The Berke Report

Collaborations / Licensing Updates for the Third Week of April 2023

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- 04.24.23 - CBER to Launch Operation Warp Speed for Rare Diseases by Year's End (biospace)
  - Operation Warp Speed worked so well to accelerate the development of COVID-19 vaccines the FDA now has its sights set on a similar initiative for rare disease treatments. The program aims to have cell and gene therapies for rare diseases enter the market as quickly as possible without compromising their safety and effectiveness, as well as to ensure these therapies are made available at viable prices for both manufacturers and patients. There were a lot of unknowns with the development of COVID-19 vaccines during the launch of Operation Warp Speed in 2020. But these vaccines were still developed and made available to the general public in record time, saving an estimated 3.2 million lives and $1.15 trillion in the U.S. alone. A cornerstonce of Operation Warp Speed was for Marks and his vaccine experts to remain in constant contact with manufacturers on the regulatory requirements for submissions.
- 04.21.23 -RetinAI Joins Forces with Boehringer Ingelheim to Advance Novel Treatments for Patients with Geographic Atrophy using Artificial Intelligence (PR)
  - RetinAI's AI tools for identifying novel biomarkers will be tested for the analysis of Boehringer Ingelheim's imaging datasets from clinical studies and real-world evidence to identify additional, novel biomarkers and predictors of disease progression. This integration of advanced digital technologies and AI could help accelerate the development of urgently needed novel treatments and enable earlier and more precise diagnosis contributing to Boehringer Ingelheim's vision of preventing vision loss and blindness caused by retinal diseases.
- 04.21.23 - Tubulis and BMS Team Up to Develop Antibody-Drug Conjugates for Cancer (biospace)
  - German biotech Tubulis announced on Thursday a strategic license agreement with the global pharmaceutical company Bristol Myers Squibb (BMS) to develop safer and more effective antibody-drug conjugates (ADCs) to treat solid tumors in cancer patients. As part of this agreement, Tubulis is expected to garner an upfront payment of $22.75 million, with the potential to receive more than $1 billion of future product development, regulatory, and commercialization payments, in addition to royalties. The deal will offer BMS access to Tubulis's Tubutecan payloads and its P5 conjugation platform that the company says, based on preclinical analyses, will likely facilitate the development of more stable and safer ADCs.
- 04.20.23 - Twist Bioscience Enters into Third Collaboration with Astellas to Support Antibody Discovery for Immunotherapies (PR)
  - -Twist Bioscience, a company enabling customers to succeed through its offering of high-quality synthetic DNA using its silicon platform, today announced a collaboration with Astellas Pharma by which Astellas will license a suite of Twist's VHH antibody libraries to be used by Astellas for drug discovery and development. Under the terms of the agreement, Astellas will license a suite of Twist's VHH libraries for a period of five years and will use the libraries to conduct research and development activities. Twist will receive an upfront payment and will be eligible to receive annual maintenance fees and fees per product through payments associated with specific clinical and commercial milestones. Twist will also be eligible to receive royalty payments on product sales.
- 04.17.23 - Genmab and argenx Enter Partnership to Advance Antibody Therapies in Immunology and Oncology (medtechalert)
  - Genmab and argenx announced today that they have entered into a collaboration agreement to jointly discover, develop and commercialize novel therapeutic antibodies with applications in immunology, as well as in oncology therapeutic areas. The multiyear collaboration will leverage the antibody engineering expertise and knowledge of disease biology of both companies to accelerate the identification and development of novel antibody therapeutic candidates with a goal to address unmet patient needs in immunology and cancer.
- 04.17.23 - Pipeline Therapeutics Announces Global License and Development Agreement for Investigational Neuroscience Therapy, PIPE-307 (PR)
  - Under the terms of the agreement, Pipeline will grant Janssen a worldwide, exclusive license to research, develop and commercialize PIPE-307 in all indications. Pipeline will have the right to continue to advance PIPE-307 for the treatment of RRMS through conduct of a Phase 2 clinical trial. Upon closing of the transaction, Pipeline will receive $50M in an upfront payment from Janssen and separately up to $25M in an equity investment from Johnson & Johnson Innovation – JJDC, Inc. and up to $25M in equity investments from Pipeline's existing investors. Pipeline is also eligible to receive approximately $1 billion in success-based payments including clinical, regulatory and commercial milestones, as well as tiered double-digit royalty payments, which increase if the co-development option for PIPE-307 is exercised by Pipeline.
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