. When injected intravenously, the DeltaRex-G nanoparticles seek out and accumulate in the cancerous lesions where Signature (SIG) proteins are abnormally found, in the vicinity of cancer cells, hence augmenting effective drug concentration.

US Marine Corps Officer and Naval Aviator (Ret.)

From our experience in 5 Phase 1 and 2 US-based and 2 Philippine-based clinical trials for metastatic cancer, we have shown that intravenous DeltaRex-G has minimal, if any, systemic toxicity, and may be effective in prolonging life of Stage 4 cancer patients. According to Dr. Don A. Brigham, Director, Business Development, “This is the litmus test for DeltaRex-G in eradicating microscopic disease and preventing recurrence of breast cancer. If successful, this FDA authorization of DeltaRex-G as first line therapy for early-stage breast cancer establishes a precedent for the use of DeltaRex-G in patients who refuse to receive toxic chemotherapy and radiation therapy (“Right to Try” Law of 2018).

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>
> *Don A. Brigham, PhD*

A Phase 2/3 clinical trial is planned to evaluate if DeltaRex-G is equally effective (not-inferior-to) than standard chemotherapy/radiation therapy as first-line therapy for early-stage hormone receptor positive and HER2/neu amplified breast cancer. To donate for the Breast Cancer clinical trial:

- Click on the DONATE button at www.avenifoundation.org
- Send a check to: Aveni Foundation, 2811 Wilshire Blvd., Suite 414, Santa Monica CA 90403
- Wire funds to: Chase Bank, Account Name: Aveni Foundation, Routing No: 322 271 627 Checking Acct. No.: 317 312 673, SWIFT CHASUS33

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

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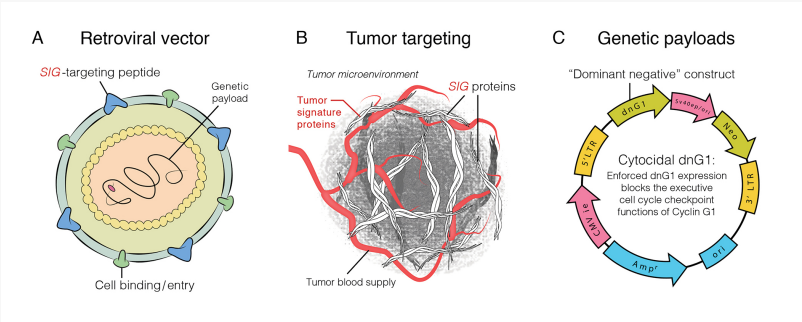

Graphic illustration of DeltaRex-G vector. The DeltaRex-G vector displaying a Sig targeting peptide (A), for binding to Signature (Sig) Proteins in the tumor microenvironment [TME] (B), and encodes a dominant negative human cyclin G1 inhibitor gene (C).
