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The Berke Report

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

Manufacturing & CDMOs Updates:

- 10.05.22 - Almac Introduces New Cryogenic Service Solution in its Durham, NC Campus to support cell and gene therapies. (Contract Pharma)
  - This latest investment from the company's overall $4million investment to date in cold chain technology in NC includes the Cryogenic Service Solution to ensure an unbroken chain of custody from product line to patient, for sponsors of advanced therapy trials.
- 10.11.22 - Eli Lilly faces fresh FDA rebuke at a troubled plant in New Jersey: report (Fierce Pharma)
  - The U.S. FDA has logged multiple new quality control lapses at Lilly's plant in Branchburg, New Jersey, Reuters first reported, citing an agency report seen by the news outlet. Problems at Branchburg stretch back to at least 2020, when the FDA cited Lilly on two counts of inadequate "control of computer systems," a Lilly spokesperson said at the time.Those two findings included deleted data on the company's manufacturing processes and failed quality control for audit paper trails, sources told Reuters at the time. Last May, meanwhile, Reuters reported employees at the site accused an executive of altering FDA-required documents in a bid to downplay serious quality control problems. Several weeks after that, the Department of Justice handed down a subpoena linked to the Branchburg site, which had been producing doses of Lilly's COVID-19 antibody treatment.
- 10.12.22 - Ionis announces plan for new manufacturing facility in Oceanside, Ca (PR)
  - The company entered into an agreement with Sudberry Properties to develop and lease a new development chemistry and manufacturing site in Oceanside, Calif. Sudberry will develop and construct the shell for the approximately 217,000-square-foot building. Ionis will design and construct improvements to customize the facility. Under the terms of the agreement, Ionis will lease the property for 20 years, with two 10-year options to renew and a right of first offer to purchase the property. onis expects to occupy the new facility in 2025, with active pharmaceutical ingredient ("API") manufacturing beginning in mid-2026. At approximately 217,000 square feet, the new facility will be more than double the size of Ionis' existing development chemistry and manufacturing facility, which is in Carlsbad.
- 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.
- 10.27.22 - SAB Biotherapeutics Announces Exclusive Manufacturing Partnership with Emergent BioSolutions (Biospace)
  - Under the terms of the agreement, Emergent will provide end-to-end Good Manufacturing Practice (cGMP) manufacturing services to SAB, including process development and manufacturing clinical investigational drug product to support SAB's clinical programs, and commercial manufacturing services upon regulatory approval of SAB's therapeutics. The agreement also provides the opportunity for Emergent to utilize SAB's novel DiversitAb™ platform, the only one in the world that produces fully-human polyclonal antibodies utilizing transchromosomic cows, for future development of undisclosed programs. Financial details of the agreement were not disclosed.
- 10.27.22 - Cambrex to Invest $16.5 Million in New R&D Facility in Minneapolis, Minnesota and Expansion in Charles City, Iowa (PR)
  - Cambrex announced it is investing in a new, 21,000-square-foot research and development facility in Minneapolis, Minnesota, expanding its capacity for small molecule development and manufacturing. Strategically located near the Minneapolis–St. Paul Airport, the new facility will specialize in analytical and chemical development for pharmaceutical drug candidates and will operate as an extension of Cambrex's flagship facility in Charles City, Iowa. Cambrex is expected to add approximately 40 new jobs over the next 2-3 years at the new site in Minneapolis.Cambrex will simultaneously launch a multi-phase, 9,000-square-foot expansion and 21,000-square-foot renovation project in Charles City, Iowa. The expansion will add a new quality control laboratory and administrative office space, which will bring 40 new jobs at the site.
- 10.28.22 - Curia breaks ground on $100M expansion project in New Mexico (Endpts)
  - According to the New Mexico Governor's office, Curia is slated to invest $100 million into its Albuquerque site. The State of New Mexico is also contributing $5 million to the project through the Local Economic Development Act job creation fund. The project is slated to create 274 jobs with salaries over $50,000. The Governor's office states that the fill-finish line will be up and running by 2025.

