PROJECT EVOLUTION

Projectevolution.org

1ST HALF FEBRUARY 2023 ADVANCED THERAPIES COLLABORATIONS & M&A

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

Collaborations

- 02.16.23 - Indee Labs Partners with GenScript to Develop Direct DNA Knock-in Kit for Large Transgene Inserts (PR)
  - Indee Labs, the developer of Hydropore™ for non-viral intracellular delivery, is partnering with GenScript USA Inc., the world's leading provider of life-science research tools and services, to deliver GenScript's non-viral DNA payloads into cells at greater efficiency, and to enable the integration of longer DNA inserts than those allowed by traditional viral methods. As part of the collaboration, GenScript is providing a variety of single-strand and double-strand (ssDNA and dsDNA) constructs for direct DNA inserts, while the team at Indee Labs is optimizing the Hydropore protocol and evaluating functional differences between T cells processed with Hydropore and electroporation. Looking ahead, the companies will work on co-marketing a complete non-viral solution to the gene and cell therapy community.
- 02.16.23 - Akamis Bio, Parker Institute for Cancer Immunotherapy, and Cancer Research Institute Announce Expanded Partnership to Advance Novel Treatments for Pancreatic Cancer.
  - As part of the Akamis Bio, PICI, and CRI partnership, NG-350A, an immuno-stimulatory tumor gene therapy driving intratumoral expression of a CD40 agonist monoclonal antibody, will be evaluated in combination with standard-of-care chemotherapy and the CTLA-4 inhibitor ipilimumab (YERVOY®). The NG-350A combination therapy will be part of cohort C in REVOLUTION, a platform clinical study investigating novel therapeutic combinations for the treatment of previously untreated metastatic pancreatic cancer. In 2018, Akamis Bio initiated a pre-clinical partnership with PICI, a network representing the largest concentration of immuno-oncology expertise in the world, with a focus on research to investigate the use of the company's T-SIGn® therapeutics for the treatment of solid tumors. Akamis Bio's relationship with PICI, which includes a financial investment by PICI in the company, has now expanded to include a clinical collaboration thanks to the generous financial and operational support of CRI for the inclusion of NG-350A in the REVOLUTION study.
- 02.14.23 - Gritstone bio and the National Cancer Institute (NCI) Establish a Clinical Trial Agreement to Evaluate a Neoantigen Cell Therapy-Vaccine Combination (PR)
  - NCI will lead the Phase 1 study using Gritstone's proprietary "off the shelf" vaccine technology for mutant KRAS solid tumors. Under the terms of the agreement, NCI will identify patients with metastatic cancer that are eligible for adoptive cell transfer based on the presence of a G12V or G12D KRAS mutation (KRASmut). Gritstone will provide the SLATE-KRAS vaccine as requested by NCI for the trial.
- 02.14.23 - GSK, Vir end COVID antibody collab (Pharmamanufacturing)
  - Vir Biotechnology and GSK have amended a 2020 research collaboration agreement, leaving Vir to advance next-gen COVID solutions independently or with other partners. Back in April 2020, GSK and Vir entered into a collaboration to research and develop solutions for coronaviruses. As part of the deal, GSK paid $250 million to gain access to Vir's proprietary monoclonal antibody platform technology to accelerate existing and identify new anti-viral antibodies that could be developed as therapeutic or preventive options. In 2021, the two expanded their collaboration to include the R&D of new therapies for influenza and other respiratory viruses.
- 02.13.23 - Operation Warp Speed for rare diseases: CBER leader says pilot is coming soon (endpts)
  - The next generation of Operation Warp Speed is coming soon, and this time it's going to take aim at rare diseases, Peter Marks, the director of the FDA's Center for Biologics Evaluation and Research, told attendees of the Biopharma Congress in Washington, DC on Monday. " I think the goal is to take a drug with some promise in the rare disease space for diseases that don't have alternatives … and then take these products, maybe they have breakthrough or advanced therapy designation, they have promise and there is a product in development and not just a concept. And then give them the opportunity with not just chemistry, manufacturing and controls, which we have a pilot for, but allow the clinical development to happen in constant communication and sharing of potential results before a submission of an NDA or BLA. That's the idea, is to move things as fast as possible."
- 02.12.23 - IASO Bio Announces CT103A Granted Regenerative Medicine Advanced Therapy (RMAT) and Fast Track (FT) Designations by the FDA (PR)
  - Equecabtagene autoleucel (CT103A) is a BCMA chimeric antigen receptor autologous T cell injection, a lentiviral vector containing a CAR structure with a fully human scFv, CD8a hinger and transmembrane, 4-1BB co-stimulatory and CD3ζ activation domains. Based on strict selection and screening, utilizing a proprietary in-house optimization platform, and integrated in-house manufacturing process improvement, the construct of CT103A is potent and shows prolonged persistency in patients. The NMPA accepted the New Drug Application for equecabtagene autoleucel for the treatment of relapsed/refractory multiple myeloma (RRMM). Equecabtagene autoleucel also received Breakthrough Therapy Designation by the NMPA in February 2021 and Orphan Drug Designation (ODD) in February 2022 and IND approval in December 2022 by the U.S. FDA. In addition to multiple myeloma, the NMPA has approved IND application of equecabtagene autoleucel for the new expanded indication of Neuromyelitis Optica Spectrum Disorder (NMOSD). IASO Bio and Innovent Biologics, Inc. (1801.HK) are jointly developing equecabtagene autoleucel for the treatment of RRMM in mainland China.
- 02.09.23 - The University of California and Foundery Sign Master Agreement to Translate Novel Discoveries into Transformational Immunotherapies (PR)
  - Unique industry-academic partnership supports UCSF investigator research while creating opportunities for downstream drug development and shared economics. The master agreement is structured to enable UCSF researchers to propose candidate drug targets or compelling biology relevant to the identification, prevention, treatment or amelioration of human diseases with underlying immune dysfunction. Foundery's team of highly experienced and accomplished scientists subsequently conduct translational research on prioritized candidate targets in Foundery's internal laboratories. If the research results in a candidate molecule or platform with therapeutic potential, Foundery aims to transition the preclinical candidate either directly via sale to biopharmaceutical partners or through the creation of a financing syndicate with later-stage venture capital funds to further develop the program.
-

