MedNess Newsletter October 18, 2023

From MedNess <newsletter@medness.org>

Para sarah@medness.org

Fecha miércoles, 18 de octubre de 2023 a las 04:54

MedNess (Onco-This-Week)

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October 18, 2023

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MedNess News Highlights this week

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MedNess Neuro

AbbVie acquires Mitokinin in its Neuroscience pipeline

Earlier this month, AbbVie acquired Mitokinin, a discovery-stage biotechnology company developing a disease modifying treatment for Parkinson's Disease (PD). PD is a neurodegenerative movement disorder where dopaminergic neurons of the brain that control movement are preferentially lost, causing slowness in movement, rigidity of limbs and trunk, tremors, and postural instability. It affects over 10 million people worldwide. Dysfunctional mitochondria is a contributing factor to PD pathogenesis and progression. Current available drugs only symptomatically treat a subset of PD symptoms. There is no disease modifying treatment available that can slow the disease progression. Mitokinin's lead candidate, MTK-458, is a selective activator of Pten induced kinase 1 (PINK1). PINK1 is associated with early-onset PD. Although mutation in PINK1 is rare, there are 145 known possible pathogenic mutations. PINK1 acts as quality control that enables neuronal cells to destroy damaged mitochondria. The level of active form of PINK1 is tightly regulated within neurons. PINK1 can only get catalytically active on the surface of damaged mitochondria. MTK-458 selectively enhances this active-form of PINK1 without impacting the regulation of the protein as a whole. In addition to PD, the effect of MTK-458 is also under study in models of Huntington's Disease, Alzheimer's Disease, and non-central nervous system diseases of aging where mitochondria are damaged. PD, the fastest-growing neurological disease in the United States, is a major unmet medical need. With this acquisition, AbbVie has grown its neuroscience portfolio and will accelerate the potential new treatment option for PD to investigational new drug (IND) enabling studies.

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Drug Approvals

FDA Approves Pfizer’s BRAFTOVI + MEKTOVI for BRAF V600E-Mutant mNSCLC

“Today’s approval builds on our long-standing commitment to deliver innovative, personalized medicines to patients with lung cancer. By pursuing precision medicines that target a patient’s specific type of cancer, we are leveraging our deep understanding of tumor biology to help address the underlying cause of disease,” said Chris Boshoff, M.D., Ph.D., Chief Oncology Research and Development Officer and Executive Vice President at Pfizer. “Since its initial FDA approval in 2018, BRAFTOVI + MEKTOVI combination therapy has helped thousands of people living with BRAF V600E- or V600K-mutant unresectable or metastatic melanoma.2 We look forward to helping even more patients with our BRAFTOVI + MEKTOVI targeted combination therapy.”

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Drug Approvals

Regulatory news

FDA Orphan Drug Designation for SLS009 for Treatment of AML

“We are honored to receive the ODD from the FDA. This designation underscores the potential of SLS009 to address a significant unmet medical need for patients with AML,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “SLS009 is a novel and highly selective CDK9 inhibitor that has already shown a favorable safety profile, strong initial efficacy signals, and evidence of anti-tumor activity. With the support of this ODD, we look forward to accelerating SLS009 clinical development and bringing new hope to those suffering from this devastating disease.”

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Positive EU CHMP Opinion for KEYTRUDA + Chemo as 1L Treatment for HER2-Negative Advanced GEJ Adenocarcinoma Expressing PD-L1 (CPS ≥1)

“This positive CHMP opinion builds on our efforts to treat advanced gastric and gastroesophageal junction cancer in Europe, including in patients with HER2-negative disease, which accounts for the vast majority of gastric cancer cases,” said Dr. Marjorie Green, senior vice president and head of late-stage oncology, global clinical development, Merck Research Laboratories. “We look forward to the European Commission’s decision and are excited to potentially provide an immunotherapy regimen to patients in the EU with locally advanced unresectable or metastatic HER2-negative gastric or gastroesophageal junction cancer, whose tumors express PD-L1 with a combined positive score ≥1.”

