BUSINESS NEWS- 17th February 2021

Onco-NEWS

AbbVie and Caribou Biosciences Announce Collaboration and License Agreement for CAR-T Cell Products

“We are excited to partner with AbbVie on the development of new CAR-T cell therapies. This collaboration validates Caribou’s differentiated next-generation CRISPR genome editing technologies that provide best-in-class efficiency and specificity,” said Rachel Haurwitz, Ph.D., President and Chief Executive Officer of Caribou. “We believe AbbVie is an ideal partner for Caribou as we expand upon the number of targets and diseases addressable by our technologies. Genome-edited CAR-T cell therapies hold tremendous potential for patients, and this partnership accelerates our ability to address significant unmet medical need.”

Bayer and Orion Expand Development Program for NUBEQA® (darolutamide) in Prostate Cancer

“NUBEQA has already shown in men with non-metastatic castration-resistant prostate cancer (nmCRPC) that it extends metastasis-free and overall survival,” said Scott Z. Fields, M.D., Senior Vice President and Head of Oncology Development at Bayer's Pharmaceutical Division. “Given the encouraging results that we have seen with NUBEQA so far, it is important that we also evaluate the potential of NUBEQA in other stages of prostate cancer that may offer men with mHSPC a new treatment option.”

4D pharma, Merck and Pfizer to evaluate MRx0518 in combination with BAVENCIO® for the treatment of locally advanced or metastatic urothelial carcinoma

“With this second clinical trial collaboration for MRx0518 with a leading immune checkpoint inhibitor, 4D is able to evaluate MRx0518 in a new combination and earlier treatment setting. Following the promising data already generated in combination with checkpoint inhibitor pembrolizumab in refractory patients, and MRx0518 monotherapy data demonstrating single agent immuno-modulation presented last year at SITC, this collaboration allows us to continue to build a broad understanding of the safety and efficacy of MRx0518 across a range of solid tumors and stages of disease,” said Duncan Peyton, Chief Executive Officer, 4D pharma. “The combination of MRx0518 with BAVENCIO has the potential to further enhance the positive clinical outcomes achieved by BAVENCIO for the significant number of patients in this treatment setting.”

Arch Oncology to Collaborate with Merck on Ph 1/2 Trial of AO-176 in Combination with KEYTRUDA® (pembrolizumab) in Patients with Select Solid Tumors

“This collaboration with Merck is part of our commitment to conducting a broad clinical development program to evaluate AO-176’s potential for patients,” said Jackie Walling, MBChB, Ph.D., Chief Medical Officer of Arch Oncology. “In our Phase 1 trial, we saw encouraging anti-tumor activity for AO-176 as a single agent. These results led us to expand our clinical

development program to explore different combination therapy approaches. Combining either PD-1 or PD-L1 checkpoint inhibition with a CD47 blockade has strong scientific rationale and in our preclinical studies resulted in enhanced anti-tumor activity over monotherapy alone. We are excited to advance AO-176 as we aim to deliver new cancer treatments to broader groups of patients."

BioPharma News

Sandoz acquires GSK's cephalosporin antibiotics in a $500 million deal

As announced on 11th February 2021, Sandoz (Novartis Div; HQ: Basel, Switzerland) signed an agreement worth $500 million with GSK (HQ Brentford, UK), to acquire GSK's cephalosporin antibiotics business, which includes 3 key brands- Zinnat®, Zinacef® and Fortum®. This move strengthens Sandoz's commitment to the antibiotics area of pharmaceuticals.

According to the terms, Sandoz will pay GSK $350 million upon closing of the deal, which is expected to take place by second half of 2021. There will be further $150 million in (undisclosed) milestone payments. The deal is contingent on mutually agreed conditions, including regulatory approvals. Sandoz will acquire global rights to the antibiotics, including Zinnat®, Zinacef® and Fortum®, in 100 worldwide markets, barring for those brands that were previously off-loaded by GSK in US, Australia and Germany. GSK will retain rights in India, Pakistan, Egypt, Japan and China.

GSK will also be supplying Zinnat® to Sandoz under a manufacturing and supply agreement (MSA), till 4 years after deal closure. Sandoz is planning to step up the manufacturing of Zinnat® at its production facilities in Kundl, Austria.

Zinnat® is an orally bioavailable prodrug to the cephalosporin antibiotic, cefuroxime (a beta lactamase resistant broad-spectrum antibiotic). The combined annual sales (2020) of Zinnat®, Zinacef® and Fortum® was ~ $140 million.

"Cephalosporins are the largest antibiotic segment by global sales and acquiring this leading business, including the established global Zinnat® brand, will complement our #1 position in generic penicillins, the other key segment. It will also set us up for additional synergies driven by an increased promotional footprint that will support growth of both the acquired brands and the current existing Sandoz portfolio."- Sandoz CEO Richard Saynor.

