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The Berke Report

Second Half of February 2023 - Collaborations & M&A

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Collaborations

- 03.01.23 - Vertex pays ImmunoGen $15M to use antibody-drug conjugates to improve CRISPR therapy (fiercebiotech)
  - Are antibody-drug conjugates the key to better gene editing treatments? That is a question posed by the latest deal by Vertex, which is paying ImmunoGen $15 million upfront to explore the use of ADCs with its near-approval CRISPR/Cas9 therapy exagamglogene autotemcel (exa-cel). ADCs are best known as cancer drugs. In that context, the pairing of a targeting antibody and a cytotoxic payload can create treatments that wipe out cancer cells without causing unbearable systemic toxicity. Researchers have begun to explore using the same approach to selectively deplete certain cell types to prepare the body for gene therapy and stem cell transplant. Vertex has bet $15 million upfront on that idea, with potentially up to $337 million in option exercise fees and development and commercial milestone payments to follow per target. The deal allows Vertex to use ImmunoGen's ADC technology to discover novel targeted conditioning agents and then obtain a worldwide license for conditioning agents that use ImmunoGen's technology for that target.
- 02.28.23 - Tevard Biosciences announces collaboration with Vertex to develop novel tRNA-based therapies for Duchenne muscular dystrophy (PR)
  - A four-year global research collaboration aimed at creating new tRNA-based therapies for patients with Duchenne muscular dystrophy (DMD) caused by nonsense mutations with options to expand into additional muscular dystrophies and a second indication.The agreement provides access to Tevard's proprietary platforms for discovering and developing tRNA-based therapies. Under its terms, Tevard will receive up-front, option-exercise, and milestone payments, plus royalties on any approved products. Tevard will advance the research and discovery of novel tRNA-based therapies, with all program costs funded by Vertex. Vertex will be responsible for all subsequent development, manufacturing and commercialization.
- 02.28.23 - Tempus, Pfizer Enter Strategic AI Alliance in Oncology (contractpharma)
  - Through this collaboration, Pfizer has access to Tempus' AI-enabled platform and its library of de-identified, multimodal data to uncover insights for therapeutic development in oncology. Pfizer also has access to Tempus' capabilities that support therapeutic R&D, to advance its own oncology portfolio, including AI-driven companion diagnostic offerings and Tempus' clinical trial matching program, TIME, that rapidly activates studies for patients in communities across the country.
- 02.27.23 - EyePoint and Rallybio Announce Research Collaboration to Evaluate Rallybio's Inhibitor of Complement Component 5 (C5) and EyePoint's Proprietary Durasert® Technology for Sustained Intraocular Delivery in Geographic Atrophy (PR)
  - Under the terms of the research collaboration, EyePoint and Rallybio will collaborate to explore and assess the viability of utilizing Rallybio's C5 inhibitor in EyePoint's sustained release Durasert technology, with the intention to expand the collaboration upon mutual agreement following the evaluation.
- 02.24.23 - Moderna pays US government $400M 'catch-up payment' under new COVID-19 vaccine license (fiercepharma)
  - In Moderna's earnings release Thursday, the company said it recently paid the National Institute of Allergy and Infectious Diseases (NIAID) a $400 million "catch-up payment" under a new royalty-bearing license agreement between the parties. The payment is part of a license agreement between Moderna and NIAID inked late last year. With the deal, Moderna is paying the U.S. government to access "certain patent rights concerning stabilizing prefusion coronavirus spike proteins," Moderna Chief Financial Officer Jamie Mock said on a conference call Thursday. This agreement does not put Moderna out of the woods on the patent litigation front. Even after this deal, the vaccine maker is fighting with the U.S. National Institutes of Health over the origins of the core technology in the vaccine, The New York Times points out.
- 02.23.23 - AbbVie and Capsida Biotherapeutics Expand Strategic Collaboration to Develop Targeted Genetic Medicines for Eye Diseases with High Unmet Need (PR)
  - Under the terms of the expanded agreement, Capsida will receive $70 million, consisting of upfront payments and a potential equity investment. For the three programs, Capsida may be eligible to receive up to $595 million in option fees and research and development milestones, with potential for further commercial milestones. Capsida is also eligible to receive mid-to-high single-digit royalty payments on future product sales. Capsida will lead capsid discovery efforts for all programs using its high throughput AAV engineering platform and will be responsible for process development and early clinical manufacturing. AbbVie will lead innovative therapeutic cargo approaches and be responsible for development and commercialization.
- 02.23.23 - Roche and Blueprint agree to end collaboration for cancer drug Gavreto(endpts)
  - Roche is returning development and commercialization rights for cancer drug Gavreto to Blueprint Medicines. The two companies are dissolving their collaboration following a Roche decision to opt out for "strategic reasons," a Blueprint spokesperson told Endpoints News in an email. The return of the rights to Blueprint excludes Gavreto in Greater China where Roche already has a license agreement with CStone Pharmaceuticals to commercialize the drug, according to a news release on Thursday. The drug is currently indicated to treat RET-mutant medullary thyroid cancer, RET fusion-positive thyroid cancer and tumor lysis syndrome (TLS). The drug is also approved for treating RET fusion-positive advanced non-small cell lung cancer (NSCLC).

