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Project Evolution's U.S. Advanced Therapies October 2022 Recap

In a Fast-Moving Industry, Stay Up-to-Date on the Happenings. Here is a Glimpse of Our Favorite Stories from October 2022.

Funding Updates:

- 10.01.22 - NeuShen Therapeutics Closes Pre-A Financing with ~$20M (PR)
  - NeuShen Therapeutics, Inc., a biotechnology company focusing on developing innovative treatments for central nervous system (CNS) disorders with dual platforms of AAV-based gene therapy and small molecule discovery, announced today the closure of ~$20 million Series pre-A financing led by LAPAM, a China based venture capital. NeuShen was founded by a group of industrial executives who have extensive global experiences in central nervous system (CNS) drug development. The new capital will be used to expand the team and catalyze in-house CNS drug discovery in both the US and China.
- 10.04.22 - Cellarity Announces Close of $121 Million Series C Financing (PR)
  - Cellarity, a life sciences company founded by Flagship Pioneering to transform the way medicines are created, announced today the completion of a $121 million Series C financing, bringing its total funding raised to date to $274 million. In addition to participation by Flagship Pioneering and other Series B investors, four new investors participated, including Kyowa Kirin Co. Ltd. and Hanwha Impact Partners. The proceeds of the financing will be used to grow Cellarity's talent base, strengthen its platform, and advance its pipeline toward the clinic.
- 10.11.22 - Immatics to Raise $110M in Stock Offering Following Promising Solid Tumor Data (Biospace)
  - Immatics announced plans to raise about $110 million in a common stock offering Monday following the release of promising early-stage data that supports its ACTengine technology platform. Immatics, based in Houston, TX and Tuebingen, Germany. Immatics also announced interim Phase Ia clinical data of the expansion cohort A. Cohort A tested the company's ACTengine IMA203 as a monotherapy for recurrent and/or refractory solid tumors patients using TCR-T cells directed against an HLA-A*02-presented peptide derived from PRAME (PReferentially expressed Antigen in MElanoma).
- 10.12.22 - Vita Therapeutics Closes $31 Million Series B Financing to Develop Cell Therapies for Neuromuscular Diseases and Cancers (PR)
  - Vita Therapeutics, a cell engineering company harnessing the power of genetics to develop novel cellular therapies to treat muscular dystrophies and cancers, today announced the completion of a $31 million Series B financing. The fundraise was led by Cambrian BioPharma and new investor Solve FSHD. New investors included Riptide Ventures and Cedars Sinai, which participated alongside TEDCO and other existing investors. Proceeds from the financing will be used to advance Vita's lead pre-clinical program VTA-100 for limb-girdle muscular dystrophy (LGMD2A) to the clinic. It will also fund the development of Vita's newest program, VTA-120 for the treatment of patients with facioscapulohumeral muscular dystrophy (FSHD), and to further expand Vita's discovery pipeline. Since inception, Vita has raised a total of $66 million.
- 10.13.22 - Carmine Therapeutics Announces First Close of Series A to Develop Next generation, Non-viral gene therapy (PR)
  - Carmine is developing next-generation, non-viral gene therapies for a broad spectrum of diseases based on our proprietary Red Cell Extracellular Vesicle Gene Therapy ("REGENT™") technology platform. The REGENT platform offers the potential to deliver therapeutic payloads to a broad array of tissues including the CNS, the ability to carry DNA or RNA payloads ranging from 20bp to >30kb as well as the ability to carry multiple payloads simultaneously. All existing investors including EVX Ventures, and Simcere Pharmaceuticals participated, and they were joined by new lead Investor Huagai Capital, and others, including the Cystic Fibrosis Foundation, which joined the round based on Carmine's potential to provide an innovative approach to gene therapy in cystic fibrosis.
- 10.17.22 - Treeline Bio deepens investor roots with fresh funding for cancer drug research (Biopharma Dive)
  - Cancer biotechnology startup Treeline Biosciences has raised another $262 million to fund its oncology research, according to a regulatory filing made last week. The latest financing was led by private equity firm KKR, the company said Monday in an update posted to LinkedIn, and brings the total amount raised by the secretive startup to at least $473 million. Treeline is led by two biotech executives well known for their past cancer drug development work. Its CEO, Josh Bilenker, sold Loxo Oncology to Eli Lilly for $8 billion in 2019. Co-founder Jeffrey Engelman was previously the global head of oncology at the Novartis Institutes of BioMedical Research.
- 10.24.22 - Prime time for IPO as gene editing biotech goes public with $175M (FiercePharma)
  - Gene editing biotech Prime Medicine is thawing a frosty market with a $175 million IPO, one of the sector's largest debuts this year, especially for a company with no clinical data to hand. The preclinical company, which has yet to specify on its website which therapeutic areas it will focus on, is braving the cold IPO market, which all but froze over for biotech since 2021's record-breaking year of listings.