BigHat Biosciences raises $19 million in series A funding for automating wet-lab with AI/deep learning to generate high quality next-gen antibodies

BigHat Biosciences (BigHat, San Carlos, CA) announced raising $19 million in series A funding, on 10th February 2021. The investors include lead investor Andreessen Horowitz, along with prior investors 8VC, AME Cloud Ventures, and Innovation Endeavors. The funding was received for its integrated wet-lab and AI/deep learning platform that can manufacture high quality antibodies to scale within days as opposed to months or years by more conventional laboratory approaches.

BigHat's proprietary platform combines wet-lab cells, which use synthetic biology to produce antibodies discovered in silco, with quality monitoring by AI/deep learning-based program that shortlists antibodies with high structural and functional parameters for the next cycle of in silco

fine tuning and antibody production. Reiteration of this AI-guided procedure leads to antibodies with desirable properties of affinity, avidity, solubility etc. to be manufactured to scale against any known/hypothetical antigen. This accelerates candidate discovery and validation, reducing time to enter clinical trials. BigHat established proof of concept by producing a highly neutralizing antibody to SARS-CoV-2 using its platform. For this, it has received the 'Amgen's Golden Ticket to MBC BioLabs' that grants it free access to laboratory space and to Amgen's experts in science and business.

The newly acquired capital will be used to expand the in-house team to recruit experts in antibody, protein and AI/ML engineering, as well as, computational biologists. The money will also be used to advance their internal pipeline towards clinical trials.

"The relevant search space for protein therapeutics is orders of magnitude larger than a purely experimental approach anchored in naturally-occurring sequences can efficiently traverse… This is why we believe BigHat's platform, which combines machine learning, synthetic biology, and high-throughput experimentation, holds tremendous promise."- Vineeta Agarwala, General Partner at Andreessen Horowitz.

Abbvie enters collaboration and license agreement over CAR-T therapies offered by Jennifer Doudna's Caribou Biosciences

The announcement came in on 10th February 2021. AbbVie (Chicago) will collaborate with Caribou Biosciences (Caribou; Berkley, CA) over Caribou's allogenic CAR-T cell engineering platform that can override host immune rejection. Abbvie will acquire exclusive rights to this genome editing and cell therapy technology, called Cas12a CRISPR hybrid RNA-DNA (chRDNA), in relation of CAR-T products against Abbvie specified targets. These products will be in the form of 'off the shelf' CAR-T cell therapies.

Abbvie will pay Caribou $40 million in upfront cash and equity, while also offering $300 million in regulatory, development and launch milestones. Caribou may also receive commercial milestone payments and tiered royalties from global sales. According to the terms, Caribou will conduct pre-clinical R&D, and manufacturing for the collaboration.

Caribou was founded by the CRISPR pioneer Jennifer Doudna in 2011. Its internal programs include allogenic CAR-T cell therapies targeting CD-19 in relapsed/refractory B cell non-Hodgkin lymphoma, CB-011 in multiple myeloma, and CB-012, CD371 in acute myeloid leukemia. These programs are being evaluated in Phase I trials.

"We believe AbbVie is an ideal partner for Caribou as we expand upon the number of targets and diseases addressable by our technologies. Genome-edited CAR-T cell therapies hold tremendous potential for patients, and this partnership accelerates our ability to address significant unmet medical need."- Rachel Haurwitz, Ph.D., President and Chief Executive Officer of Caribou.

$80 million raised in series C funding for neuroregenerative medicines developed by Pipeline Therapeutics

Pipeline Therapeutics (Pipeline; SanDiego, CA) is a biopharmaceutical company that develops first-in-class small molecule drugs for neuroregeneration. The company's pipeline includes

PIPE-505 for sensorineural hearing loss and PIPE-307 for multiple sclerosis at developmental stages. On 11th February 2021, the company announced raising $80 million in series C funding to further its development candidates to clinical trials as well as to accelerate new drug discovery efforts. The funding partners include Perceptive Advisors, Franklin Templeton, Casdin Capital, Samsara BioCapital, Suvretta Capital, and Red Tree Venture Capital. It has also received funding from a new health-care focused investor and an undisclosed but prominent global investment fund.

Pipeline focusses on synaptogenesis, remyelination and axonal repair areas of neuroregeneration for drug discovery.

“We are delighted to welcome the new investors in our Series C round, and are grateful to our existing shareholders for their continued support…We are proud to have this significant support for our mission of developing first- and best-in-class neuroregenerative product candidates for unserved and underserved neurological indications.”- Carmine Stengone, President & CEO, Pipeline Therapeutics.