

Press Release

Exyte Empowers the Biopharmaceutical Industry: First ExyCell® Facility Launched in Shanghai

Stuttgart and Bergisch Gladbach, 29 July 2021. Exyte has successfully completed the construction of the first ExyCell® facility in China, the CliniMACS Cell Factory® of Miltenyi Biotec, a global provider of integrated solutions for Advanced Therapy Medical Products (ATMPs). The patented ExyCell technology was developed by Exyte as an end-to-end, integrated facility solution with standardized and modularized elements. These pre-configured and pre-fabricated modules enable fast-track construction thereby shortening time-to-market for new therapeutics and vaccines. The ExyCell facility is installed on the fourth floor of the ATLATL building located in the Zhangjiang High-Tech Park, and Miltenyi Biotec is now transferring production technology from Germany to China with regular operations for ATMP production is expected by autumn 2021. The facility will soon be open to visitors by appointment.

Through their cooperation, Exyte and Miltenyi Biotec have developed an innovative, sustainable, and cost-effective facility for cell therapy manufacturing. This facility combines the CliniMACS Cell Factory manufacturing platform with the pre-fabricated ExyCell module enabling a fast deployment of small, medium, and large scale cell manufacturing facilities based on a flexible cell therapy manufacturing module. Endusers can purchase a personalized version of this pre-engineered and pre-fabricated manufacturing module ready to host their CliniMACS Cell Factory for ATMPs.

Chris Miller, President Global Business Unit Biopharma and Life Sciences at Exyte stated: “The completion of the first ExyCell facility with our partner Miltenyi Biotec marks an important milestone. We consider ExyCell to be a transformational development of our “next generation” of award winning modular concepts.” Exyte has developed and implemented several other modular facilities including the renowned Catapult Development and Manufacturing Centre for cell and gene therapy in Stevenage, UK, several modular biotech facilities in China, and a large modular biomanufacturing facility for upstream and downstream processing in Lithuania. All these plants have been designed and constructed, shipped, and installed for operational readiness.

Dr. Boris Stoffel, Member of the Management Board of Miltenyi Biotec, emphasized the importance of this partnership: “As a company, we want to enable our customers in their efforts to make innovative cell and gene therapies available to patients worldwide. We believe that combining the proven CliniMACS Cell Factory manufacturing platform with the pre-fabricated ExyCell module will help fast-tracking new therapies to the benefit of global healthcare.”

The effective combination of the CliniMACS Cell Factory ballroom concept built into the ExyCell module allows the flexibility to build, scale-up, expand, or repurpose a facility with minimal impact to ongoing production operations. The ExyCell platform can either be purchased in its standard version or adapted to specific needs of production capacity, cleanroom size, control systems, and finishing options. Exyte can build and qualify a turn-key ExyCell facility in a matter of months. The ExyCell facility sizes start from 75 m² for a fully equipped and operational turnkey facility hosting a CliniMACS Cell Factory with one to twelve CliniMACS

Prodigy® units, scaling up to several thousand square meters to accommodate several hundred units. The ExyCell facility can be either realized in an existing building or built in a greenfield setting and presents clients with the opportunity for a significant reduction in construction timelines and overall energy use. The design is adaptable to any process layout and meets the requirements for current Good Manufacturing Practice (cGMP).

Innovations in process technology, adaptable plant design, combined with the integration of physical and virtual supply chains allow biopharmaceutical manufacturers to remain competitive in a dynamic market. Biopharmaceutical manufacturers will benefit from the end-to-end sustainable solutions, which can be deployed globally, are cost predictable, provide speed to market, and flexibility for facility re-purposing. This reflects the characteristics of a drug lifecycle, mitigates associated risks, and effectively protects the CAPEX (capital expenditure) and OPEX (operational expenditure).



ExyCell module assembled in Exyte Workshop



The ExyCell module ready to host the CliniMACS Cell Factory at the Miltenyi Biotech office in Shanghai

About Exyte

Exyte is a global leader in the design, engineering and delivery of facilities for high-tech industries. With a history of more than 100 years, the company has developed a unique expertise in controlled and regulated environments. Exyte has a truly global footprint, serving the most technically demanding clients in markets such as semiconductors, batteries, pharmaceuticals, biotechnology, and data centers. The company offers a full range of services from consulting to the managing of turnkey solutions – delivered to the highest quality and safety standards. Solving the most complex challenges, Exyte forges trusted, long-lasting relationships with its clients. In 2020, Exyte generated sales of EUR 4.1 billion with around 4,900 highly experienced and motivated employees. The company is ideally positioned to further strengthen its market leadership with its broad industry insight and its exceptional talents.

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About Miltenyi Biotec

Miltenyi Biotec is a global provider of products and services that empower biomedical discovery and advance cellular therapy. Our innovative tools support research at every level, from basic research to translational research to clinical application. Used by scientists and clinicians around the world, our technologies enable solutions for cellular research, cell therapy, and cell manufacturing. Our more than 30 years of expertise spans research areas including immunology, stem cell biology, neuroscience, and cancer. Today, Miltenyi Biotec has more than 3,500 employees in 28 countries – all dedicated to helping researchers and clinicians make a greater impact on science and health.

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