Manufacturing Updates:

- 10.04.22 - Kite Pharma gets FDA to sign off on new California-based vector manufacturing facility (Endpts)
  - Kite's global head of technical operations Chris McDonald tells Endpoints News that the facility has been in the works for about four years, after Kite teamed up with its parent company Gilead. Gilead acquired Kite Pharma for just shy of $12 billion in 2017. Kite has employed 100 workers focused on viral vectors in the facility, and since the building is located on Gilead's campus, the parent pharma will be providing logistical support, such as cafeteria staff and building security. The building also touts two manufacturing suites: One is fully dedicated on retroviral vectors in current commercial products, and the other is set aside for future expansion for pipeline products and potentially different types of vectors.
- 10.06.22 - J&J, Legend double CAR-T manufacturing investment to $500M as Carvykti eyes wider myeloma use (Fierce Pharma)
  - Manufacturing has constrained Legend Biotech and Johnson & Johnson's supply of their CAR-T therapy Carvykti to heavily pretreated multiple myeloma patients. As the drug targets earlier treatment—and larger markets—the partners have decided to literally double down on production. J&J and Legend will double investment in their Raritan, New Jersey, manufacturing facility, bringing the total to $500 million, Legend CEO Ying Huang, Ph.D., told investors during a conference Monday. The cell therapy manufacturing site currently makes Carvykti for the U.S.
- 10.10.22 - Ray Therapeutics and Forge Biologics Expand Their Viral Vector cGMP Partnership to Encompass Plasmid DNA Manufacturing (PR)
  - Forge will provide research-grade and GMP-Pathway plasmid manufacturing services, in addition to adeno-associated viral vector (AAV) process development, scale-up engineering, and cGMP manufacturing services for Ray Therapeutics' program, RTx-015. The program will continue to utilize Forge's platform manufacturing processes, including its proprietary HEK 293 suspension Ignition Cells™ and pEMBR™ adenovirus helper plasmid. All development and cGMP manufacturing activities will occur at the Hearth, Forge's 200,000 square foot gene therapy cGMP production facility in Columbus, Ohio.
- 10.12.22 - Charles River Launches nAAVigation Vector Platform to Accelerate Gene Therapy Programs (PR)
  - Leveraging decades of Adeno-Associated Virus (AAV) vector contract development and manufacturing (CDMO) experience and biologics testing expertise, Charles River has established a platform which streamlines the pathway to GMP AAV vector manufacturing without the need for significant process development. The nAAVigation platform has the capability to reduce a program's timeline to GMP for viral vector gene therapy developers by 55 percent, translating to fewer than eight (8) months compared to traditional manufacturing workflows.
- 10.12.22 - Inceptor Bio and Avectas Announce Collaboration to Improve Manufacturing of CAR-T Cell Therapies for the Treatment of Solid Tumors (PR)
  - Under the agreement, Inceptor will utilize Avectas' SOLUPORE® technology as an alternative to electroporation for engineering T cells with the goal to yield a healthier T cell product. Avectas' SOLUPORE® technology is well suited to Inceptor Bio's CAR-T cell process, which aims to improve the quality of the engineered T cells, and ultimately, enhance their durability in the tumor microenvironment. By combining Avectas' SOLUPORE® delivery with Inceptor Bio's CAR-T cell therapy platform, the engineered cells have the potential for improved performance and efficacy.
- 10.12.22 Cellusion and Minaris Regenerative Medicine, a member of Showa Denko Materials, Enter into Business Alliance for the Manufacturing of CLS001 for a Corneal Endothelial Cell Regenerative Therapy (PR)
  - Under the LOI, Cellusion and Minaris will develop the manufacturing process of Cellusion's leading program, CLS001, a novel regenerative medicine product for bullous keratopathy treatment. Minaris' Allendale, New Jersey team will perform process optimization to meet requirements from the FDA.
- 10.18.22 - Charles River and Nanoscope Therapeutics Announce Multifaceted Gene Therapy Manufacturing Partnership (PR)
  - Through this partnership, Nanoscope will have access to established manufacturing platforms and multiple Charles River CDMO centers of excellence, leveraging a comprehensive range of services including but not limited to GMP cell banking, High Quality (HQ) and GMP-grade plasmid DNA manufacture, and GMP adeno-associated virus (AAV) production.
- 10.20.22 - Catalent Announces $12 Million Expansion Program at Kansas City Facility (Contract Pharma)
  - The project will see the addition of two new analytical development laboratories to support the growing demands of assay development for both traditional biologic and advanced biologic modality programs. The first of the two new laboratories will cover approximately 3,500 square feet and will be completed by the end of October 2022, with the second, measuring 3,000 square feet, due to be operational in the first quarter of 2023. The expansion will create approximately 50 new scientific jobs at the site by February 2023.
- 10.24.22 - FUJIFILM Diosynth Biotechnologies and RoosterBio Announce Collaboration to enable GMP Manufacturing of Cell and Exosome Therapies (PR)
  - This collaboration offers biopharma customers an end-to-end solution for developing and producing MSC and exosome therapeutics, allowing for a seamless transition of programs from RoosterBio's process and analytical development services into FUJIFILM Diosynth Biotechnologies' advanced therapies GMP capabilities. Manufacturing services and expertise provided by FUJIFILM Diosynth Biotechnologies will include cell expansion and collection of MSCs, downstream processing for exosome purification, and drug product manufacturing. Terms of the agreement were not disclosed.

