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

Funding Updates:

- 12.01.22 - Lundbeck-partnered preclinical biotech nabs Series A from AstraZeneca (Endpts)
  - Cambridge, MA biotech Rgenta Therapeutics has secured $52 million in a Series A to take oral small molecules into the clinic.The 20-person biotech, which is already allied with Lundbeck, looks to ink more pharma partnerships within its core areas of oncology and neuroscience rare diseases, as well as in other disease areas the startup thinks the RNA-targeting platform can go. The Series A comes from AstraZeneca's $1 billion fund with China International Capital Corporation Limited, or CICC Healthcare Investment Fund, as well as Korea Investment Partners, Delos Capital, Lilly Asia Venture, Vivo Capital, Matrix Partners China and others, like $20 million seed round leader Boehringer Ingelheim Venture Fund. Other backers include Kaitai Capital and Legend Star Fund.
- 12.05.22 - Karyopharm Announces $165 Million Private Placement (PR)
  - Karyopharm expects to use the proceeds from the private placement, together with its existing cash, cash equivalents and investments, for the advancement of the Company's clinical development programs with selinexor and eltanexor as well as for working capital and other general corporate purposes. Karyopharm Therapeutics is a commercial-stage pharmaceutical company pioneering novel cancer therapies. Since its founding, Karyopharm has been an industry leader in oral Selective Inhibitor of Nuclear Export (SINE) compound technology, which was developed to address a fundamental mechanism of oncogenesis: nuclear export dysregulation. Karyopharm's lead SINE compound and first-in-class, oral exportin 1 (XPO1) inhibitor, XPOVIO® (selinexor), is approved in the U.S. and marketed by the Company.
- 12.06.22 - Entact Bio Emerges With $81M to Play Matchmaker to Protein-Enhancing Drugs (Medcitynews)
  - Taking the opposite approach of targeted protein degradation, biotech company Entact Bio is developing medicines that stabilize proteins and even enhances their function. This approach that could apply to cancer and certain rare diseases, and Entact's $81 million in Series A financing enables it to work on multiple programs in parallel.
- 12.06.22 - Bouncing from major setback, Summit hands out $500M cash for cancer drug — thanks to a loan from billionaire CEO (Endpts)
  - After hitting a dead end with Summit Therapeutics' lead program, Bob Duggan has found the drug that he believes will usher into a compelling second act. So compelling, in fact, that it involves $500 million cash — and he's taking money out of his own pocket to fund the deal. Striking a partnership with Akeso Therapeutics out of China, Summit is bringing in a bispecific antibody that blocks both PD-1 and VEGF called ivonescimab. Akeso, which has a PD-1/CTLA-4 bispecific approved in China, has already taken ivonescimab into multiple clinical trials, including a Phase III in lung cancer.
- 12.06.22 - Baudax Bio Announces Closing of $5 Million Public Offering (PR)
  - Baudax Bio is a pharmaceutical company focused on innovative products for hospital and related settings. The Company has a pipeline of innovative pharmaceutical assets including two clinical-stage, novel neuromuscular blocking (NMBs) agents, one in a Phase II study and an additional unique NMB in a dose escalation Phase I study, as well as a proprietary chemical reversal agent specific to these NMBs. Baudax Bio has received approval for and marketed ANJESO®, the first and only 24-hour, intravenous (IV) COX-2 preferential non-opioid, non-steroidal anti-inflammatory (NSAID) for the management of moderate to severe pain
- 12.06.22 - Vega Therapeutics launches and unveils its first-in-class antibody therapy for von Willebrand disease at ASH Annual Meeting (PR)
  - With $40 million in financing to date, company has advanced lead drug candidate, VGA039, to clinical stage to treat von Willebrand disease (VWD)/ Oral presentation at ASH will feature preclinical data of VGA039, a monoclonal antibody with potential to be a universal hemostatic therapy for bleeding disorders. Company has received approval of Clinical Trial Application for Phase 1 study of VGA039. Vega has been funded with $40 million to date by Star Therapeutics and its investors, including Westlake Village BioPartners, OrbiMed, Redmile Group, RA Capital, Cowen Healthcare Investments, Cormorant Asset Management, and New Leaf Venture Partners. Proceeds from this funding have enabled Vega to discover VGA039 as a wholly owned drug candidate and advance it to the clinic, including interrogating the novel biology of Protein S in bleeding disorders and conducting antibody development.