- 02.09.23 - Entrada Therapeutics Closes Agreement with Vertex to Discover and Develop Endosomal Escape Vehicle-Therapeutics for Myotonic Dystrophy Type 1 (DM1) (PR)
  - Under the terms of the agreement announced on December 8, 2022, Entrada will receive an upfront payment of $224 million, as well as an equity investment of $26 million at $16.26 per share. Entrada is eligible to receive up to $485 million for the successful achievement of certain research, development, regulatory and commercial milestones, and tiered royalties on future net sales for any products that may result from this collaboration agreement. The agreement includes a four-year global research collaboration whereby Entrada will continue to advance and receive payments for certain research activities related to ENTR-701, as well as additional DM1-related research activities. Vertex will be responsible for global development, manufacturing and commercialization of ENTR-701 and any additional programs stemming from Entrada's DM1 research efforts. Company's cash runway extended into the second half of 2025
- 02.08.23 - Element Biosciences and Bio-Rad Partner to Deliver Seamless RNA Sequencing Workflow Between Element's AVITI™ System and Bio-Rad's SEQuoia™ Express and SEQuoia™ Complete Stranded RNA Library Prep Kits (PR)
  - The Element AVITI Sequencing Platform's novel Avidity Sequencing chemistry can be easily adapted for use with the Bio-Rad SEQuoia Complete Stranded RNA Library Prep Kit and the SEQuoia Express Stranded RNA Library Prep Kit to obtain RNA sequencing accuracy and repeatability among samples and different RNA inputs. The SEQuoia Complete Stranded RNA Library Prep Kit offers unbiased transcriptome profiling during RNA sequencing by capturing a broad range of RNA subtypes in a single workflow, whether using low or high input RNA. The SEQuoia Express Stranded RNA Library Prep Kit offers the additional benefit of a highly efficient 3-tube workflow for detection of long RNAs that can be completed in only 3 hours.
- 02.01.23 - MD Anderson and Federation Bio Announce Collaboration to Develop Novel Microbiome Treatment for Patients with Immunotherapy-Resistant Cancers (PR)
  - The University of Texas MD Anderson Cancer Center and Federation Bio, a biotechnology company pioneering bacterial cell therapies, today announced a strategic collaboration to design and manufacture a complex, synthetic microbial consortium with the goal of expanding the number of cancer patients who respond to immunotherapy. The agreement pairs Federation Bio's proprietary ACT™ (anerobic co-culture technology) platform with the expertise and capabilities of MD Anderson's Platform for Innovative Microbiome and Translational Research (PRIME-TR).