- 10.25.22 - Andelyn Biosciences announces opening of its state-of-the-art GMP manufacturing facility to meet industry demand (Bio-itworld)
  - This investment is the latest execution of Andelyn's Biosciences' growth plan after its launch and opening of the GMP Andelyn Plasmid Core in August 2022 and Andelyn Development Center in June of 2022. Located in Columbus, Ohio, the ACC is an advanced 200,000SF gene therapy GMP clinical and commercial manufacturing facility. The site has the capability to support any scale of gene therapy viral vector production using various modalities, including adherent, iCELLis®, and suspension platform capacity of up to 8 X 2000L.
- 10.26.22 - Lonza Expands Cell and Gene Sites in the U.S. and The Netherlands (Contract Pharma)
  - The expansions further strengthen Lonza's global process development service offering by adding capabilities and capacity to its existing laboratories. Alongside its rapidly growing team of CGT process development experts, the expansions support the company's ability to meet the increasing global demand for cell and gene therapies process development expertise. In Houston, the expansion includes 15,000 ft2 of new laboratory suites, including viral vector-based process development and analytical development laboratories. Lonza's Geleen facility will add over 4,500 ft2 of laboratory space. The new laboratories are expected to be operational by the end of 2022. These expansions come in addition to Lonza's recent acquisition of exosome development services laboratories in Siena, Italy, further expanding Lonza's CGT process development footprint across the globe.
- 10.26.22 - Fujifilm starts build-out for massive NC plant, the latest piece of its multibillion-dollar CDMO expansion effort (Fierce Pharma)
  - Earlier this month, when Fujifilm Diosynth broke ground in North Carolina on a facility destined to become its showcase, the occasion was more about the company than the plant. While the $2 billion complex will eventually house 725 employees and is billed as the largest end-to-end biologics production plant in the world, it's just one of several investments Tokyo-based Fujifilm has undertaken in its campaign to build CDMO capacity.
- 10.27.22 - Landmark Bio Unveils New State-of-the-Art Full-Spectrum Biomanufacturing Innovation Center (PR)
  - The 44,000 sf fully integrated development and manufacturing facility includes laboratory space for translational research and early development, process and analytical development, and technology innovation. The manufacturing area is comprised of eight cleanrooms for cell therapies, genome editing, viral vector, mRNA and lipid nanoparticle production, as well as fill and finish and in-house QC testing. In addition, Landmark Bio provides wraparound services such as drug development and regulatory consulting, program management, and other support services. The facility currently has about 60 staff members and will grow to more than 100 people in the coming years. Founding partners include Harvard University,MIT, Cytiva, FUJIFILM Diosynth Biotechnologies, and Alexandria Real Estate Equities, Inc. Other collaborating institutions include Beth Israel Deaconess Medical Center, Boston Children's Hospital, Mass General Brigham, and the Dana-Farber Cancer Institute.
- 10.31.22 - BioCentriq Cuts the Ribbon to Officially Open Additional GMP Manufacturing Site in South Brunswick, NJ (PR)
  - The site includes two ISO-7 certified clean rooms with separate air handling units. Both will be operated under well-established GMP procedures and systems. They are specially designed to handle multiple equipment platforms and support autologous and allogeneic cell therapy manufacturing projects. The site also includes quality control and process development laboratories.