- 12.06.22 - Entact Bio Launches with $81 Million Series A to Develop Precision Medicines for Targeted Protein Enhancement (PR)
  - Series A financing to advance its proprietary Encompass™ platform for developing enhancement-targeting chimeric (ENTAC™) molecules.The round was co-led by Qiming Venture Partners USA and venBio Partners, with participation by new investors Abingworth, Brandon Capital, Janus Henderson Investors, Logos Capital, Surveyor Capital (a Citadel company), and WEHI (Walter and Eliza Hall Institute of Medical Research), and founding investors 4BIO Capital and Arkin Bio Ventures.
- 12.07.22 - Apogee Therapeutics Launches with $169 Million to Develop Potentially Best-in-Class Therapies for Immunological and Inflammatory Disorders (PR)
  - Oversubscribed $149M Series B financing co-led by new investors Deep Track Capital and RTW Investments, LP adds to Series A investment from founding investors Fairmount and Venrock Healthcare Capital Partners earlier this year. As first spinout company from Paragon Therapeutics, Apogee is advancing a pipeline of product candidates, led by APG777, which is expected to enter the clinic in 2023.Michael Henderson, M.D., Chief Executive Officer and Board member, leads an experienced team with a proven track record of executing quickly across early and late stages of drug development.

- 12.08.22 - Eigen Therapeutics Emerges From Stealth With $7M in Funding to Develop Therapies That Address Cancer Heterogeneity (PR)
  - Eigen Therapeutics, the biotech startup on a mission to make cancer easier to find and eliminate, announced today their launch. They also announced a $7 million seed round led by Josh Kopelman at First Round Capital, with participation from Builders VC, Kevin Mahaffey, Hawktail, Matthew De Silva (founder at Notable Labs), Varsha Rao, Bioverge, Alumni Ventures, Mount Pleasant Ventures, and others. Eigen was founded by an engineer and a scientist, Transon Nguyen and Kamran Ali, who have assembled a diverse team of experts in technology and biological sciences. Both founders are veterans of Notable Labs, where they gained deep experience in the cancer drug discovery industry, and where they began to grapple with the gaps in targeted therapy success rates.
- 12.12.22 - CF Foundation Invests Up to $4.85 Million in Aridis Pharmaceuticals for Testing of Anti-Infective (PR)
  - Through the Infection Research Initiative, the CF Foundation is pursuing novel approaches to treating drug-resistant infections. One approach is through funding the completion of this Phase 2a clinical trial of an inhaled form of gallium. In this trial, gallium is used to replace iron, a nutrient that all bacteria need to grow. Without iron, bacteria starve and die as a result. Because gallium is not an antibiotic, it could provide an alternative method to fight antibiotic-resistant bacteria. Aridis completed enrollment of the Phase 2a clinical trial in November and expects to report top-line data in the first quarter of 2023. Including this funding, the CF Foundation has provided a total of $12.5 million in support. Gallium was previously approved for IV use in some people and is also being studied in a Phase 1 trial to determine its effectiveness in treating infections in people with CF.
- 12.12.22 - Black Diamond Therapeutics Announces Spinout of Launchpad Therapeutics, Inc., an Antibody-Focused Precision Oncology Company (PR)
  - Black Diamond Therapeutics, Inc.,, a precision oncology medicine company pioneering the discovery and development of MasterKey therapies, today announced the formation of Launchpad Therapeutics, Inc., an antibody-focused precision oncology company, together with a $30 million Series A investment by founding investors, Versant Ventures and New Enterprise Associates. In connection with the transaction, Black Diamond contributed undisclosed early discovery-stage antibody programs and granted Launchpad a license to use Black Diamond's Mutation-Allostery-Pharmacology (MAP) Drug Discovery Engine to discover, develop and commercialize large molecule therapeutics. In exchange, Black Diamond received a minority ownership stake in Launchpad.
- 12.13.22 - Flagship Pioneering Unveils Montai Health to Treat and Preempt Chronic Disease Afflicting Two Billion People Worldwide (PR)
  - Montai is building the world's first Anthromolecule™ Bioactivity Atlas founded on a privileged class of molecules with a long history of safe, chronic human consumption.Flagship has initially committed $50 million to support the development of Montai's platform and its initial pipeline of new medicines. The company also announced that Margo Georgiadis, MBA, Flagship Pioneering CEO-Partner, who previously served as the CEO of Ancestry and President of the Americas at Google, is leading Montai as CEO.