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Regulatory News

Trial Results

New Data Demonstrating Superiority of TPST-1120 Arm Across Multiple Study Endpoints in Randomized 1L HCC Study presented

“This comprehensive analysis of more mature clinical data shows an even greater benefit than the earlier interim analysis of the TPST-1120 triplet therapy over standard of care alone, both for the entire study population and in subpopulations of patients, the latter of which was predicted by TPST-1120’s proposed mechanism of action,” said Stephen Brady, president and chief executive officer of Tempest. “First-line HCC remains an indication with substantial opportunity to improve patient outcomes and, based upon these data, we are excited about the opportunity to move TPST-1120 into a pivotal study. Given these new data and the Phase 1 evidence of activity beyond HCC, we look forward to advancing discussions with potential partners who share our vision for TPST-1120.”

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Pivotal KEYNOTE-671 Trial Meets Dual Primary Endpoint of OS in Resectable Stage II, IIIA or IIIB NSCLC

“This is a significant milestone in the treatment of resectable non-small cell lung cancer, as it represents the first Phase 3 study to show a statistically significant overall survival benefit for these patients with stage II, IIIA or IIIB (T3-4N2) non-small cell lung cancer. These results build upon the previously reported event-free survival data, and demonstrate the potential for this KEYTRUDA-based regimen to help extend the lives of these patients,” said Dr. Marjorie Green, senior vice president and head of late-stage oncology, global clinical development, Merck Research Laboratories. “We’re excited by the progress we have made to help patients with earlier stages of non-small cell lung cancer, who are in need of additional treatment options.”

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Trial Results

Trial Status

Enrollment ex-China in Phase 3 REGAL Clinical Trial for Galinpepimut-S in AML Expected to be Completed in November 2023

“We are pleased to be so close to achieving this most important milestone – the completion of enrollment in the REGAL study – and, at the same time, it is important to note that we already have a sufficient number of patients enrolled for the pre-specified analyses,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “Furthermore, 3D Medicines’ enthusiasm for the REGAL study remains high. We expect the first patient dosing in China to take place this quarter which will trigger the milestone payment, and we are exploring options to potentially expedite the payment. Importantly, adding approximately 25 patients from China could potentially facilitate drug approval in this significant market, assuming positive data, further yielding additional milestone payments and royalties for SELLAS.”

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Clinical trials of nanrilkefusp alfa as monotherapy and in combinations with pembrolizumab and cetuximab to be discontinued

“While we are disappointed with this outcome, we will continue to gather and analyze the full body of data from these studies to inform our future development plans for nanrilkefusp alfa, especially its potential utility in combination with other cancer immunotherapies,” said Richard Sachse, M.D., Ph.D., chief medical officer of SOTIO. “We are grateful to the patients, families and investigators that participated in these trials and whose contributions are essential to improving the standard of care for solid tumor cancers.”

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Trial Statuses

Business News

Olema Oncology Announces Expansion of Collaboration Agreement with Novartis

“The amendment announced today significantly increases the size of our ongoing Phase 1/2 clinical study testing palazestrant in combination with ribociclib, in collaboration with Novartis,” said Sean P. Bohen, M.D., Ph.D., President and Chief Executive Officer of Olema Oncology. “With the Phase 1b dose escalation portion now successfully completed, we are currently in Phase 2 dose expansion at the 120 mg dose of palazestrant in combination with 600 mg of ribociclib. We believe that this expanded study now has the potential to generate a clinical dataset sufficient to support the regulatory pathway for a first-line pivotal trial.”

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MediLink Therapeutics Announces Strategic Collaboration And Worldwide License Agreement With BioNTech To Develop Next-Gen Anti-Cancer ADCs

“Under the terms of the agreement, MediLink will grant BioNTech exclusive global rights for the development, manufacturing, and commercialization of one of MediLink’s ADC assets excluding Mainland China, Hong Kong Special Administrative Region, and Macau Special Administrative Region. In exchange, BioNTech will provide MediLink with an upfront payment totaling of $70 million and additional development, regulatory and commercial milestone payments potentially totaling over $1 billion. The completion of the agreement is subject to customary closing conditions, including clearance under the Hart-Scott-Rodino (“HSR”) Antitrust Improvements Act.”

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