M&A Updates:

- 10.01.22 - Solid Biosciences Announces Acquisition of AavantiBio and Concurrent $75 Million Private Placement (PR)
  - Solid Biosciences Inc. (Nasdaq: SLDB), a life sciences company focused on advancing meaningful therapies for Duchenne muscular dystrophy (Duchenne), and AavantiBio, Inc., a privately-held gene therapy company focused on transforming the lives of patients with Friedreich's ataxia and rare cardiomyopathies, today announced that the companies have entered into a definitive merger agreement whereby Solid will acquire AavantiBio, including its pipeline assets and net cash. The combined company will focus on advancing a portfolio of neuromuscular and cardiac programs, led by SGT-003, a differentiated gene transfer candidate, for the treatment of Duchenne. Additional pipeline programs include AVB-202, a gene transfer candidate for the treatment of Friedreich's ataxia, AVB-401 for BAG3 mediated dilated cardiomyopathy, and additional assets for the treatment of undisclosed cardiac diseases. Following approval by Solid stockholders, the combined company will operate as Solid Biosciences, will trade on Nasdaq under the ticker symbol "SLDB" and Bo Cumbo, the current Chief Executive Officer of AavantiBio, will assume the role of President and CEO of Solid Biosciences.
- 10.03.22 - AMPLIFYBIO ACQUIRES PACT PHARMA ASSETS TO ENHANCE CELL AND GENE THERAPY CHARACTERIZATION CAPABILITIES (PR)
  - AmplifyBio, a contract research organization (CRO) focused on accelerating innovation across pharmaceutical modalities; today announced the acquisition of select assets from PACT Pharma, Inc., a privately held biopharmaceutical company developing neoantigen-specific T cell receptor cell therapies. The deal will provide AmplifyBio with advanced characterization platforms, bioinformatics capabilities, and 40 drug development experts to enhance their cell and gene therapy service offerings. AmplifyBio will also acquire the South San Francisco advanced laboratory space.