- 12.14.22 - Alpha-9 Theranostics Announces Oversubscribed $75 Million Series B Financing to Advance Portfolio of Radiopharmaceuticals for Cancer (PR)
  - Alpha-9 is engineering highly effective, bespoke radiopharmaceuticals for the treatment of solid and hematologic malignancies. These molecules are optimized to selectively deliver radiation to tumor sites while minimizing off-target effects. The Series B funding will support advancement of the company's five programs into the clinic over the next two years while expanding its early-stage programs.The round was led by Nextech Invest, with participation from Frazier Life Sciences, Samsara BioCapital and Quark Venture in addition to existing investors Longitude Capital and BVF Partners.
- 12.15.22 - Enlaza Therapeutics Launches with $61 Million Seed Financing to Advance the First Covalent Biologic Therapeutic Platform (PR)
  - The financing was led by Avalon Ventures and joined by Lightspeed Venture Partners, Frazier Life Sciences, and Samsara BioCapital. The financing will be used to further advance Enlaza's proprietary War-LockTM platform and build a pipeline of covalent biologics with an initial focus on developing novel, differentiated cancer therapeutics with targeted efficacy and low toxicity.
- 12.16.22 - Evelo Biosciences Announces $45 Million Loan Agreement with Horizon Technology Finance Corporation to Refinance Existing Debt (PR)
  - The $45 million term loan, which provides for three years of interest-only payments followed by a two-year amortization period, replaces the Company's existing senior secured debt which would have begun amortizing in March 2023.
- 12.21.22 - Madrigal Pharmaceuticals Announces $300+ Million in Financing Events to Advance Resmetirom Program (PR)
  - In connection with Madrigal's December 19, 2022 announcement of positive topline data from its pivotal Phase 3 MAESTRO-NASH clinical trial of resmetirom, Hercules Capital, Inc. (NYSE:HTGC) confirmed that Madrigal has achieved its clinical milestone under the Company's Credit Facility with Hercules, thereby enabling Madrigal to draw upon a $50 million clinical milestone tranche over the next three months.
- 12.23.22 - TERNS ANNOUNCES CLOSING OF PUBLIC OFFERING OF SHARES OF COMMON STOCK, INCLUDING FULL EXERCISE OF UNDERWRITERS' OPTION TO PURCHASE ADDITIONAL SHARES (PR)
  - Terns intends to use the net proceeds from the offering, together with its existing cash and cash equivalents, to advance its clinical-stage development pipeline, including the TERN-501, TERN-701 and TERN-601 clinical programs and for working capital and general corporate purposes.

Collaboration Updates:

- 12.08.22 - Vertex and Entrada Therapeutics Establish Collaboration to Discover and Develop Endosomal Escape Vehicle (EEV) Therapeutics for Myotonic Dystrophy Type 1 (DM1) (PR)
  - Entrada to receive $224 million upfront payment and $26 million equity investment, as well as potential milestone payments and royaltie. Global collaboration includes ENTR-701, Entrada's EEV-investigational candidate for the treatment of DM1
- 12.12.22 - Watch out, Amgen. Mirati kicks off KRAS showdown with FDA approval for Krazati (fiercepharma)
  - Mirati Therapeutics' Krazati, also known as adagrasib, will take on Amgen's first-to-market Lumakras thanks to an FDA accelerated approval in previously treated KRAS G12C-mutated non-small cell lung cancer (NSCLC). Krazati marks Mirati's first commercial product, and the biotech will focus on efficacy in its marketing pitch, CEO David Meek told Fierce Pharma in an interview ahead of the approval. J.P. Morgan analyst Eric Joseph, Ph.D., has in late November put Krazati's risk-weighted peak sales estimate across multiple indications at $1.7 billion but then lowered the number to $1.3 billion a few days ago, as blockbuster hopes for the drug have dwindled since a Keytruda combination readout.
- 12.13.22 - Praxis Precision Medicines and UCB Announce Epilepsy Research Collaboration (PR)
  - Under the terms of the collaboration, UCB retains an exclusive option to in-license global development and commercialization rights to any resulting KCNT1 small molecule development candidate. Praxis will receive an upfront payment from UCB, and if the option is exercised by UCB, would be eligible to receive an option fee and future success-based development and commercialization milestone payments, for a total of up to approximately $100 million, in addition to tiered royalties on net sales of any resulting products from the collaboration. Further financial details of the agreement were not disclosed.
