Immediate Release

Geneos Therapeutics Announces Clinical Updates on Personalized Cancer Vaccine Program

Highlighted its Phase Ib/Ila trial in advanced hepatocellular cancer and a case study for treatment of anaplastic astrocytoma at the American Society of Clinical Oncology (ASCO)

Data from first 10 patients in the HCC trial demonstrates clinical responses

Abstract #: TPS2680
Abstract #: e14561

PLYMOUTH MEETING, PA – June 03, 2021 – Geneos Therapeutics, a clinical stage company focused on the development of tumor neoantigen targeted personalized immunotherapies for cancer, announced today positive preliminary results of its ongoing first-in-human trial. GT-30 is a phase I/II trial of personalized vaccine, GNOS-PV02, in combination with plasmid pIL-12 and pembrolizumab in patients in second line advanced hepatocellular carcinoma (HCC).

As of May 13, 2021, 12 patients had initiated treatment in the GT-30 trial and received at least 1 dose of combination therapy. The treatment was generally safe and well tolerated with no serious treatment-related adverse events noted on the trial. Ten patients had reached at least the first on-treatment imaging timepoint of 9 weeks to enable evaluation of objective response by RECIST 1.1. The best overall response by the data cut-off date consisted of 3 patients achieving a partial clinical response (PR); 4 patients demonstrated stable disease (SD); and 3 patients had progressive disease (PD); representing an overall response rate (ORR) of 3/10 (30%) and a disease control rate of 7/10 (70%). The ORR of anti-PD1 as monotherapy in HCC is 14%-17%. Immune analysis of the pre-treatment and on-treatment patient samples demonstrated the induction and expansion of T cell clones in the peripheral blood and infiltration of T cells in the tumor tissue following vaccination.

Dr. Mark Yarchoan, Assistant Professor of Oncology, Johns Hopkins University will discuss the clinical trial design and advantages of Geneos’ GT-EPIC platform in an ASCO 2021 oral poster presentation titled:

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“Personalized DNA neoantigen vaccine in combination with plasmid IL-12 and pembrolizumab for the treatment of patients with advanced hepatocellular carcinoma.” – Yarchoan et al

Geneos is also presenting data from its ongoing collaboration with Dr. Tanner Johanns and colleagues at Washington University School of Medicine to treat a patient with newly diagnosed anaplastic astrocytoma/GBM under a single patient compassionate use IND. The patient is undergoing monotherapy treatment with their personalized cancer vaccine (GNOS-PV) and pIL12 in an adjuvant setting following resection of their tumor. As of the ASCO 2021 conference date the patient remains recurrence free 36 months since primary surgery and 23 months since initiation of the GNOS-PV + pIL12 treatment. The interim data demonstrated that the treatment was generally well tolerated with no treatment related serious adverse events. The patient received a vaccine comprising of 30 tumor antigens including 27 cancer neoantigens and 3 shared antigens. On-
treatment immune analysis showed the induction and persistence of neoantigen directed T cells in the patient’s blood to 28 of 30 (93%) encoded antigens following GNOS-PV + pIL12 treatment.

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“Personalized DNA neoantigen vaccine in combination with plasmid IL-12 for the treatment of a patient with anaplastic astrocytoma.” – Johanns et al

“We are encouraged by the interim data from our personalized cancer vaccine program showing tumor shrinkage in combination with anti-PD1. Our GT-EPIC™ platform’s ability to drive CD8 T cells leading to meaningful clinical responses in intractable tumors is exciting,” said Dr. Niranjan Y. Sardesai, President and CEO of Geneos Therapeutics. “A distinguishing feature of our HCC trial is that all the patients receive their first dose of GNOS-PV02+pIL12 at the same time as they receive their first dose of PD1 thus enabling direct comparison to the historical responses achieved by PD1 alone. These early data represent the first objective responses reported in HCC patients with plasmid DNA encoded cancer vaccines.”

About Geneos Therapeutics

At Geneos Therapeutics, we believe that personalized therapies are the future of cancer treatment. Our passion is to develop personalized therapies to unleash the most powerful force against cancer – the patients’ own immune system. Our approach using our GT-EPIC™ platform is to target unique neoantigens (abnormal mutations produced by cancer cells) from individual patient tumors to develop novel and personalized treatments for cancer.

About GT-30 trial:

The GT-30 trial (NCT04251117) is a single-arm phase I/II clinical trial to assess the safety, immunogenicity, and preliminary efficacy of GNOS-PV02 in combination with cytokine IL-12 (pIL12; INO-9012) and pembrolizumab in patients with advanced HCC. Twenty-four patients are anticipated to be enrolled. After progression or intolerance with first-line therapy, patients can commence trial therapy with concurrent personalized vaccine and pembrolizumab. Patients are recruited upon diagnosis or during first-line treatment with tyrosine kinase inhibitors (TKI). Tumors are biopsied for exome and transcriptome sequencing. The tumor specific vaccine is designed, optimized and manufactured during first-line therapy. Each vaccine encodes up to 40 neoantigens, which includes all detected neoantigens for the majority of HCC patients. GNOS-PV02 + pIL12 are administered Q3w for the first 4 doses and Q9w thereafter until disease progression. Pembrolizumab is delivered Q3w until disease progression. Immunogenicity of each of the vaccine epitopes is determined by ex vivo ELISpot and flow cytometry. Clinical activity is assessed by RECIST1.1 at baseline and every 9 weeks. Serial biopsies are obtained at 9 weeks and upon disease progression to evaluate changes in the exome, transcriptome and changes to the tumor microenvironment.

About GT-EPIC™ Platform:

Geneos Therapeutics’ GT-EPIC™ Neoantigen-Targeting Platform is based on clinically-validated DNA medicines technology exclusively licensed from Inovio Pharmaceuticals, Inc. (NASDAQ: INO) for use in developing personalized, neoantigen-targeting immunotherapies. The GT-EPIC™ platform allows Geneos to develop exquisitely personalized DNA-based therapies tailored to each patient’s unique tumor mutations. The platform is developed to deliver the following key advantages: ability to drive potent and broad T cell immune responses, capability to target an unprecedented number of neoantigens in a single formulation, and a rapid manufacturing turnaround time. Geneos believes that these are three key differentiators that will drive the company, and the oncology space, into the next generation of neoantigen targeted immunotherapies.

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This press release contains certain forward-looking statements relating to our business, including our plans regarding the development of tumor neoantigen targeted personalized immunotherapies for cancer, our expectations regarding our research and development programs, including the planned expansion and conduct of clinical trials and the availability and timing of data from those trials, and the use of our capital resources. Actual events or results may differ from the expectations set forth herein. There can be no assurance that any product candidate in Geneos’ pipeline will be successfully developed, manufactured or commercialized, that final results of clinical trials will be supportive of regulatory approvals required to market licensed products, or that any of the forward-looking information provided herein will be proven accurate. Forward-looking statements speak only as of the date of this release, and Geneos undertakes no obligation to update or revise these statements, except as may be required by law.