VGXI Enables Rapid GMP DNA Manufacturing Timeline for Geneos Therapeutics Personalized Cancer Immunotherapy

VGXI, Inc., Geneos Therapeutics' CDMO partner, completes manufacturing of first GMP Lot under Clinical Manufacturing Supply Agreement.

THE WOODLANDS, TX AND PLYMOUTH MEETING, PA (PRWEB) MAY 19, 2020

Leading plasmid DNA contract manufacturer VGXI, Inc. announced it has completed accelerated cGMP manufacturing of the first clinical batch of a personalized neoantigen vaccine for its client Geneos Therapeutics, Inc. Geneos is focused on developing DNA-based, neoantigen-targeting personalized cancer immunotherapies. Starting with receipt of seed plasmid DNA from Geneos, the VGXI team achieved a record-setting timeline of 5 days from host cell transformation to filled drug product manufacturing, and less than 2 weeks from transformation to release and shipment of the patient's first dose. Overall, these timelines are a fraction of the 6 to 8 month turnaround time for GMP plasmid DNA that is standard in the industry, and they have been accomplished while maintaining the exceptional product quality for which VGXI is well known.

"Decades of experience and optimization of VGXI's established, proprietary methods for DNA plasmid purification have allowed us to support the unique requirements of our client's project." Stated VGXI CEO Young Park. "This achievement represents the first personalized neoantigen vaccine product manufactured for Geneos' clinical studies, and I am confident we will continue to deliver unparalleled product quality and rapid turnaround for subsequent patients as enrollment of the trial proceeds."

VGXI's efforts represent a critical element of Geneos' integrated GT-EPIC[™] platform. Geneos has established a broad collaboration created specifically to achieve the rapid biopsy-to-treatment turnaround times needed for personalized cancer therapies. The full GT-EPIC[™] platform includes patient tumor exome/transcriptome sequencing and identification of the relevant neoantigen targets followed by neoantigen vaccine design, synthesis of the

seed plasmid DNA, vaccine manufacture, and final delivery of the personalized neoantigen vaccine – with all platform elements executed within an overall timeline of 6 - 8 weeks. The patient specific GMP product lots manufactured under the VGXI supply agreement will support Geneos' previously announced GT-30 clinical trial focused on the treatment of patients with advanced hepatocellular cancer.

Dr. Niranjan Y. Sardesai, Geneos' Co-Founder, President & CEO said, "Achievement of rapid biopsy-to-treatment manufacturing turnaround times is an important differentiating milestone for the GT-EPIC[™] platform in enabling these personalized treatments to be available faster for advanced cancer patients. We are pleased with our plasmid manufacturing partnership with VGXI in support of our GT-30 clinical trial. With their proven GMP manufacturing expertise, VGXI rose to the challenge and has enabled us to achieve our rapid manufacturing goals."

ABOUT VGXI, INC.

VGXI, Inc. has nearly 20 years of experience and is a leading provider of plasmid DNA manufacturing and



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Contact Author

CHRISTY FRANCO

VGXI, Inc. 2814663790 Email >

JEFF RICHARDSON

Geneos Therapeutics 267-440-4211 Email >

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This achievement

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development services. The company has a reputation of success in manufacturing DNA products under cGMP conditions for clinical trials in the US, EU, Asia, Canada, and Australia, and its cGMP and non-GMP products have passed rigorous reviews by several international regulatory agencies. VGXI's ability to work with unique requirements and create custom manufacturing solutions is based on its patented manufacturing process, flexible cGMP production facility, and experienced development team. VGXI, Inc. is a wholly-owned subsidiary CDMO of GeneOne Life Science, Inc. To learn more, visit https://www.vgxii.com.

ABOUT GENEONE LIFE SCIENCE

GeneOne Life Science Inc. ("GeneOne" KOSPI: 011000) is an international DNA vaccine and product developer, and leading contract manufacturer of DNA plasmid-based agents for pre-clinical and clinical trials for global companies and institutions. It researches and develops DNA vaccines and products to prevent and treat incurable diseases in South Korea and internationally. The company is headquartered in Seoul, South Korea. VGXI, Inc., GeneOne's wholly-owned subsidiary located in Texas, is a leading cGMP DNA plasmid manufacturing facility. For more information, visit http://www.genels.com.

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 – your body's 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 treatments for cancer. We have an experienced management team with a track record of success in building immunotherapy-based companies. Geneos was created as a spinout of Inovio Pharmaceuticals, Inc. (NASDAQ: INO). For more information, visit http://www.geneostx.com

CAUTIONARY FACTORS THAT MAY AFFECT FUTURE RESULTS

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