

Ncardia launches Cellistic, an iPSC cell therapy CDMO

Ncardia launches Cellistic™, the only iPSC-based cell therapy process development & manufacturing partner purpose-built to make large-scale allogeneic cell therapy production a reality today.

GOSSELIES, BELGIUM (April 19, 2020)

Ncardia has launched a new business, Cellistic™ to focus Ncardia's induced pluripotent stem cell (iPSC) expertise on the cell therapy development and manufacturing sector. This strategy expands on Ncardia's existing drug discovery solutions business and capitalizes on the company's deep expertise in iPSC differentiation and expansion to focus dedicated resources and capabilities to address the growing need for iPSC cell therapy solutions, including the development of robust cell-specific manufacturing platforms.

The development of cell therapies derived from iPSCs offers the possibility of effective treatments for many diseases and reducing the cost and complexity of current autologous cell therapies. However, there are a number of challenges that must be addressed in order to deliver on the promise of large-scale allogeneic cell therapy. Creating an effective therapeutic not only requires intimate knowledge of the disease being targeted, but also deep understanding of the processes required to generate the most relevant cell type to treat the disease, and the expertise to scale that process to clinically and commercially feasible volumes. These differentiation and expansion activities present unique challenges and require unique experience and skills which, until the launch of Cellistic™ have not been available to therapeutic developers without extensive investment in internal capabilities.

Cellistic™ consolidates in one business unparalleled depth of knowledge in human biology with scalable industry-ready process science capabilities, bringing more than 10 years of iPSC-based development expertise purpose-built to enable the industry to deliver therapies to millions of patients around the world. Cellistic's services are designed to address significant unmet needs from therapeutic developers in allogeneic cell therapy, including immediate access to a broad range of differentiation and bioreactor-based expansion protocols; comprehensive, scalable cGMP capacity; analytical support; and clinical readiness support for global regulatory submissions. Cellistic™ is integrating these offerings in complete workflows based on proprietary cell-specific manufacturing platforms which will offer therapeutic developers support for IND-filing and will include the GMP capacity to commercialize the iPSC-based therapies of the future.

"Patients and biopharmaceutical companies are seeking cell-based treatments more urgently than ever – and for a broadening range of diseases," says Stefan Braam, PhD, Ncardia CEO and CSO. "What has hindered the ongoing evolution of cell-based therapies is the reliance on slower, more expensive, one-batch-per-patient autologous approaches and scale-limited manufacturing processes. For more than a decade, we have been working to develop the scientific, technological and large-scale allogeneic manufacturing capabilities whose time has come."

Ncardia's technology portfolio and expertise have been validated by a collaboration and partnering track record in process development and scale-up with Bluerock Therapeutics and other companies.

"Producing predictably differentiated, characterized and functional cells for large-scale allogeneic iPSC treatments requires the kind of development and production sensitivity that comes only from years of

scientific, real-world process and production expertise,” says Elena Matsa, PhD, Vice President of Cell Technology. “Cellistic™ brings exactly that level of knowledge. We know how to handle cells, how to verify cell type and functionality, and how to manufacture safe and efficacious end-products at scale. Our proprietary manufacturing infrastructure has been developed and fine-tuned for more than a decade and is unique in the industry.”

“For more than a decade, Ncardia has invested strategically in developing the expertise and technical know-how to enable large-scale production of allogeneic iPSC treatment modalities – well ahead of market demand for them,” says Andy Holt, Chief Commercial Officer. “Our long-held commitment to this science is now being given the resources to advance clinical programs, as patients and biopharmaceutical companies turn more urgently to cell-based therapeutics as the only modality with the promise to treat many disease states unresponsive to other therapies. We have been growing into this opportunity since our inception. We believe that the market is now not only ready for, but in great need of, our unique capabilities to advance cell therapy innovations to patients.”

About Cellistic™

Launched in April 2022, Cellistic™ specializes in process development and manufacture of cell therapies based on human induced pluripotent stem cell (iPSC) technology. Its focus and expertise in iPSC reprogramming, differentiation, and expansion protocol development positions the business to be the partner of choice for innovative cell therapy developers to commercialize novel advanced therapies. Leveraging more than a decade of Ncardia’s scientific and technical knowledge and experience, Cellistic™ possesses unique capabilities for the design and optimization of proprietary manufacturing platforms for iPSC-based cells that deliver quality products at scale. For more information, visit www.cellistic.com.

About Ncardia

Ncardia is a leader in contract research, development and manufacture of iPSC-based solutions for early and preclinical drug discovery. Its goal is to enable pharmaceutical and therapeutics companies to make more confident decisions in discovery and development by integrating iPSC technologies into their screening processes. Ncardia’s capabilities include disease modeling, manufacturing, assay development and high-throughput screening especially for cardiac and neurodegenerative diseases. Ncardia was founded in 2011 and is majority-owned by KINICITI a private equity-backed advanced therapies platform. For more information, visit www.ncardia.com.