The Berke Report

First Half of March - Collaborations & M&A

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Collaborations

- 03.17.23 - Pfizer pays Royalty Pharma $475m following US approval of migraine nasal spray (pmlive)
  - Royalty Pharma first signed a deal for the programme in 2020, when it offered Biohaven Pharmaceutical $250m in development funding in exchange for milestones and future royalties. This deal was inherited by Pfizer in October last year when it acquired Biohaven for $11.6bn. The FDA's decision on Zavzpret, announced by Pfizer, makes Zavzpret the first and only CGRP receptor antagonist nasal spray for the acute treatment of migraine with or without aura in adults.The pivotal study also demonstrated pain relief as early as 15 minutes in a pre-specified secondary endpoint versus placebo.
- 03.16.23 - Evotec Announces Progress In Strategic Protein Degradation Partnership With Bristol Myers Squibb (PR)
  - The partnership continues to deliver on its goal to build a leading pipeline of novel molecular glue degraders, targeting high-value targets in the field of oncology and beyond. Originally entered strategic partnership in 2018 and expanded it in May of 2022, because of the highly productive initial collaboration generating a promising pipeline. Since the expansion, Evotec has significantly scaled up its activities to develop highly promising compounds from BMS's industry-leading library of cereblon E3 ligase modulators ("CELMoDs™").
- 03.16.23 - Synaffix Announces Expansion of ADC Collaboration with MacroGenics (medtechalert)
  - Synaffix is focused on commercializing its clinical-stage platform technology for the development of antibody-drug conjugates (ADCs) with best-in-class therapeutic index, has expanded of its license agreement with MacroGenics, a biopharmaceutical company focused on developing and commercializing innovative monoclonal antibody-based therapeutics for the treatment of cancer. The expansion comes just a year after the original February 2022 deal, increasing the total potential consideration by up to $2.2 billion, plus tiered low to high single-digit royalties on potential net sales of any resulting products. MacroGenics currently has the option to pursue up to seven ADC programs under the expanded deal, which includes three programs from the original collaboration.
- 03.15.23 - Prelude Therapeutics Announces Clinical Trial Collaboration with BeiGene to Evaluate PRT2527 in Combination with Zanubrutinib in Hematologic Cancers (PR)
  - Inhibition of BTK is an active therapeutic approach in several B cell malignancies and the combination of CDK9 inhibition with BTK inhibition has demonstrated, in recent data publications, synergistic clinical efficacy over BTK inhibition alone; hence, there is a strong rationale for studying the combination in patients with certain hematologic malignancies. Under terms of the clinical trial collaboration agreement, BeiGene will provide zanubrutinib to Prelude, and Prelude will retain all global operational, development and commercialization rights and responsibilities for PRT2527.
- 03.14.23 - BlueRock (BR) Therapeutics to use Rune Labs' clinical trial platform to better characterize Parkinson's disease state in cell therapy trials (PR)
  - Cell therapy developer BlueRock is first to deploy StriveStudy, in conjunction with Rune Labs' StrivePD platform, to remotely collect real-time patient data and monitor patient compliance in research study. Collaboration is part of BR's commitment to change the standard of care for treating Parkinson's disease which includes a first-in-class stem cell-based therapy bemdaneprocel (BRT-DA01), currently in a phase 1 clinical study.Results from the Phase 1 study are expected in the second half of 2023. Rune Labs launches StriveStudy clinical development platform to streamline enrollment, enable real world evidence generation, monitor patient compliance with a study, and improve patient study experience..
- 03.13.23 - RoosterBio & Repligen Collaborate to Advance Scalable Exosome Bioprocessing (PR)
  - RoosterBio, a leading supplier of human mesenchymal stem/stromal cells (hMSCs), highly engineered media, development services, cell engineering, and advanced therapy bioprocess solutions, has selected Repligen Corporation, company focused on bioprocessing technology, as a collaboration partner to advance scalable exosome bioprocessing. The goal of the collaborations is to deliver solutions for manufacturing of exosomes using scalable and low shear technologies that enable cost-effective commercialization of these advanced therapies.
- 03.09.23 - Merck partners with ModeX Therapeutics on Epstein-Barr jab (pharmamanufacturing)
  - ModeX Therapeutics, an OPKO Health Company, has entered an exclusive license and collaboration agreement with Merck to work on the development of a nanoparticle vaccine candidate targeting the Epstein-Barr virus. The deal outlines that ModeX will receive up to $875.2 million in milestone payments, with an initial payment of $50 million. The two will work together to advance ModeX's preclinical jab, MDX-2201, and submit an Investigational IND for the drug candidate. Once the jab has an accepted IND, Merck will take over the clinical and regulatory activities as well as commercialization. MDX-2201 was designed using ModeX's ferritin nanoparticle vaccine platform, which enables expression of up to 24 copies of a recombinantthe antigen on its surface, enhancing the presentation of key components of the virus.

