PROJECT EVOLUTION

Projectevolution.org

1ST HALF FEBRUARY 2023 ADVANCED THERAPIES

CDMO & BIOMANUFACTURING

REACH OUT TO BRYAN KENNEDY AT BK@PROJECTEVOLUTION.ORG WITH ANY QUESTIONS

- 02.16.23 - LIfT BioSciences and Minaris Regenerative Medicine Enter into a Manufacturing Partnership (PR)
  - Under the terms of the agreement, Minaris, in conjunction with LIfT Biosciences are confident they can develop a Good Manufacturing Practice (GMP)-compliant manufacturing process to supply LIfT's clinical trial programmes in Europe, currently anticipated to start in Q1 2024. N-LIfT is made from Immunomodulatory Alpha Neutrophils committed myeloid progenitors (IMANp) that are manufactured ex vivo from hematopoietic stem cells (HSCs) of healthy donors who exhibit exceptional innate cancer killing properties. The unique mechanism of action of N-LIfT allows the product to work effectively through the innate immune pathway as well as activating multiple other factors of the adaptive immune system.
- 02.15.23 - Nexcella Enters into U.S. GMP Manufacturing Agreement to Expand Ongoing NXC-201 Phase 1b/2 Clinical Trial to the U.S. (PR)
  - Nexcella, Inc. initiates process of bringing NXC-201 to the United States by entering into an agreement with a well-known GMP cell therapy manufacturer that will supply Phase 1b/2 NXC-201 clinical trial material. NXC-201 is in development for the treatment of patients with relapsed or refractory multiple myeloma and light chain (AL) amyloidosis. Nexcella believes recently reported Phase 1b data from the ongoing Phase 1b/2 clinical trial supports investigating NXC-201 as the first potential outpatient CAR-T cell therapy
- 02.14.23 - A biomanufacturing site is coming to Canada's Prince Edward Island (endpts)
  - The governments of Canada and Prince Edward Island are placing a CAN 50 million ($37.4 million) investment into what is being dubbed the BioAccelerator, with the project being spearheaded by Prince Edward Island BioAlliance, a local business organization. According to an email from a PEI BioAlliance spokesperson, both the Canadian government and the local government contributed CAN 25 million ($18.7 million) to the project. This will be a new 75,000-square-foot biomanufacturing facility, allowing Canadian biotechs to carry out R&D operations as well as build out any manufacturing operations. The site will also provide access to manufacturing training. According to the email from PEI BioAlliance, the site will have expertise from the National Research Council and the Canadian Alliance for Skills and Training in Life Sciences.
- 02.14.23 - Charles River and Purespring Therapeutics Announce Gene Therapy Manufacturing Collaboration (yahoofinance)
  - Plasmid CDMO alliance supports first gene therapy platform targeting kidney diseases. Purespring is engaged in the development of novel therapies which have the potential to stop or significantly slow down chronic kidney diseases for which there is no current therapy available, except for dialysis or transplantation. With an innovative focus on the podocyte, a specialized kidney cell type implicated in many kidney diseases, Purespring's Adeno Associated Virus (AAV) based gene therapy presents a lower-dose, local delivery approach which maximizes both safety and efficacy, as well as lowering the cost of goods. Expanding its comprehensive cell and gene therapy portfolio to span plasmid DNA, viral vector, and cell therapy production, through the acquisitions of Cobra Biologics, Vigene Biosciences, and Cognate BioServices in 2021, and in addition to recent expansion projects, Charles River offers end-to-end support and supply chain simplification for developers seeking to accelerate their program while ensuring the highest quality control.
- 02.14.23 - Lonza opens US lab as part of early development services expansion (fiercepharma)
  - Lonza is opening a new laboratory in Cambridge, Massachusetts, as part of the Swiss CDMO's plan to expand its early development services (EDS) division in North America. The 17,000-square-foot facility is expected to begin operating in May and complements the company's existing EDS facility located in Cambridge, U.K
- 02.10.23 - Evotec receives € 150 m loan from European Investment Bank (PR)
  - Through this new financing of € 150 m, the EIB reiterates its supports to Evotec, a company that it already supported in 2017 with a financing of € 75 m. This new agreement is to be signed in Toulouse during a visit of the site on which the new biologics manufacturing facility will be built. The EIB funding specifically supports Evotec's business strategy through a unique, innovative and flexible financing structure including a low fixed interest rate plus a reward-sharing component for the EIB. The loan with a total volume of up to € 150 m will be invested over a period of three years and each tranche will mature seven years after draw down. Evotec will use the financing to fund its internal R&D activities, equity investments, as well as the new biologics manufacturing facility, J.POD® Toulouse, France (EU).
- 02.07.23 - Thermo Fisher Scientific launches Cell Therapy Collaboration Center Program in Singapore to accelerate therapy development across Asia Pacific (PR)
  - Thermo Fisher Scientific Inc., the world leader in serving science, today announced the launch of its new Cell Therapy Collaboration Center Program in Singapore to accelerate cell therapy development across the Asia Pacific region. The center, based in Singapore, will serve as the Asia Pacific hub to provide cell and gene therapy (CGT) developers with tailored support on their path to clinical manufacturing and commercial success.
- 02.02.23 - BioNTech Strengthens Manufacturing Capabilities with First In-House Plasmid DNA Manufacturing Facility in Germany (PR)
  - Plasmids are an important starting material for the manufacturing of mRNA- and cell-based drugs. The new plasmid manufacturing facility aims to increase BioNTech's autonomy and flexibility in manufacturing an important starting material for its oncology and COVID-19 vaccine pipeline The investment of approximately €40 million is part of a long-term development plan for BioNTech's manufacturing site in Marburg
- 02.02.23 - Center for Breakthrough Medicines (CBM) Launches Precision Plasmids™ Manufacturing to Accelerate Advanced Therapies into the Clinic (PR)
  - CBM, a contract development, and manufacturing organization (CDMO), has launched its plasmid manufacturing offering, Precision Plasmids™ to provide phase-appropriate plasmid on-demand for any company seeking to accelerate their path to clinic for cell and gene therapies. CBM offers NO WAIT TIMES for Precision Plasmids™ R&D grade for pre- and early clinical phases, and Precision Plasmids™ Pro grade for toxicology studies, Ph1-2 vector production, or as a starting material for mRNA. Both Precision Plasmids™ R&D and Pro are available now, while Precision Plasmids™ GMP grade will be available in April 2023.
- 02.01.23 - Bionova Scientific initiates expansion project to quadruple GMP biologics manufacturing capacity (PR)
  - Following Bionova Scientific's recent integration into the Asahi Kasei Group, project is the first phase of a wider strategic initiative to expand capacity and enhance end-to-end biologics development and manufacturing services. Bionova Scientific currently operates two facilities in Fremont: a headquarters and state-of-the-art development and GMP manufacturing facility on West Warren Avenue, and a nearby dedicated warehouse and storage facility on Fremont Boulevard. The new facility, located on Laurelview Court, will act as a replacement headquarters and development center, housing Bionova Scientific's administrative functions and biologics development teams that are currently located in the West Warren facility. In turn, the West Warren facility will become devoted to manufacturing operations, using advanced single-use equipment systems. The administrative offices and the labs for cell line development, process development and analytical services are expected to be moved to the Laurelview facility in mid-2023, making room for Bionova Scientific to quadruple its current biologics GMP manufacturing capacity in the West Warren facility shortly thereafter.