- 12.14.22 - PrecisionLife Enters Multi-Target R&D Partnership with Ono Pharmaceutical (ContractPharma)
  - PrecisionLife Limited, a global techbio company generating insights into disease biology to create novel precision medicines in chronic diseases, has entered into a multi-target discovery and validation partnership with Ono Pharmaceutical Co., Ltd., an R&D-orientated pharmaceutical company. The R&D collaboration will leverage PrecisionLife's combinatorial analytics-generated insights to identify novel therapeutic targets and patient stratification biomarkers in central nervous system (CNS) disorders for development by Ono. PrecisionLife is a leader in analyzing multi-modal datasets including genomic, clinical, and epidemiological data to accurately stratify patients and understand subgroup-relevant disease risks and drivers
- 12.15.22 - AbCellera, Abbvie Enter Strategic Antibody Alliance (ContractPharma)
  - AbCellera has entered into a multi-year, multi-target strategic collaboration with AbbVie Inc. The partnership will leverage AbCellera's antibody discovery and development engine to deliver optimized development candidates for up to five targets selected by AbbVie across multiple indications. Under the terms of the agreement, AbbVie has the right to develop and commercialize therapeutic antibodies resulting from the collaboration. AbCellera will receive research payments and is eligible to receive downstream clinical and commercial milestone payments and royalties on net sales of products.
- 12.19.22 - Biogen Reaches Agreement with Genentech to Receive Royalties on the Potential Commercialization of a Late-Stage Bispecific Antibody as Part of Anti-CD20 Collaboration (PR)
  - Under the terms of the agreement, Biogen will have no payment obligations and will receive tiered royalties on potential net sales of glofitamab within the United States as part of the companies long-standing collaboration on antibodies targeting CD20. Glofitamab is an investigational T-cell engaging bispecific antibody targeting CD20 and CD3 in development for B-cell non-Hodgkin's lymphoma and other blood cancers.
- 12.21.22 - Zymeworks sings to the tune of $325M with Jazz opt-in for HER2 cancer drug (Endpts)
  - After announcing it would dole out $50 million to become the second partner on Zymeworks' HER2 bispecific, Jazz Pharmaceuticals was met with some questions from analysts around the financing engineering of the deal, particularly curious as to why the duo linked up before a crucial readout of the drug, known as zanidatamab. But with a 41.3% objective response rate in a pivotal trial in biliary tract cancer earlier this week, the pair will march forward. Jazz is forking over $325 million to exclusively develop and commercialize zanidatamab in the US, Europe and Japan. If the collaborators make it to the end of the album, the payout could be $1.76 billion for Zymeworks, as well as tiered royalties between 10% and 20% on Jazz's net sales. BeiGene holds the China, South Korea, Australia and New Zealand rights to the drug.
- 12.23.22 - Mersana Inks Cancer Therapy Development Deal With Merck Germany (Yahoofinance)
  - Mersana would receive $30 million in an upfront payment and up to $800 million in development, regulatory and commercial milestones. Under the agreement, Mersana would develop cancer drug candidates against up to two targets that would utilize its platform to combine Merck KGaA's proprietary antibodies. Pre-clinical activities will be split between the companies. Merck Germany will be solely responsible for all clinical development and potential commercialization activities relating to any resulting product candidates.Mersana said it was also eligible to receive royalties of up to low double-digit percentages on global net sales for any approved ADCs developed under the agreement.

M&A Updates:

- 12.06.22 - Enzyvant Announces Merger with Altavant (PR)
  - Enzyvant Therapeutics, Inc. and Altavant Sciences, Inc., both wholly owned subsidiaries of Sumitovant Biopharma Ltd., today announced a merger to form a biopharmaceutical company focused on delivering life-altering therapies for people with rare diseases. The combined company retains the name Enzyvant and is equipped with a full range of capabilities spanning non-clinical and clinical development and commercialization and is in the process of developing in-house manufacturing.