- 02.23.23 - Keymed, Lepu Biopharma Enter Global License Agreement with AstraZeneca for CMG901 (contractpharma)
  - Keymed Biosciences Inc., and Lepu Biopharma Co., Ltd., have entered into exclusive license agreement with AstraZeneca for CMG901, a potential first-in-class Claudin 18.2 antibody drug conjugate (ADC). Under the terms of the agreement, AstraZeneca will be responsible for the research, development, manufacture and commercialization of CMG901 globally. CMG901 is currently in a Phase I clinical trial for the treatment of Claudin 18.2-positive solid tumors. Preliminary results from the Phase 1 trial indicated that CMG901 has a favorable safety and tolerability profile and encouraging anti-tumor efficacy across the dose levels tested. Also under the terms of the agreement, KYM Biosciences, the joint venture established by Keymed and Lepu Biopharma, will receive an upfront payment of $63 million on transaction closing and additional development and sales-related milestone payments of up to $1.1 billion as well as royalties. The transaction is expected to close in the first half of 2023, subject to customary closing conditions and regulatory clearances.
- 02.22.23 - Cue Biopharma Enters into a Strategic Collaboration and Option Agreement with Ono Pharmaceutical for CUE-401 (PR)
  - CUE-401, is a bispecific protein designed to induce and expand regulatory T cells (Tregs) for the treatment of autoimmune and inflammatory diseases. Under the terms of the agreement, Ono will pay Cue Biopharma an upfront payment and fully fund all research activities related to CUE-401 through a specified option period. During this option period Cue Biopharma will be responsible for the research and development of CUE-401. Upon Ono's exercise of its option to license CUE-401, Cue Biopharma will receive an option exercise payment and be eligible for development and commercial milestone payments up to an aggregate of approximately $220 million, as well as tiered royalties on sales. Upon any such exercise, Ono will receive worldwide rights to develop and commercialize CUE-401, with Cue Biopharma retaining a 50% co-development and co-commercialization right in the United States.
- 02.14.23 - New $17 million grant establishes LJI as global hub for immunology data curation and analysis (PR)
  - A new grant of over $17 million from the National Institute of Allergy and Infectious Diseases (NIAID) has established La Jolla Institute for Immunology (LJI) as the leading institute for human immunology data curation, analysis, and dissemination. With this funding, LJI has taken the helm of the Human Immunology Project Consortium Data Coordinating Center, a critical tool in the effort to fuel scientific collaboration in immunoprofiling and highlight findings from the overall Human Immunology Project Consortium (HIPC).The HIPC program was established by NIAID in 2010. Today, eight HIPC centers are spread across the nation and include the laboratory of LJI Professor Alessandro Sette, Dr.Biol.Sci. HIPC researchers are focused on unraveling how the many immune cells and signaling molecules of the human immune system work together in response to autoimmune diseases, pathogens like SARS-CoV-2 and influenza, vaccinations, and life events such as pregnancy. HIPC projects have shed light on the immunoprofile or "signature" of steady-state versus active immune responses.
    - Benaroya Research Institute
    - Columbia University
    - Icahn School of Medicine at Mount Sinai
    - La Jolla Institute for Immunology
    - Massachusetts Institute of Technology
    - Seattle Children's Research Institute
    - Stanford University
    - Yale School of Medicine

