Elegen and Nutcracker Therapeutics to Pilot First Fully Cell-Free Manufacturing Process for RNA-based Personalized Cancer Therapeutics

Fully cell-free process aims to further democratize personalized cancer therapeutic manufacturing with shorter turnaround times and negligible bioburden and endotoxin risks.

SAN CARLOS and EMERYVILLE, Calif., July 11, 2025 — Elegen, a global leader in next-generation DNA manufacturing, and Nutcracker Therapeutics, a global leader in next-generation RNA design and manufacturing, today announced the launch of a pilot program to demonstrate the industry's first fully synthetic, cell-free manufacturing platform for RNA-based personalized cancer therapeutics (PCTs). The pilot marks another step toward making PCTs more accessible, timely, and scalable.

As late-stage PCT clinical trials progress and therapy developers work to create the next generation of PCTs, the speed, reliability, scaling and cost of traditional production methods pose a major challenge. Specifically, the first step of DNA template production is hindered by the use of bacterial cells in the process, which can be unreliable and introduce contamination that must be removed. The second step of GMP-grade RNA production from the template is impeded by a slow, unreliable, and inefficient process in which only one therapy can be made per GMP suite. Consequently, PCT production is slow, very costly, and does not scale for individualized therapies — a new manufacturing paradigm is needed.

Nutcracker Therapeutic's NMU-Symphony™ system, the second generation of its Nutcracker® Manufacturing Unit (NMU), brings the fastest, most scalable, and cost-efficient GMP RNA manufacturing platform available today. Fully enclosed and built for speed, it reliably delivers clinical-grade PCTs consistent with just a three-week overall turnaround time, from RNA sequence design to released nanoparticle formulated drug product — cutting traditional timelines in half. By incorporating Elegen's cell-free GMP-ready DNA template production, the combination of the two platforms will enable an even faster and more scalable synthesis of longer, more complex neo-antigen sequences, while eliminating risks of bioburden and endotoxin contamination.

With a faster, more reliable and lower-cost solution, Elegen and Nutcracker Therapeutics aim to democratize PCTs, making them accessible to more developers and saving critical time for cancer patients, where even days can make a meaningful impact.

"Integrating cell-free DNA with cell-free biochip-based RNA production gives researchers and partners worldwide access to a more reliable, streamlined, and cost-effective platform to rapidly test and advance new therapies," said Matthew Hill, founder and CEO of Elegen. "By eliminating cells from the process, we can accelerate the development and evaluation of new therapeutic modalities, helping patients receive treatment as quickly as possible."

"We're not just improving our manufacturing process, we're laying the foundation to democratize PCTs with truly scalable solutions," added Benjamin Eldridge, co-founder and chief technology officer of Nutcracker Therapeutics. "Achieving that vision means giving developers the ability to

produce clinical-grade RNA without investing hundreds of millions in infrastructure. This is a key step toward our mission of delivering scalable, low-cost, and rapid formulated RNA manufacturing for individualized therapies."

Elegen's cell-free ENFINIA DNA with an unparalleled combination of speed, length, accuracy and complexity integrates seamlessly with Nutcracker Therapeutics' existing RNA-based PCT development process, which leverages artificial intelligence and machine learning technologies through its CodonCracker™ RNA design software, the NMU-Symphony™ microfluidics biochip-based system, and ProcessVision™ technology for real-time performance and quality monitoring. Combined, Elegen and Nutcracker Therapeutic's technologies enable the efficient, flexible, and GMP-ready production of individualized nanoparticle-formulated RNA therapeutics.

About Elegen, Inc.

Elegen brings unique insights and technical innovation to create high-quality synthetic DNA faster, catalyzing the next revolution in the life sciences. Elegen uses proprietary cell-free technologies to build longer, higher-quality DNA on a faster timeline for agricultural, chemical, healthcare and pharma industries. Founded in 2017, Elegen is privately held and based in the San Francisco Bay Area.

For more information, visit elegenbio.com and connect with us on LinkedIn and X (Twitter).

About Nutcracker Therapeutics, Inc.

Nutcracker Therapeutics, Inc., is a biotechnology company that combines advanced engineering with high-precision biosynthesis to unlock the promise of RNA for therapeutic developers. The company's mission is to democratize safe and effective RNA-based personalized therapeutics through its complete technology platform, which encompasses the design, delivery, and manufacturing of RNA molecules. Armed with this high-tech advantage, Nutcracker Therapeutics' unique scalable RNA platform significantly reduces costs and cycle times, while maintaining the highest quality.

For more information, visit www.nutcrackerx.com.

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