- 12.13.22 - Takeda to Acquire Late-Stage, Potential Best-in-Class, Oral Allosteric TYK2 Inhibitor NDI-034858 From Nimbus Therapeutics (PR)
  - Nimbus to receive $4 billion in upfront cash, and up to $2 billion in commercial milestone payments. NDI-034858 has potential best-in-class profile among new therapeutic class of selective allosteric TYK2 inhibitors for immune-mediated diseases. With Phase 3 Study in Psoriasis Expected to Start in 2023, NDI-034858 Has the Potential to Demonstrate Best-in-class Efficacy and Safety in Psoriasis As Well As Multiple Other Immune-Mediated Diseases, Including Inflammatory Bowel Disease, Psoriatic Arthritis and Systemic Lupus Erythematosus. Acquisition Strengthens Takeda's Growing Late-stage Pipeline, in Alignment With the Company's Therapeutic Area Strategy and Expertise in Immune-Mediated Diseases
- 12.14.22 - Say goodbye to Vallon as a low-profile NKT cell startup steps into its battered shoes on Nasdaq (Endpts)
  - Eight months after Vallon Pharmaceuticals' late-stage shot at R&D glory ended in a short, sharp implosion with the failure of a Phase III study for its lead ADHD drug, the tiny biotech will hand over its public listing in a reverse merger that will shove a low-profile NKT cell player into the public arena. Vallon $VLON will now disappear under the storm-tossed seas of Nasdaq, as GRI Bio in San Diego tries its hand at drug development as a public company.GRI got started as a spinout of the lab of Vipin Kumar, the CSO and co-founder of the biotech which is now advancing his NKT therapeutics for inflammatory conditions in the clinic.Their lead drug is GRI-0621, which the biotech describes as "a small molecule RAR-βγ dual agonist that inhibits the activity of human NKT I cells.
- 12.12.22 - Updated: Horizon's $28B sale to Amgen was kicked off by Sanofi's interest (Endpts)
  - Amgen plans to buy Horizon Therapeutics for about $28 billion in cash, bringing on board two blockbuster drugs to ease the hit the biotech giant faces from biosimilar competition. The companies announced the deal in a press release Monday morning, about two weeks after it was disclosed that Amgen, Sanofi and Johnson & Johnson's Janssen were all in talks. Amgen struck the agreement after agreeing to pay $116.50, a 48% premium over Horizon's price, before the talks became public on Nov. 29. The match helps solve a serious problem for Amgen: what to do about the $30 billion in sales it's likely to lose from biosimilar drugs that will eat into its existing products, according to one estimate from Jefferies.
- 12.14.22 - Novartis, busy with its restructuring, sells 5 eye drugs for up to $175M (fiercepharma)
  - Amid a major restructuring and the spinoff of generics unit Sandoz, Novartis isn't done shaking things up.The pharma giant has sold five of its ophthalmic drugs to eye therapy company Harrow for a one-time payment of $130 million, plus additional milestone payments of $45 million.The sale includes cataract surgery recovery eye drops Ilevro and Nevanac, bacterial conjunctivitis eyedrop Vigamox, inflammation eye drops Maxidex and the injectable Triesence. The deal puts Harrow on the map into "a leadership position in the U.S. ophthalmic pharmaceuticals market," Mark L. Baum, Harrow's CEO and chairman, said in a statement.
- 12.20.22 - KKR to Acquire Bushu Pharmaceuticals (PR)
  - Founded in 1998, Bushu Pharma is a leading pure-play pharmaceutical CDMO based in Japan, which is the third-largest pharmaceutical market in the world. The Company is committed to producing, processing and delivering high-quality healthcare products to patients spanning categories including pharmaceuticals – such as oral solid dosages and injectables – and clinical trial materials. The Company additionally applies advanced quality control processes and supply chain management support for the inspection, packaging and distribution of pharmaceutical products. Bushu Pharma has Good Manufacturing Practice ("GMP") certifications globally, and manufacture products for worldwide end-markets, with a particular focus on Japan and Asian countries, such as China.
- 12.27.22 - Gilead to Acquire All Remaining Rights to Potential First-in-Class Immunotherapy GS-1811 From Jounce Therapeutics (PR)
  - Agreement Covers Buyout of Remaining Financial Obligations for Anti-CCR8 Antibody in Development as a Potential Treatment for Solid Tumors. xisting license agreement for GS-1811 (formerly JTX-1811), enabling Gilead to buy out remaining contingent payments potentially due under the license agreement executed in August 2020. As part of the transaction, certain operational obligations of the parties related to GS-1811, an anti-CCR8 antibody, set forth in the license agreement have also been terminated. Gilead will acquire certain related intellectual property, including all outstanding rights of Jounce to GS-1811, pursuant to the transaction agreement. GS-1811, a potentially first-in-class immunotherapy, is designed to selectively deplete immunosuppressive tumor-infiltrating T regulatory cells in the tumor microenvironment and is currently in Phase 1 clinical development as a possible treatment for patients with solid tumors.