M&A

- 02.28.23 - Latest biotech-on-biotech merger sees aimless Adamis snapped up by DMK (fiercebiotech)
  - Adamis Pharmaceuticals, which was left floundering after its sole remaining clinical asset—a COVID-19 antiviral called Tempol—flunked a phase 2/3 trial last September. It sent the biotech on a hunt for "strategic alternatives," leading it to accept a merger with neurology-focused DMK Pharmaceuticals. The merged company will be led by DMK's CEO Eboo Versi, M.D., Ph.D., and will be focused on developing DMK's pipeline of "endorphin-inspired" candidates. Chief among these is DPI-125, which is in a clinical trial for opioid use disorder. The terms of the agreement will see DMK merge into a subsidiary of Adamis, with DMK shares converted into the right to receive a number of shares of Adamis stock. In order to complete the transaction, Adamis will also ask its shareholders for permission to conduct a reverse stock split—a method for companies facing being kicked off the Nasdaq to increase their share price by reducing their overall number of shares.
- 02.27.23 - Dr Reddy's acquires Mayne Pharma's USA prescription portfolio for $105 mn (PR)
  - The acquisition will complement DRL's US retail prescription pharmaceutical business with limited competition products. Dr Reddy's Laboratories (DRL) has entered into a definitive agreement to acquire the US generic prescription product portfolio of Australia-based Mayne Pharma Group for $90 million (Rs 738 crore) upfront and contingent payments of up to $15 million (Rs 123 crore). The portfolio includes approximately 45 commercial products, four pipeline products, and 40 approved non-marketed products, including a number of generic products focused on women's health. For the financial period ended June 30, 2022, Mayne Pharma reported total revenue of $111 million for the acquired portfolio.

- 02.27.23 - Pfizer makes moves to acquire Seagen in potential $30B+ deal (endpts)
  - Pfizer is in talks to acquire cancer drugmaker Seagen in a deal that could be worth more than $30 billion, after acquisition talks between Merck and the biotech broke down last year, the Wall Street Journal reported Sunday night. A potential deal between Pfizer and Seagen isn't a guarantee and the talks are still at an early stage, the WSJ reported, citing people familiar with the matter. Representatives for Seagen and Pfizer declined to comment.
- 02.22.23 - Kite Completes Acquisition of Tmunity (PR)
  - The acquisition of Tmunity complements Kite's existing in-house cell therapy research capabilities by adding additional pipeline assets, platform capabilities, and a strategic research and licensing agreement with the University of Pennsylvania (Penn). It will provide Kite with access to pre-clinical and clinical programs, including an 'armored' CAR T technology platform, which potentially could be applied to a variety of CAR T's to enhance anti-tumor activity, as well as rapid manufacturing processes. In addition, as part of the acquisition, the Tmunity founders, who remain in their roles at Penn, will also provide consulting services to Kite as senior scientific advisors.
- 02.23.23 - Jounce to lay off half its workers, merge with UK biotech Redx (biopharmadive)
  - Jounce Therapeutics will lay off 57% of its workers and combine with U.K.-based Redx Pharma in a reverse merger that will create a company focused on medicines for cancer and fibrotic disease. If shareholders approve the deal, Redx shareholders would own 64% of the combined company after a share exchange and reverse split. The combined company, which would carry an implied valuation of $425 million, will be listed as REDX on the Nasdaq stock exchange following the deal's closing. The companies expect the all-share merger to be completed in the second quarter. Forty-seven Jounce employee in research and development will be retained and based in Massachusetts, but Jounce's current clinical programs will not be advanced beyond ongoing studies. The deal would bring to an end Jounce's decade-long run as an up-and-coming cancer immunotherapy biotechnology company. Its lead candidate, an antibody aimed at triggering an immune response by T cells against solid tumors, was the centerpiece of a lucrative deal signed with Celgene in 2016. But the drug, called vopratelimab, faced multiple clinical setbacks and last year, after Phase 2 trial results showed it failed to shrink tumors, the company began to review whether the drug was worth the investment. After the merger, Redx will prioritize development of its selective ROCK2 inhibitor, called RXC007, now in a Phase 2a trial in idiopathic pulmonary fibrosis. Topline data for the trial is expected in the first quarter of 2024. U.S. regulators recently put the trial under a partial clinical hold for its longer-term dosing until they receive additional non-clinical data.