- 10.28.22 - Aphena Pharma completes $20m expansion project in Tennessee, US (NS Packing)
  - Aphena president and COO Eric Allen said: "The expansion added a new 500,000-square-foot facility that is purpose-built for FDA pharmaceutical packaging of solid dose and biologic products. The firm manages solid dosage, liquid, gel, cream, ointment, foam, suspension, and lotion-based products in two distinct US Food and Drug Administration (FDA) and Drug Enforcement Administration (DEA)-registered facilities in the US. In November 2020, the pharmaceuticals company commissioned a new facility in Tennessee, US to offer cold chain storage and large-scale biologics packaging and distribution services.
- 10.31.22 - Lannett Expands Liquid Drug Manufacturing Capabilities (ContractPharma)
  - Receives FDA approval to manufacture Numbrino, the company's branded topical anesthetic product, at its main plant in Seymour, IN. The company previously manufactured Numbrino and other liquid drug products at its Carmel, NY, plant, which it sold in March of this year as part of a restructuring and cost reduction plan.
- 10.31.22 - Paratek Announces First Milestone Towards Creating a U.S. Manufacturing Supply Chain for NUZYRA® (omadacycline) under BARDA Project BioShield Contract (PR)
  - This milestone follows a successful technology transfer by Paratek and its tablet manufacturing partners in the United States and Europe.NUZYRA is the company's broad-spectrum, novel antibiotic available in both intravenous and oral formulations. Onshoring of the manufacturing process for the tablets is the first completed step in the technology transfer process, with the active pharmaceutical ingredient (API) for NUZYRA and NUZYRA vials scheduled to be completed in 2023 and 2024, respectively. The commercial availability of NUZYRA tablets manufactured in the United States represents the first of several steps to create an end-to-end U.S. supply chain for NUZYRA under the Project BioShield public-private partnership with the Biomedical Advanced Research and Development Authority (BARDA).

Clinical and Commerical Updates:

- 10.07.22 - FDA Approves Boostrix Vaccine for Use During Third Trimester of Pregnancy to Prevent Whooping Cough in Infants Younger Than Two Months of Age (PR)
  - Boostrix was initially approved by the FDA in 2005 as a single dose for booster immunization against tetanus, diphtheria and pertussis in individuals 10 through 18 years of age. Subsequently, the FDA also approved Boostrix to include use in individuals 19 years of age and older and to include use of an additional dose 9 years or more after the initial dose of a Tdap vaccine. The FDA's approval of Boostrix has always included its use during pregnancy to protect the vaccinated individual. Today's approval is specific to use in pregnancy to prevent pertussis in infants younger than 2 months of age. Since 2012, the CDC has recommended the use of Tdap vaccines during the third trimester of each pregnancy.
- 10.07.22 - FDA Expands Label for Alnylam's Oxlumo for Sickest Patients with Rare Disease PH1 (Biospace)
  - The U.S. FDA approved Alnylam Pharmaceuticals' Oxlumo for an expanded indication, rare disease primary hyperoxaluria type 1 (PH1), with the label to include patients with the most severe kidney impairment, including hemodialysis. PH1 is a group of ultra-rare autosomal-recessive metabolic stone diseases. Although it has a variety of presentations, it often presents with kidney stones, which is caused by mutations in the AGXT gene.
- 10.19.22 - U.S. FDA Grants Emergency Use Authorization for Novavax COVID-19 Vaccine, Adjuvanted as a Booster for Adults (Biospace)
  - Novavax COVID-19 Vaccine, Adjuvanted (NVX-CoV2373) has received emergency use authorization (EUA) from the U.S. Food and Drug Administration (FDA) to provide a first booster dose at least six months after completion of primary vaccination with an authorized or approved COVID-19 vaccine to individuals 18 years of age and older for whom an FDA-authorized mRNA bivalent COVID-19 booster vaccine is not accessible or clinically appropriate, and to individuals 18 years of age and older who elect to receive the Novavax COVID-19 Vaccine, Adjuvanted because they would otherwise not receive a booster dose of a COVID-19 vaccine.
- 10.27.22 - FDA accepts ARS' filing for approval of nasal spray EpiPen rival for review (Fierce Pharma)
  - ARS Pharmaceuticals has taken a step toward FDA approval of its epinephrine nasal spray. Seeking to challenge EpiPen, the San Diego-based company has had its application for approval accepted and assigned a mid-2023 PDUFA decision date to the process. The candidate, branded Neffy, is designed to provide injection-like absorption of epinephrine at a low dose from a small, rapidly administered and reliable nasal spray. ARS is pitching the product as a solution to issues that it argues can delay or prevent the use of Viatris' injectable allergic reaction incumbent EpiPen, such as fear of needles, a lack of portability and the complexity of the device.
- 10.27.22 - Janssen's Tecvayli granted FDA approval for multiple myeloma (PM Live)
  - Specifically, patients treated with Tecvayli must have received four or more prior lines of therapy, including a proteasome inhibitor, immunomodulatory drug and anti-CD38 monoclonal antibody. The FDA's decision is supported by evidence from the pivotal phase 2 MajesTEC-1 clinical trial in RRMM patients who had received a median of five prior lines of therapy. An overall response rate of 61.8% was achieved in the study, notably with 28.2% of patients achieving a complete response or better, the company reported.