Clinical and Commerical Updates:

- 12.01.22 - Rigel Announces U.S. FDA Approval of REZLIDHIA™ (olutasidenib) for the Treatment of Adult Patients with Relapsed or Refractory Acute Myeloid Leukemia with a Susceptible IDH1 Mutation (PR)
  - U.S. FDA has approved REZLIDHIA™ (olutasidenib) capsules for the treatment of adult patients with relapsed or refractory (R/R) acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test. REZLIDHIA is an oral, small molecule, inhibitor of mutated IDH1 designed to bind to and inhibit mIDH1 to reduce 2-hydroxyglutarate levels and restore normal cellular differentiation of myeloid cells.
- 12.01.22 - Otsuka and Sunovion Initiate Clinical Development of Ulotaront for the Adjunctive Treatment of Major Depressive Disorder (PR)
  - Otsuka Pharmaceutical Development & Commercialization, Inc. (Otsuka) and Sunovion Pharmaceuticals Inc. (Sunovion) today announced that the first patient has been enrolled in a Phase 2/3 clinical study to evaluate ulotaront (SEP-363856), a trace amine-associated receptor 1 (TAAR1) agonist with 5-HT1A agonist activity, as an adjunctive therapy in the treatment of adults living with major depressive disorder (MDD). Ulotaront, which is also being evaluated in Phase 3 clinical development for the treatment of schizophrenia, is the first TAAR1 agonist to be studied as an adjunctive therapy in the treatment of MDD.

- 12.05.22 - Syndax Pharmaceuticals and Incyte Announce Axatilimab Phase 1/2 Data in Patients with Chronic Graft-Versus-Host Disease Published in the Journal of Clinical Oncology (PR)
  - Treatment with axatilimab resulted in an overall response rate (ORR) of 67% across all patients; and an ORR of 82% in patients dosed at 1 mg/kg every 2 weeks in the Phase 2 portion of the trial. Broad multi-organ clinical benefit including in lung, skin, and joints and fascia observed in heavily pretreated patient population
- 12.07.22 - With clear PhII win in IBD, Prometheus thwarts Pfizer comparisons as it follows Humira 'playbook' (Endpts)
  - Prometheus Biosciences reported a clear Phase II win in two inflammatory bowel disease conditions in a clinical development race with Pfizer, planting the biotech's flag in a field of antibodies attempting to go against black box-cornered JAK inhibitors and AbbVie's Humira. In the study, 47% of patients had previously been treated with at least one advanced therapy, including Xeljanz, Rinvoq or Zeposia, CMO Allison Luo said on the call with analysts.
- 12.13.22 - Erasca Announces FDA Clearance of IND Application for CNS-Penetrant KRAS G12C Inhibitor ERAS-3490 in KRAS G12C-Mutated Advanced or Metastatic Solid Tumors (PR)
  - In April, Erasca presented nonclinical data for ERAS-3490 at the American Association for Cancer Research (AACR) Annual Meeting showing robust anti-tumor activity in KRAS G12C mutant MIA PaCa-2, NCI-H1373, and NCI-H2122 CDX subcutaneous models. ERAS-3490 also demonstrated robust anti-tumor activity and dose-dependent survival benefit in the KRAS G12C NSCLC intracranial model NCI-H1373-luc, a nonclinical model of NSCLC CNS metastases.
- 12.13.22 - Moderna vaccine succeeds in early-stage skin cancer study with Merck's Keytruda (Biopharmadive)
  - A Moderna personalized cancer vaccine combined with Merck & Co.'s immunotherapy Keytruda kept people with melanoma alive and disease free after surgery significantly longer than Keytruda alone in a mid-stage trial, the companies said Tuesday. It was the first major finding for one of Moderna's non-COVID vaccines, which was a focus for its investors before the pandemic began in 2020. The companies said they hope to get a Phase 3 trial underway in 2023 and will begin testing the combination in other types of cancer. In October, Merck paid $250 million to license the Moderna vaccine, for which it had originally signed an option in 2016. Combination therapies are one way that Merck could help stave off biosimilar competition to Keytruda when the drug's main patent expires in 2028.