- 10.03.22 - Alexion, AstraZeneca Rare Disease to Acquire LogicBio® Therapeutics to Accelerate Growth in Genomic Medicine (PR)
  - LogicBio has developed technology platforms for the delivery and insertion of genes to address genetic diseases, as well as a platform designed to improve viral vector manufacturing processes. These platforms, coupled with LogicBio's highly experienced team and Alexion's advancements with AstraZeneca, will drive future scientific possibilities and next generation medicines to treat rare genetic diseases. Under the terms of the agreement, Alexion, through a subsidiary, will initiate a cash tender offer to acquire all outstanding shares of LogicBio for $2.07 per share. Both boards have unanimously approved the transaction.
- 10.04.22 - Ginkgo Bioworks Acquires Circularis to Strengthen Capabilities in Cell and Gene Therapy (PR)
  - The Circularis platform strengthens Ginkgo's platform for development of cell and gene therapies, providing the capability to rapidly identify novel promoters with appropriate strength and tissue-specificity designed into customer specific delivery modalities. Leveraging Ginkgo's ability to explore large numbers of genetic designs, these promoter libraries can be explored in combination with modified therapeutic payloads and capsids to provide gene therapy developers a solution that works across any range of cell or organism models. Similarly, the Circularis platform will give Ginkgo the ability to rapidly identify context-specific promoters for cell therapy applications, such as those that modulate gene expression in the tumor microenvironment.
- 10.06.22 - Cytiva strengthens cell line development with CEVEC acquisition (PR)
  - Viral vector manufacturing and cell line development are keystone technologies in the making of gene therapies. 46 scientific experts based in Cologne, Germany, join the Cytiva team in the genomic medicine space. Cytiva customers will have immediate access to technologies that solve some of the most significant challenges in bringing gene therapies to patients.
- 10.18.22 - Lilly to Acquire Akouos to Discover and Develop Treatments for Hearing Loss (PR)
  - Transaction valued at approximately $487 million plus a contingent value right for an aggregate amount up to approximately $610 million. Akouos has integrated expertise across otology, inner ear drug delivery, and gene therapy with the goal of addressing the needs of people living with disabling hearing loss worldwide. Akouos's lead product candidate, AK-OTOF, is a gene therapy for the treatment of hearing loss due to mutations in the otoferlin gene (OTOF). Additional pipeline programs span across multiple inner ear conditions.
- 10.23.22 - Syncona to Acquire Applied Genetic Technologies Corporation (PR)
  - Applied Genetic Technologies Corporation (Nasdaq: AGTC), a clinical-stage biotechnology company focused on the development and commercialization of adeno-associated virus (AAV)-based gene therapies for the treatment of rare and debilitating diseases with an initial focus on inherited retinal diseases (IRDs), today announced that it has entered into a definitive agreement pursuant to which a newly established portfolio company of Syncona Limited (LON: SYNC), a leading healthcare company focused on founding, building and funding global leaders in life science, will acquire AGTC, through a tender offer, for approximately $23.5 million ($0.34 per share) in cash at the closing of the transaction plus potential future aggregate cash payments of up to $50.0 million (up to $0.73 per share) pursuant to contingent value rights (CVRs).

Collaboration Updates:

- 10.04.22 - Autolus Therapeutics Announces Collaboration with Bristol Myers Squibb for Use of Autolus' Proprietary Safety Switch System (PR)
  - Under the terms of the agreement, Autolus will receive an upfront payment for access to the RQR8 safety switch for the initial set of cell therapy programs with the potential for near-term option exercise fees and development milestone payments. In addition, Autolus would be entitled to receive royalties on net sales of all Bristol Myers Squibb cell therapy products that incorporate the RQR8 safety switch.
- 10.13.22 - Xcell Biosciences and aCGT Vector Collaborate to Accelerate Development of Cell and Gene Therapies (PR)
  - Xcellbio, an instrumentation company focused on cell and gene therapy applications, and aCGT Vector, a point-of-care cell and gene therapy-as-a-service (TaaS) company, today announced a collaboration to improve manufacturing and analytic procedures used to develop personalized cell and gene therapies for cancer patients. Through this alliance, aCGT Vector will provide its point-of-care, GMP-licensed manufacturing platform to validate Xcellbio's core next-generation manufacturing and analytical AVATAR AI technology for use in precision cancer treatment.
- 10.20.22 - Kite And Refuge Biotechnologies Announce Exclusive License Agreement For Investigational Gene Expression Platform For Blood Cancers (PR)
  - Refuge's proprietary platform is a synthetic biology system that utilizes an expression modulation strategy to repress or activate transcription of target genes. Early pre-clinical data suggest a potential for this highly modular platform to regulate target antigen-dependent gene expression as a means to improve upon both the efficacy and safety of first-generation CAR T-cell therapies. Kite will have an exclusive license to Refuge's intellectual property portfolio for use in blood cancers, as well as a library of synthetic gene expression programs for these indications. Refuge will retain all rights and programs related to solid tumor indications.