- 03.08.23 - Tessa Therapeutics Enters into Cooperative Research and Development Agreement (CRADA) with the U.S. National Cancer Institute (PR)
  - Tessa is advancing a pipeline of products that utilize CD30.CAR-modified EBVSTs, including its lead allogeneic cell therapy, TT11X, which is being co-developed with the Baylor College of Medicine for the treatment of relapsed or refractory CD30-positive lymphomas the company plans to extend its allogeneic EBVST platform to other cancer indications, including solid tumors. Under terms of the CRADA, Tessa will collaborate with the NCI's Division of Cancer Treatment and Diagnosis to identify potential opportunities to expand the applicability of TT11X as a treatment of non-Hodgkin lymphoma. In this collaboration, NCI Cancer Therapy Evaluation Program (CTEP) will serve as the regulatory sponsor and conduct mutually approved clinical trials through NCI funded clinical network groups and using drug supply and other necessary support provided by Tessa. Tessa is currently advancing a Phase 1 clinical trial in the United States investigating TT11X in CD30-positive lymphomas.
- 03.06.23 - Grifols, Selagine Partner to Develop Immunoglobulin Eye Drops (contractpharma)
  - Grifols, a producer of plasma-derived medicines, entered a global collaboration and licensing agreement with Selagine who is developing novel therapeutics for ocular diseases, to treat dry eye disease (DED) with immunoglobulin eye drops. The potential Ig treatment, following clinical development and regulatory authorizations, would become Grifols' first ocular-surface indicated medicine as well as the company's first-ever product for DED, which affects more than 100 million people globally. Under terms of the agreement, Grifols will have worldwide exclusive commercial rights to Selagine's treatment, which will be developed combining Grifols' expertise in developing and manufacturing innovative Ig therapies and Selagine's cutting-edge research, medical expertise and clinical experience treating debilitating eye diseases. In a pilot phase I/II clinical trial, Selagine treated subjects with eye drops based on Grifols Flebogamma DIF twice daily for eight weeks and secured a significant reduction in the signs and symptoms of DED, and with no difference in tolerability or adverse events.

M&A

- 03.15.23 - Eton Pharmaceuticals Announces Acquisition of Rare Disease Product Candidate ET-600 (medtechalert)
- Eton Pharmaceuticals, an innovative pharmaceutical company focused on developing and commercializing treatments for rare diseases, today announced the acquisition of rare disease product candidate ET-600 from Tulex Pharmaceuticals. ET-600 is an innovative product candidate under development for the treatment of an endocrinology condition that is estimated `to impact less than 5,000 pediatric patients in the United States. Eton expects to submit a New Drug Application (NDA) for the product to the U.S. Food and Drug Administration in the second quarter of 2024, which could allow for an approval and launch of the product in early 2025. If approved, ET-600 is expected to be a patent-protected, durable product that can generate significant long-term revenue and profit for the company.
- 03.14.23 -PerkinElmer completes $2.45B spinoff to create new diagnostics, life sciences company (fiercebiotech)
  - Right on schedule, PerkinElmer has completed the split it announced last August, selling off its applied science, food and enterprise services businesses to private equity firm New Mountain Capital and combining the remaining life sciences and diagnostics businesses into a new, standalone company. While the businesses sold to New Mountain will retain the PerkinElmer name, the newly formed medtech supplier will go by a different moniker—though its name, logo and ticker symbol have yet to be announced. Under the terms of the deal laid out last year, New Mountain offered up $2.3 billion in upfront cash to take over the trio of PerkinElmer businesses, which produce hardware used in food safety, environmental testing, forensics, semiconductor manufacturing and more. The deal also set aside another $150 million in cash that could be paid out to PerkinElmer in the future, depending on how much New Mountain earns from future sales of the newly acquired businesses.
- 03.13.23 - Sanofi to acquire Provention Bio, adding to portfolio TZIELD, the first disease-modifying treatment for the delay of Stage 3 type 1 diabetes (T1D) (PR)
  - Sanofi has agreed to acquire Provention Bio, Inc., for $25.00 per share in cash, representing an equity value of approximately $2.9 billion. The transaction adds an innovative, fully owned, first-in-class therapy in type 1 diabetes to Sanofi's core asset portfolio in General Medicines and further drives its strategic shift toward products with a differentiated profile. TZIELD (teplizumab-mzwv) was approved in the U.S. last year as the first and only therapy to delay the onset of Stage 3 type 1 diabetes (T1D) in adults and pediatric patients aged 8 years and older with Stage 2 T1D. The acquisition is a strategic fit for Sanofi at the intersection of the company's growth in immune-mediated diseases and disease-modifying therapies in areas of high unmet need, and its expertise in diabetes. Sanofi will continue to utilize its capabilities in diabetes to maximize TZIELD's potential as a transformative therapy globally and in the U.S., aiming to delay the onset of Stage 3 type 1 diabetes for some of the approximately 65,000 people diagnosed every year1. The purchase builds on an existing co-promotion agreement with Provention Bio that is already delivering TZIELD to patients in need of this immune-mediated therapy.