- 12.15.22 - Ocugen Announces OCU400 Receives Orphan Drug Designations for Retinitis Pigmentosa and Leber Congenital Amaurosis (PR)
  - "Receiving orphan drug designation is incredibly encouraging at this stage in the development of OCU400," said Arun Upadhyay, PhD, Chief Scientific Officer, Ocugen. "We are excited by the potential of OCU400, a nuclear hormone-based modifier gene therapy product, to treat RP and LCA in a gene agnostic manner. We look forward to working collaboratively with the FDA and other agencies to progress OCU400 through clinical development to commercialization."
- 12.15.22 - Kintara Therapeutics Receives Orphan Drug Designation for VAL-083 for Treatment of Diffuse Intrinsic Pontine Glioma (DIPG) (PR)
  - VAL-083 is a 'first-in-class', small-molecule chemotherapeutic with a novel mechanism of action that has demonstrated clinical activity against a range of cancers, including central nervous system, ovarian and other solid tumors (e.g., NSCLC, bladder cancer, head and neck) in U.S. clinical trials sponsored by the National Cancer Institute (NCI). Based on Kintara's internal research programs and these prior NCI-sponsored clinical studies, Kintara is currently advancing VAL-083 in the Global Coalition for Adaptive Research registrational Phase 2/3 clinical trial titled Glioblastoma Adaptive Global Innovative Learning Environment (GBM AGILE) Study to support the development and commercialization of VAL-083 in GBM.
- 12.19.22 - Ferring grabs first gene therapy approval in bladder cancer (Pharmamanufacturing)
  - Ferring Pharmaceuticals announced that the U.S. FDA has approved its novel adenovirus vector-based gene therapy, Adstiladrin — marking the first gene therapy approval for bladder cancer. Specifically, Adstiladrin was approved for the treatment of adult patients with high-risk, Bacillus Calmette-Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.
- 12.20.22 - Amneal Announces 26 Generic New Product Launches in 2022 and First Injection Large Volume Bag Approval (PR)
  - The company announced that the Company has successfully launched 26 new generic products in 2022. In the fourth quarter of 2022, the Company launched 8 new generic products, including clindamycin phosphate gel 1%, ipratropium bromide nasal sprays, and prednisolone sodium phosphate oral solution. Esmolol hydrochloride in sodium chloride injection is indicated for tachycardia. For full prescribing information, see package insert located here. According to IQVIA®, U.S. annual sales for this product for the 12 months ended October 2022 were $57 million.
- 12.20.22 - Astellas, Seagen and Merck Announce FDA Acceptance of Supplemental Biologics License Applications for PADCEV® with KEYTRUDA® for the First-Line Treatment of Certain Patients With Locally Advanced or Metastatic Urothelial Cancer (PR)
  - This combination has the potential to be the first treatment option combining an antibody-drug conjugate plus an immunotherapy in this treatment setting. FDA granted the applications priority review with a PDUFA date of April 21, 2023
- 12.29.22 - Vericel Announces FDA Approval of NexoBrid for the Treatment of Severe Thermal Burns in Adults (PR)
  - Potential to become the new standard of care for eschar removal in patients with deep partial- and/or full- thickness thermal burns. Label supported by robust clinical data demonstrating significantly higher incidence of complete eschar removal in patients treated with NexoBrid compared to placebo

CDMO & Manufacturing Updates:

- 12.01.22 - August Bioservices Closes $65M Series B (PR)
  - August Bioservices, LLC ("August Bio"), a pharmaceutical CDMO providing drug discovery, development and pharmaceutical manufacturing services, today announced that it secured $65 million in Series B funding led by Oak HC/FT, who led the Series A in July 2020. This round includes participation from existing investor, Polaris Partners. Funding enables August Bio to add capacity for large batch sterile pharmaceutical manufacturing
- 12.08.22 - The CDMO space does not have the capacity to meet fill-finish demand, says Lonza (BioprocessintI)
  - Pipeline expansions are placing pressure on fill-finish capabilities and have caused a surge of investment in infrastructure, says Peter Droc, head of drug product services at Lonza. Swiss contract development manufacturing organization (CDMO) Lonza has made a string of investments to bolster its fill-finish capabilities. In July 2022, the firm forked out $521 million to construct a commercial large-scale fill-finish facility at its site in Stein, Switzerland. And less than a year before this – at the same plant – it added additional drug product manufacturing capabilities to accelerate its service offerings in Basel and Visp. Additionally, in August 2021 Lonza installed an aseptic fill-finish manufacturing line at its mammalian plant located in Guangzhou, China.