- 10.25.22 - GSK, dialing back cell therapy work, ends deals with Lyell and Adaptimmune (Biopharma Dive)
  - GSK is trimming back in cancer cell therapy research, disclosing plans to end partnerships with Lyell Immunopharma and Adaptimmune that were intended to develop immunotherapies for solid tumors. In a regulatory filing late Monday, Lyell, a well-funded cell therapy developer that went public last year, said the British drugmaker ended a 2019 deal following a "strategic review" of its pipeline. U.K. biotechnology company Adaptimmune, in a separate announcement, said it regained rights from GSK to two cell therapy programs.
- 10.25.22 - ABL, RD-Biotech Sign Strategic Partnership in Cell and Gene Therapy GMP Mfg. (Contract Pharma)
  - ABL, a pure play Contract Development and Manufacturing Organization (CDMO) with specialized expertise in the development and manufacturing of solutions for biopharma, and RD-Biotech, a CRO/CDMO providing custom services in development and production of plasmid DNA, monoclonal antibodies and recombinant proteins, have signed a strategic partnership in Cell and Gene Therapy (C>) GMP manufacturing. This collaboration brings together RD-Biotech's plasmid DNA (pDNA) GMP manufacturing services with ABL's viral vector GMP manufacturing to offer a new and flexible end-to-end service to C> developers.
- 10.26.22 - Schmidt Futures Announces UC San Diego as Partner of $148M Initiative Accelerating AI Use in Science (UCSD)
  - The program will initially support approximately 160 postdoctoral fellows across nine universities around the world each year, to learn and apply AI methods to their research. UC San Diego will select a new cohort of postdoctoral scholar fellows each year for six years.
- 10.27.22 - Obsidian Therapeutics Announces Extension of Multi-Year Collaboration Agreement with Bristol Myers Squibb (PR)
  - Bristol Myers Squibb has opted to extend the term of the parties' multi-year strategic collaboration for the discovery and development of novel, regulated cell therapies that utilize Obsidian's cytoDRiVE® technology for the controlled expression of the immune enhancer CD40L. Today's announcement builds on the existing relationship between Obsidian and Bristol Myers Squibb, initiated in 2019, and follows the first opt-in decision by Bristol Myers Squibb in 2020.
- 10.27.22 - 2seventy inks T cell partnership with Chinese biotech; Antisense drug causes brain side effect — report (Endpts)
  - The bluebird bio spinout, which formed last year, announced a deal Thursday morning with JW Therapeutics to put together a therapy platform to speed up T cell-based immunotherapy products for China, Macao and Hong Kong. The initial focus of the collaboration is 2seventy bio's TCR program called Mage-A4, which focused on solid tumors and is currently being developed as part of a previous collaboration with Regeneron. As part of the agreement, 2seventy will grant JW Therapeutics a license for the MAGE-A4 cell therapy in China, Hong Kong and Macao. JW Therapeutics will bear responsibility for in-China development, manufacturing and commercialization. 2seventy, however, will still have access to receive milestones and royalties on product revenue and have access to JW's clinical data in order to "support development in other geographies."

Clinical & Commercial Updates:

- 10.03.22 - Oncternal Therapeutics Receives IND Clearance for ONCT-808, its autologous CAR T Product Candidate Targeting ROR1 for the Treatment of Aggressive B Cell Lymphoma (PR)
  - Oncternal Therapeutics, Inc. (Nasdaq: ONCT), a clinical-stage biopharmaceutical company focused on the development of novel oncology therapies, today announced the receipt of a 'Study May Proceed' letter from the U.S. Food and Drug Administration (FDA), 30 days after submitting its Investigational New Drug (IND) application for a Phase 1/2 dose escalation study of ONCT-808, an autologous chimeric antigen receptor (CAR) T therapy targeting ROR1, in patients with aggressive B cell non-Hodgkin's lymphoma (B NHL), including those who have failed previous CD19 CAR T treatment.
- 10.06.22 - Mustang Bio Announces First Patient Treated in Its Multicenter Phase 1/2 Clinical Trial of MB-106, a First-in-Class CD20-targeted, Autologous CAR T Cell Therapy to Treat B-cell Non-Hodgkin Lymphoma and Chronic Lymphocytic Leukemia (PR)
  - Enrollment continues in clinical trial of MB-106 under Mustang's IND; next data disclosure anticipated 4Q 2022. Ongoing clinical trial of MB-106 at Fred Hutch continues to demonstrate high efficacy, durable responses, and favorable safety profile across wide range of hematologic malignancies
- 10.11.22 - Forge Biologics Announces Updated Positive Clinical Data in RESKUE, a Novel Phase 1/2 Gene Therapy Trial for Patients with Krabbe Disease (PR)
  - Subjects treated with FBX-101 have shown increased galactocerebrosidase (GALC) enzyme activity in plasma and cerebrospinal fluid (CSF), normal white matter myelination and normalization of motor development in two children 90 days and 9 months post-treatment. FBX-101 has been well tolerated, with no treatment related serious adverse events and absence of humoral response against the vector post intravenous administration
- 10.11.22 - Cabaletta Bio Announces CABA-201, a Newly Designed CD19-Targeting CAR T Cell Therapy Engineered to Address a Broad Range of Autoimmune Diseases (PR)
  - The company has obtained exclusive worldwide license for a fully human CD19 binder with clinical tolerability data that support potential clinical development in autoimmune diseases. CABA-201 Investigational New Drug (IND) application planned for the first half of 2023 with initial clinical data expected by the first half of 2024, pending IND clearance.

- 10.12.22 - FDA Accepts BioMarin's Biologics License Application (BLA) for Valoctocogene Roxaparvovec AAV Gene Therapy for Adults with Severe Hemophilia A (PR)
  - FDA accepted the Company's resubmission of the Biologics License Application (BLA) for its investigational AAV gene therapy, valoctocogene roxaparvovec, for adults with severe hemophilia A. The Prescription Drug User Fee Act (PDUFA) target action date is March 31, 2023. At this time, the FDA has not communicated any plans to hold an advisory committee meeting. If approved, valoctocogene roxaparvovec would be the first gene therapy in the U.S. for the treatment of severe hemophilia A.
- 10.17.22 - NKGen Biotech Receives IND Clearance from FDA for SNK02 Allogeneic Natural Killer Cell Therapy for Solid Tumors (PR)
  - FDA has granted IND clearance to commence a Phase 1, open-label, dose-escalation study of its cryopreserved "off-the-shelf" allogeneic blood-derived NK cell therapy (SNK02) to evaluate safety and tolerability in participants with pathologically confirmed solid tumors refractory to standard of care therapy.
- 10.17.22 - Decibel Therapeutics Receives FDA Clearance of IND Application for DB-OTO, a Gene Therapy Product Candidate Designed to Provide Hearing to Individuals with Otoferlin-Related Hearing Loss (PR)
  - The IND for DB-OTO provides clearance for the Company to initiate a pediatric Phase 1/2 clinical trial in the U.S. in children and infants, and is part of an international regulatory strategy for clinical development. One-time administration of DB-OTO has resulted in production of otoferlin protein and durable auditory brainstem responses to sound in a congenitally deaf rodent disease model. DB-OTO is Decibel's second hearing therapeutic candidate to enter clinical investigation.
- 10.31.22 - Cellular Biomedicine Group Announces FDA Clearance of IND Application for Novel TIL Therapy C-TIL051 (PR)
  - FDA granted clearance of the Investigational New Drug (IND) application to proceed with Phase 1 clinical development of its novel Tumor Infiltrating Lymphocyte (TIL) product C-TIL051 for late-stage Non-Small Cell Lung Cancer (NSCLC) patients that are relapsed or refractory to anti-PD1 therapy. C-TIL051 is an autologous adoptive cell therapy comprised of a patient's ex vivo expanded lymphocytes using CBMG's proprietary manufacturing process.

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Project Evolution is an innovative HUMAN CAPITAL solution that enables leading Life Scientific organizations to identify and secure the talent required to drive innovation. Our collaborative platform is powered by the industry-leading capabilities of Berke Executive Search and GTS Scientific. The highly-successful Joint Venture bridge Executive and Contingent placement and enable organizations of all sizes the ability to secure highly specialized talent quickly and efficiently.

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