CRO Updates:

- 10.12.22 - Thermo Fisher Scientific Expands Clinical Research Operations in Richmond, VA (Contract Pharma)
  - The new unit will support increasing demand across biopharma for consistent, high-quality laboratory services to accelerate drug development. The 59,000-square-foot facility is part of the previously announced $97 million investment by the company to expand its bioanalytical laboratory operations in Richmond and add more than 500 jobs over the next three years. The current laboratory services operation in Richmond, which Thermo Fisher acquired through the purchase of PPD, Inc. in December 2021, now comprises more than 350,000 square feet, making it one of the largest laboratories of its kind in the world. The entire Richmond operation employs about 1,300 local professionals, including Ph.D.-level scientists, analytical laboratory staff and other scientific professionals. The bulk of the expansion with this new facility will occur in liquid chromatography-mass spectrometry for drug discovery through to clinical testing, as well as subsequent enhancements in cell and gene therapy, biomarkers, vaccine sciences and immunochemistry.
- 10.22.22 - Symeres acquires Exemplify BioPharma, further strengthening its strategic foothold in the US (PR)
  - Exemplify BioPharma, based in Cranbury, New Jersey (US), is a provider of high-quality integrated end-to-end small molecule Chemistry Manufacturing and Controls (CMC) services to pharmaceutical and biotech partners. The company offers functional expertise and consultancy services in Process Chemistry, Analytical Chemistry, and Formulation Development for a successful transition of programs from late-stage lead optimization through candidate selection to first-in-human. Exemplify employs 20 people, of which the majority are Ph.D-level scientists. The company will remain under the current management of co-founders: Yadan Chen, Chief Executive Officer, and Dr. Paul O'Shea, Chief Scientific Officer.
- 10.31.22 - H.I.G. Capital Completes Sale of Taconic Biosciences to Avista Capital Partners (Valdosta Daily Times)
  - Headquartered in Rensselaer, New York, and founded in 1952, Taconic is a leading global provider of murine research models and services to the pharmaceutical, biotechnology, CRO, and academic research industries. The Company specializes in genetically engineered models (GEMs), precision research models, and integrated model design and colony management services. H.I.G. acquired Taconic in February 2019 from the Company's founders. Through partnership with the H.I.G. team, Taconic achieved outstanding growth through continued focus on GEMs, significant investments in optimizing existing facilities, as well as greenfield expansion at its Indiana facility. Terms of the transaction were not disclosed.
- 10.28.22 - Thermo Fisher to Invest $59 Million to Expand Operations in Kentucky (ContractPharma)
  - The PPD clinical research business of Thermo Fisher Scientific Inc. has announced plans to invest $59 million to significantly expand its laboratory operations in Highland Heights, Kentucky. The current 71,600-square-foot operation will grow to 114,000 square feet and be completed in stages by the end of 2024, creating 200 new jobs over the next five years. The current operation employs nearly 650 Ph.D.-level scientists, analytical laboratory staff and other scientific and support professionals.