- Catalent to Expand Its Biologics Analytical Services with New Facility in Durham, North Carolina (LifeSciKnowledgeHub)
  - Catalent plans to invest up to $40 million to fit out the 80,000 square-foot facility with state-of-the-art equipment and instrumentation, including automation and digitization capabilities. When complete it will provide comprehensive solutions that include bioassays, physico-chemical testing, and full product and process characterization, as well as process validation support, stability testing, in-process manufacturing and formulation analysis, and post-packaging identification. Catalent expects to complete the facility by mid-2023, which will support the hiring of over 200 scientists and technicians over the next five years.
- 12.14.22 - Societal CDMO Announces Closing of $35.6 Million Concurrent Public Offerings (PR)
  - Societal intends to use the net proceeds from the proposed offerings for the repayment of its outstanding debt facility with Athyrium and associated costs to satisfy closing conditions for a capital structure refinancing, including a sale-leaseback transaction in connection with its facility in Gainesville, Georgia and a new 3-year Term A Loan debt facility with Royal Bank of Canada. Societal intends to use the net proceeds from the proposed offerings, together with proceeds from the new Term A Loan and the sale-leaseback transaction, to repay in full and retire the outstanding debt facility with Athyrium, with any remaining proceeds to be used for general corporate and working capital purposes.
- 12.19.22 - Formulated Solutions to Acquire Newly Updated FDA Approved Drug Production Site (ContractPharma)
  - Strengthens its capabilities in topicals, metered dose nasal sprays and pressurized package manufacturing. Formulated Solutions, a Florida-based Contract Development and Manufacturing Organization (CDMO), has agreed to acquire a newly updated 455,000 ft2 FDA approved pharmaceutical liquids, semi solids, aerosol, BoV, and metered dose nasal spray production facility located in Cleveland, TN.
- 12.20.22 - SCORPION BIOLOGICAL SERVICES BECOMES SCORPIUS BIOMANUFACTURING TO REFLECT EXPANSION (PR)
  - Scorpion Biological Services today announced it has changed its name to Scorpius BioManufacturing reflecting the company's recently expanded manufacturing capabilities and the grand opening of its new biomanufacturing facility in San Antonio in October. The new facility offers GCP, GLP and GMP biomanufacturing capabilities in both mammalian and microbial modalities. Suites and equipment trains are flexible, with bioreactor sizes ranging from 50 L up to 2,000 L, and best-in-class equipment installed across the facility to produce high-quality material for clients. Scorpius offers the capability to manufacture a wide range of products, including cell therapy, recombinant proteins from mammalian or microbial systems, and DNA vectors.
- 01.02.22 - Polysciences Announces New Bioprocessing Brand, Kyfora Bio (PR)
  - Building on Polysciences' extensive experience in developing and manufacturing monomers, polymers, microspheres, and specialty reagents for the medical device, diagnostic, and pharmaceutical industries, Kyfora Bio will focus on the synthesis of cationic polymers, lipids, and other materials used in nucleic acid delivery for cell and gene therapies.Based in Horsham, PA, Kyfora Bio will occupy a 45,000 square foot cGMP facility outfitted with administrative offices, R&D laboratories, manufacturing suites, and QC laboratories for chemical and biological performance testing. The new site is a short drive from Polysciences' 250,000 square foot Warrington, PA campus which serves as the company's headquarters and houses manufacturing, R&D, QA/QC, and product storage facilities.
- 01.03.22 - Bristol Myers Squibb Completes Sale of Manufacturing Facility in Syracuse, NY (ContractPharma)
  - Bristol Myers Squibb has entered into a newly established contract manufacturing organization (CMO) relationship with Lotte, under which Lotte Biologics will manufacture product for Bristol Myers Squibb at the Syracuse facility.
- 01.03.22 - GHO Capital and The Vistria Group Complete Acquisition of Leading CDMO Alcami Corporation (PR)
  - The CDMO was acquired from funds affiliated with Madison Dearborn Partners and Ampersand Capital Partners. The company is headquartered in North Carolina, Alcami operates five campuses across the United States, which support sterile fill-finish and oral solid dose drug product manufacturing; formulation development; lab services; and cGMP biostorage of high-value temperature-sensitive biologics, pharmaceuticals, and materials.