PROJECT EVOLUTION

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FIRST HALF MARCH 2023 ADVANCED THERAPIES COLLABORATIONS & M&A

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

Collaborations

- 03.14.23 - BlueRock Therapeutics to use Rune Labs' clinical trial platform to better characterize Parkinson's disease state in cell therapy trials (PR)
  - Collaboration is part of BlueRock's commitment to change the standard of care for treating Parkinson's disease which includes a first-in-class stem cell-based therapy bemdaneprocel (BRT-DA01), currently in a phase 1 clinical study.Results from the Phase 1 study are expected to be announced in the second half of 2023. Rune Labs launches StriveStudy clinical development platform to streamline enrollment, enable real world evidence (RWE) generation, monitor patient compliance with a study, and improve patient study experience. Cell therapy developer BlueRock is first to deploy StriveStudy, in conjunction with Rune Labs' StrivePD platform, to remotely collect real-time patient data and monitor patient compliance in research study.
- 03.13.23 - RoosterBio & Repligen Collaborate to Advance Scalable Exosome Bioprocessing (PR)
  - RoosterBio Inc., a leading supplier of human mesenchymal stem/stromal cells (hMSCs), highly engineered media, development services, cell engineering, and advanced therapy bioprocess solutions, today announced that it has selected Repligen Corporation, a life sciences company focused on bioprocessing technology leadership, as a collaboration partner to advance scalable exosome bioprocessing. RoosterBio's goal, in collaboration with Repligen, is to deliver solutions for manufacturing of exosomes using scalable and low shear technologies that enable cost-effective commercialization of these advanced therapies.
- 03.07.23 - Korro Bio and Genevant Sciences Enter into Collaboration Agreement to Develop RNA Editing Therapeutic for Alpha-1 Antitrypsin Deficiency (PR)
  - Korro Bio, a leading RNA editing company focused on the discovery and development of novel genetic medicines, and Genevant Sciences, a leading nucleic acid delivery company with world-class platforms and a robust and expansive lipid nanoparticle (LNP) patent portfolio, today announced that they have entered into an agreement to combine Korro's powerful RNA editing platform with Genevant's industry-leading LNP technology to develop a differentiated therapeutic option for patients with Alpha-1 Antitrypsin Deficiency (AATD). Terms of the agreement were not disclosed.
- 03.07.23 - Center for Breakthrough Medicines, Nucleus Biologics, and Stoic Bio Announce Strategic Collaboration for Steady Supply of Quality Controlled Cell Culture Media to Expedite Development of Cell and Gene Therapies (PR)
  - In a joint effort to accelerate high-quality therapies to market, Nucleus Biologics, The Cell Performance Company™, a leading provider of custom cell culture media solutions for the cell and gene therapy industry, and Stoic Bio, a provider of sustainable technology for cell media manufacturing, have announced plans for a supply agreement with the Center for Breakthrough Medicines (CBM), a leading contract development and manufacturing organization (CDMO), whose mission is to save lives by accelerating the development and manufacture of advanced therapies. This agreement makes Nucleus Biologics the preferred supplier of cell culture media and other critical biological solutions for CBM; thus, ensuring a steady, consistent supply of this critical material with tighter quality control measures.
- 03.07.23 - Danaher Partners With The University Of Pennsylvania's Center For Cellular Immunotherapies To Address Manufacturing Challenges Impacting The Uptake Of Cell Therapies (PR)
  - The multi-year partnership aims to develop new technologies that will improve the consistency of clinical outcomes for patients and overcome manufacturing bottlenecks in the delivery of next generation engineered cell products. The Beacon for Cell Therapy Innovation with Penn is a part of the Danaher Beacons program, which funds pioneering scientific research carried out in academic settings. The ultimate objective of this program is to develop innovative technologies and applications that can improve human health. The program's focus areas include genomic medicines, precision diagnostics, next generation biomanufacturing, human systems, and data sciences.
- 03.08.23 - Voyager Therapeutics Announces License Option Agreement with Novartis for Target-Specific Access to Next-Generation TRACER™ AAV Capsids for Gene Therapy Programs (PR)
  - Voyager receives $54 million upfront with potential option exercise fees and milestone payments of up to $1.7 billion plus product sales-based royalties. Novartis receives target-specific access to Voyager's novel TRACER AAV capsids for potential use with three CNS targets plus options to access capsids for two additional targets. Agreement marks the second recent major transaction leveraging Voyager's TRACER capsid discovery platform
- 03.08.23 - Tessa Therapeutics Enters into Cooperative Research and Development Agreement (CRADA) with the U.S. National Cancer Institute (PR)