M&A

- 02.16.23 - By merging with struggling Erytech, Pherecydes spies opportunity to boost AMR strategy (fiercebiotech)
  - In the year and a half since Erytech Pharma was blindsided by a phase 3 fail that forced a pivot from pancreatic cancer to leukemia, the company has been feeling out strategic options. Now, fellow French biotech Pherecydes has spotted an opportunity to take advantage of Erytech's money, expertise and U.S. footprint via a merger. The combined company will maintain Pherecydes' focus on extended phage therapies—natural bacteria-killing viruses—to combat antimicrobial resistance (AMR). The new, as yet unnamed entity will have around 41 million euros ($35.6 million) in the bank that could fund both current and new clinical programs into the third quarter of 2024. Pherecydes already has plans for two new midstage trials in the U.S. One study in patients with endocarditis due to S. aureus is expected to launch in the middle of the year, with a trial in complex urinary tract infections due to E. coli penciled in for the first quarter of 2024.
- 02.14.23 - Sesen Bio and Carisma Therapeutics Announce Increased Special Cash Dividend and Stockholder Support for Pending Merger (PR)
  - In connection with the Support Agreement, Sesen Bio and Carisma have further amended the previously amended merger agreement announced on December 29, 2022, which has been unanimously approved by the Boards of Directors of both companies: Increased the one-time special cash dividend expected to be paid to Sesen Bio stockholders to $75 million, $0.36 per share1. This represents an increase from the expected special cash dividend of approximately $70 million, approximately $0.34 per share, under the first amendment to the merger agreement, and an increase from the up to $25 million special cash dividend under the terms of the original merger agreement; Extended the period of time for payments under the Contingent Value Right ("CVR") related to any potential proceeds from the sale of Vicineum and Sesen Bio's other legacy assets to March 31, 2027, from December 31, 2023, under the previous terms. Under the CVR, Sesen Bio stockholders remain entitled to any proceeds from the potential milestone payment under the Roche Asset Purchase Agreement; and Michael Torok will join the Carisma Board of Directors upon closing of the merger as the only Sesen Bio representative.
- 02.13.23 - Cytek® Biosciences to Acquire Flow Cytometry and Imaging Business from DiaSorin (PR)
  - Sale of assets related to Flow Cytometry & Imaging (FCI) Business Unit. Acquisition will expand Cytek's product portfolio to include imaging and menu-based application driven flow cytometry to provide full cell analysis solutions to its customers.Transaction is in line with DiaSorin's strategic priorities communicated to the market after Luminex acquisition. Employees associated with commercial, operations, R&D and supporting functions expected to join Cytek
- 02.09.23 - Ensoma Announces Closing of Twelve Bio Acquisition (PR)
  - Ensoma, a genomic medicines company developing one-time in vivo treatments that precisely engineer any cell of the hematopoietic system to cure diseases from within, today announced the closing of its previously announced acquisition of Twelve Bio ApS, a gene editing company pioneering the therapeutic application of next-generation CRISPR-Cas medicines. The closing follows recent clearance by the Danish Business Authority pursuant to Danish foreign direct investment laws. In conjunction with the closing, Stefano Stella, Ph.D., co-founder of Twelve Bio, has joined the leadership team at Ensoma as vice president of gene editing. Additionally, Guillermo Montoya, Ph.D., co-founder of Twelve Bio, and Shengdar Q. Tsai, Ph.D., a leading expert in genome engineering and hematology and member of the scientific advisory board of Twelve Bio, will join the scientific advisory board at Ensoma.
- 02.31.23 - UniQure nabs another gene therapy for ALS (biopharmdive)
  - The therapy, developed by Apic Bio, is specifically designed to block the expression of SOD1, a gene that's long been linked to the disease. Apic Bio, a privately held developer of gene therapies for rare disorders, has agreed to sell the rights to one of its experimental ALS treatments to the biotechnology company UniQure in a deal announced Tuesday. Per deal terms, UniQure will pay $10 million up front for worldwide rights to the treatment, which was called APB-102 but will now be known as AMT-162. Apic could later be eligible for up to $45 million in additional payments should its therapy secure approval in the U.S. and Europe and hit certain sales goals. The Food and Drug Administration previously cleared AMT-162 for human testing, and UniQure plans to start a Phase 1/2 trial in the back half of this year.