- 03.13.23 - Pfizer to acquire Seagen for $43 billion (bioprocessintl)
  - After weeks of speculation, Pfizer has agreed to acquire antibody-drug conjugate (ADC) developer Seagen for $43 billion. But today, Pfizer silenced the rumors and announced it has entered into a definitive merger agreement, under which the firm will buy Seagen for $229 in cash per Seagen share for a total value of $43 billion. But today, Pfizer silenced the rumors and announced it has entered into a definitive merger agreement, under which the firm will buy Seagen for $229 in cash per Seagen share for a total value of $43 billion. Pfizer will add around 10 candidates to its pipeline through the acquisition, along with the approved cancer products products Adcetris (brentuximab vedotin), Padcev (enfortumab vedotin), Tivdak (tisotumab vedotin), and Tuksya (tucatinib).
- 03.08.23 - MacroGenics Announces Sale of TZIELD™ Royalty Interest for up to $200 Million (PR)
  - MacroGenics, a biopharmaceutical company focused on developing and commercializing innovative monoclonal antibody-based therapeutics for the treatment of cancer, today announced that it has entered into an agreement to sell its royalty interest on future global net sales of TZIELD (teplizumab-mzwv) to a wholly-owned subsidiary of DRI Healthcare Trust for up to $200 million. MacroGenics retains its other economic interests related to TZIELD, including future potential regulatory and commercial milestones. Under the terms of the agreement with DRI, MacroGenics will receive a $100 million upfront payment for the sale of its single-digit royalty on global net sales of TZIELD. MacroGenics will have the right to receive a 50% share of the royalty on global net sales above a certain annual threshold. In addition, the Company is eligible to receive up to $50 million from DRI upon the occurrence of pre-specified events tied to the advancement of TZIELD for the treatment of newly diagnosed type 1 diabetes. The Company may also receive an additional $50 million if TZIELD achieves a certain level of net sales.
- 03.08.23 - LG Chem's New US Acquisition AVEO Oncology Sets Sights On Being Global Top 20 Innovative Oncology Company (PR)
  - Mr. Shin then announced the largest-ever R&D investment plan in the Korean pharmaceutical and biotech industries in the form of more than USD $300M investment in the integrated Life Sciences-AVEO operation. Starting from this year, LG Chem will invest more than USD 1.5 billion toward R&D in the Life Sciences division over the next five years. Dr. Son followed with the announcement of a plan to enhance the competitiveness of AVEO's new drug pipeline in the U.S. oncology market. The plan would be to develop AVEO into an innovative pharma company that consistently and continuously introduces new drugs in the broader North American market. Through this strategy, AVEO would have the best chance to take the lead in developing and commercializing new anti-cancer drugs, while LG Chem could further strengthen AVEO's existing capabilities to grow into a global pharmaceutical company. Currently, AVEO is conducting clinical development of three new drug candidates: a phase 3 clinical trial to expand the indication of its existing kidney cancer drug FOTIVDA®; a treatment for head and neck cancer; a treatment for cachexia, a nutritional disorder in cancer patients. Promising anti-cancer candidates from LG Chem Life Sciences will be transferred expeditiously to AVEO who will then take charge of late-stage clinical development and commercialization in the U.S. market.
- 03.06.23 - Sun Pharma Completes Acquisition of Concert Pharmaceuticals (PR)
  - Acquisition Adds Deuruxolitinib, a Potential Best-in-Class Oral JAK Inhibitor for the Treatment of Alopecia Areata, to Sun Pharma's Global Dermatology Portfolio. Deuruxolitinib is an investigational oral selective inhibitor of Janus kinases JAK1 and JAK2. The U.S. Food and Drug Administration recently maintained Breakthrough Therapy designation for deuruxolitinib for the treatment of adult patients with moderate to severe alopecia areata and previously granted Fast Track designation for deuruxolitinib for the treatment of alopecia areata.