M&A and Collaborations Updates:

- 10.17.22 - Jazz Drops $50M for Exclusive Rights to Zymeworks' Bispecific HER2 Hopeful (Biospace)
  - Jazz Pharmaceuticals and Zymeworks Inc entered into a $50 million licensing agreement over zanidatamab, Zymeworks' bispecific antibody targeting HER2, the companies announced Wednesday. The deal will give Jazz exclusive commercialization and development rights over zanidatamab in the U.S., Europe, Japan and all other territories that aren't yet covered by existing licenses. Aside from the $50 million upfront payment, Jazz is putting $325 million more on the line if it decides to continue the collaboration. This will be decided once topline data from the HERIZON-BTC-01 trial comes in, which is expected to happen before the year ends. Zymeworks will also continue to be eligible for $524 million in certain regulatory milestones and up to $862.5 million in commercial milestones, bringing the overall potential value of the deal to $1.76 billion. Zymeworks can earn 10% to 20% of tiered royalties on net sales.
- 10.20.22 - AbbVie Gains Access to Pulmonary Fibrosis Antibody with $225M DJS Buy (Biospace)
  - AbbVie is buying DJS Antibodies for $225 million in cash to gain access to the British company's potential fibrotic diseases drug and antibody discovery program. Under the terms of the deal, announced Thursday, DJS stockholders will be eligible for additional payments based on various developmental milestones related to DJS' lead program, DJS-002. No additional financial details were disclosed.
- 10.24.22 - Sumitovant Biopharma, Sumitomo Pharma, and Myovant Sciences Enter into Definitive Agreement (PR)
  - Sumitovant will acquire all outstanding shares of Myovant not already owned by Sumitovant for $27.00 per share in cash. This corresponds to a total transaction value of $1.7 billion on a fully diluted basis, and a total company value of $2.9 billion on a fully diluted basis. Sumitovant currently beneficially owns 52% of the issued and outstanding shares of Myovant. The purchase price represents a premium of approximately 50% to Myovant's closing share price on September 30, 2022, the last day of trading prior to Sumitovant's initial non-binding proposal, and a premium of approximately 55% to the 60-day volume weighted average price of Myovant's shares through September 30, 2022. The agreement has been approved by the boards of Sumitovant and Sumitomo Pharma and unanimously recommended by a Special Committee of the independent directors of Myovant.

- 10.26.22 - GTCR Announces Partnership with Steve Powell and Mary Mattes to Form Harpula (PR)
  - GTCR, a leading private equity firm, today announced that it has entered into a Leaders Strategy™ partnership with Steve Powell and Mary Mattes to form Harpula Health Holdings, LLC ("Harpula"). Based in Raleigh, NC, Harpula will seek to acquire companies and assets in the technology-enabled pharmaceutical solutions industry as part of a strategy to build a market-leading company focused on improving the efficiency of drug research and development. GTCR's Leaders Strategy™ approach involves partnering with exceptional management leaders in its core domains to identify, acquire and build market-leading companies through transformational acquisitions and organic growth. GTCR has successfully applied The Leaders Strategy™ for several decades and maintains a culture of partnership with management teams as they build strategically attractive businesses over time. Mr. Powell and Ms. Mattes are serving as Chief Executive Officer and Chief Operating Officer of Harpula, respectively, and will make a substantial investment alongside GTCR.
- 10.28.22 - Amgen completes acquisition of ChemoCentryx in deal worth $3.7bn (PM LIVE)
  - Amgen has successfully completed its previously announced acquisition of ChemoCentryx in an agreement valued at approximately $3.7bn in cash. ChemoCentryx is a biopharmaceutical company focused on orally-administered therapeutics to treat autoimmune diseases, inflammatory disorders, and cancer.
- 10.28.22 - Eli Lilly and Purdue sign $92.5m deal for pharma manufacturing scholarships (PMLIVE)
  - The commitment includes $42.5m over ten years to scholarships for incoming Purdue undergraduate students, offering 75 to 100 students each year full tuition with a guaranteed internship or co-op at Lilly and a promise of coordinated interaction with company leaders. The programme will also provide participating students with preferred access and opportunities to compete for a role at the company following graduation, with the first scholarships being offered for autumn 2023.

Be on the Lookout for Next Months Update

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