GenVivo to Present at the 2024 American Association for Cancer Research (AACR) Annual Meeting

Presentations characterize GenVivo's targeting vector development and safety data from a Phase 1 clinical trial of GEN2.

PASADENA, CA, UNITED STATES, April 10, 2024 /EINPresswire.com/ -- GenVivo, Inc., a private clinical stage company with breakthrough off-the-shelf platforms for personalized cancer immunotherapies, today announced that two posters are being presented at the American Association for Cancer Research (AACR) Annual Meeting, April 5-10, in San Diego, CA. Data presented by GenVivo demonstrates their advances in targeted vector technology. In vitro and In vivo studies show that the pseudotyped gene delivery system has target cell specificity and increased transduction. Data from a Phase 1 clinical trial of GEN2, a non-replicating retroviral gene transfer vector encoding a sequence-optimized enhanced herpes simplex thymidine kinase (HSV-eTK) gene and Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) gene, showed no evidence or integration via peripheral blood mononuclear cells (PBMCs), or replication, via replication competent retrovirus (RCR) testing.

Presentation

- Session Title: Experimental and Molecular Therapeutics, Vector Systems, Oncolytic Virotherapy, and Gene Therapy
- Session Date and Time: Wednesday, April 10, 2024 from 9:00 AM to 12:30 PM PT

Poster 1

- Abstract Title: EVALUATION OF SCFV AND DIABODY PSEUDOTYPED SINNDBIS ENGINEERED

RETROVECTORS FOR TARGETED CANCER THERAPY

- Presenter: Makoto Sato, Ph.D., Sr. Principal Scientist in Research and Development at GenVivo, Inc.
- Abstract Number: 5605
- This study explores methods of targeting specific cancer cells and organs by modifying vector biodistribution.
- Our novel gene delivery system was pseudotyped with an engineered Sindbis Virus (SB) envelope bearing an antigen-binding domain. The SB envelope was engineered in a number of ways to improve transduction into target tissues, including direct incorporation of a single-chain variable fragment (scFV) and diabody (DB) sequences.
- HER2-targeting vectors delivering the Luciferase (Luc) reporter was evaluated in SKBR3 (HER2 over-expressing) and MDA-MB-468 (HER2-null) cancer cells. When comparing HER2-targeting vectors with scFv vs. DB sequences based on the same antibody, transduction capability was higher with the DB motif.
- Targeting vectors delivering HSV-eTK were also constructed, and ganciclovir (GCV)-mediated cell killing was evaluated in vitro. SKBR3 cells transduced with HER2-targeting vectors showed significantly more cell killing after GCV treatment than after transduction with an amphotropic vector.
- The in vivo study indicated higher transduction by anti-HER2 DB-targeted vector compared to the amphotropic control vector when dosed at the same infectious titer.

Poster 2

- Abstract Title: SERIAL ASSESSMENT OF GEN2, A RETROVIRAL VECTOR FOR GENE TRANSFER OF AN OPTIMIZED THYMIDINE KINASE AND GM-CSF, FOR GENOMIC INTEGRATION INTO PERIPHERAL BLOOD MONONUCLEAR CELLS (PBMCS) IN A PHASE 1 CLINICAL TRIAL IN ADULT PATIENTS WITH SOLID TUMORS
- Presenter: Alison L. Hannah, MD, Chief Medical Officer at GenVivo, Inc.
- Abstract Number: 7250
- GEN2 in combination with valganciclovir (an oral formulation of ganciclovir) was evaluated in a dose-escalating Phase 1 clinical trial in adult patients with advanced solid tumors (NCT04313868), with serial assessment of PBMCs to detect any GEN2 integration and replication competent retrovirus (RCR).
- PBMCs were obtained for evaluation of RCR and genomic integration of GEN2 at Cycles 1 and 2, and thereafter at 6-month intervals for 15 years, or until death or withdrawal of consent.
- All samples assayed from the intravenous cohorts 1-12 were below LOD (Limit of Detection) for RCR. All results for integration were BLOQ (Below Limit of Quantitation).
- These findings are consistent with a recent review in which no evidence of RCR in 1,595 post-treatment PBMCs obtained from 60 clinical trials was demonstrated (Mol Ther 2023 31(3):801).
- 2020 FDA Guidance for Industry, serial assessment of vector integration is mandated in a gene therapy clinical trial for up to 15 years following last dose. This guidance was conceived for gene therapy treating rare hereditary diseases in pediatric patients. Also, RCR has not been detected in any clinical lot of retroviral vectors to date (Mol. Ther. Meth. & Clin. Dev. 28:28).

• These results confirm undetectable genotoxic risk of GEN2 at all doses tested to date and support cessation of blood draws to assess RCR/integration in early state clinical trials for patients with advanced solid tumors after one year.

About GenVivo
GenVivo's approach is to synergistically attack tumors to release patient specific antigens (neoantigens), which in the presence of a cytokine, results in the generation of immune effector cells, which continuously amplify therapeutic immune responses. Our lead candidate, GEN2, is currently in a Phase 1 clinical trial (NCT04313868) in Asia. The first US enrolled patient is anticipated to be dosed in Q2 2024.

For more information about GenVivo, visit https://genvivoinc.com/

Forward-Looking Statements
This press release contains forward-looking statements of GenVivo, Inc. ("GenVivo") that involve substantial risks and uncertainties. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are based on current beliefs and expectations and are not guarantees of future performance. GenVivo may not actually achieve the plans, intentions, or expectations disclosed in these forward-looking statements, and you should not place undue reliance on these forward-looking statements. In addition, the forward-looking statements included in this press release represent GenVivo's views as of the date of this press release. GenVivo anticipates that subsequent events and developments will cause its views to change. However, while GenVivo may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so.

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