  - Tessa is advancing a pipeline of products that utilize CD30.CAR-modified EBVSTs, including its lead allogeneic cell therapy, TT11X, which is being co-developed with the Baylor College of Medicine for the treatment of relapsed or refractory CD30-positive lymphomas (NCT04288726). Tessa plans to extend its allogeneic EBVST platform to other cancer indications, including solid tumors. Under terms of the CRADA, Tessa will collaborate with the NCI's Division of Cancer Treatment and Diagnosis (DCTD) to identify potential opportunities to expand the applicability of TT11X as a treatment of non-Hodgkin lymphoma. In this collaboration, NCI Cancer Therapy Evaluation Program (CTEP) will serve as the regulatory sponsor and conduct mutually approved clinical trials through NCI funded clinical network groups and using drug supply and other necessary support provided by Tessa. Tessa is currently advancing a Phase 1 clinical trial in the United States investigating TT11X in CD30-positive lymphomas. Data from the Phase 1 study presented at the 64th Annual Meeting of the American Society of Hematology (ASH) demonstrated TT11X to be well-tolerated at all dosing levels, eliciting a 79% overall response rate and 43% complete response rate among 14 heavily pre-treated CD30-positve Hodgkin lymphoma patients.
- 03.07.23 - Center for Breakthrough Medicines, Nucleus Biologics, and Stoic Bio Announce Strategic Collaboration for Steady Supply of Quality Controlled Cell Culture Media to Expedite Development of Cell and Gene Therapies (PR)
  - The agreement also positions CBM as one of the early adopters of Krakatoa™, Stoic Bio's innovative family of point-of-use media makers that allows scientists to manufacture their own media inside their laboratory or in the bioreactor suite. The cell culture media, solubilized in the Krakatoa, results in 65% less CO2 emissions than conventional media. CBM is poised to demonstrate that developing and manufacturing lifesaving therapies doesn't have to come with a heavy environmental cost.
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- 03.06.23 - PHANES THERAPEUTICS entered into a research collaboration with Xyphos Biosciences, Inc., an Astellas Company (PR)
  - Phanes Therapeutics, Inc., a clinical stage biotech company focused on innovative drug discovery and development in oncology, today announced that it has entered into a research collaboration with Xyphos Biosciences, Inc. an Astellas Company. The collaboration will leverage Phanes' proprietary technology platforms, PACbody™ and SPECpair™, in the evaluation of cell therapies in oncology. Under the terms of the agreement, Phanes will receive a technology access payment and further collaborative research support. The details of the financial terms were not disclosed.
- 03.01.23 - Vertex pays ImmunoGen $15M to use antibody-drug conjugates to improve CRISPR therapy (fiercebiotech)
  - Are antibody-drug conjugates the key to better gene editing treatments? That is a question posed by the latest deal by Vertex, which is paying ImmunoGen $15 million upfront to explore the use of ADCs with its near-approval CRISPR/Cas9 therapy exagamglogene autotemcel (exa-cel). ADCs are best known as cancer drugs. In that context, the pairing of a targeting antibody and a cytotoxic payload can create treatments that wipe out cancer cells without causing unbearable systemic toxicity. Researchers have begun to explore using the same approach to selectively deplete certain cell types to prepare the body for gene therapy and stem cell transplant. Vertex has bet $15 million upfront on that idea, with potentially up to $337 million in option exercise fees and development and commercial milestone payments to follow per target. The deal allows Vertex to use ImmunoGen's ADC technology to discover novel targeted conditioning agents and then obtain a worldwide license for conditioning agents that use ImmunoGen's technology for that target.
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M&A

- 03.06.23 - Months after reorg, Adaptimmune merges with fellow cell therapy developer (endpts)
  - Adaptimmune is merging with TCR^2 Therapeutics in a bid to create a T cell therapy developer aimed at solid tumors. The all-stock deal brings together both companies' lead candidates — Adaptimmune's afami-cel, which targets MAGE-A4, and TCR^2's mesothelin-targeting gavo-cel — as well as a pipeline of candidates engineered with T cell receptors, or TCRs. Unlike CAR-T therapies, TCR-T is not limited to surface antigens but can target antigens inside cancer cells. Both companies had seen some tumultuous ups and downs during the biotech winter, with a mix of positive data, setbacks in the cell therapy space and a tough financing environment making for a volatile period for their shares. Just last November, Adaptimmune trimmed its pipeline and laid off a quarter of its staffers in the wake of GSK's decision to axe their partnership. With a cash runway extended into 2026, the new company will keep the Adaptimmune name and be run by the same team led by Adaptimmune CEO Adrian Rawcliffe. His key goal in the short term will be winning approval for afami-cel in synovial sarcoma, which he said would be the first engineered TCR-T cell therapy for a solid tumor. The company began a rolling BLA submission in December and expects to complete it in mid-2023.
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