MedNess Newsletter March 31, 2023

From MedNess <newsletter@medness.org>

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MedNess News Highlights this week

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Drug Approvals

Calquence granted first regulatory approval in China for adults with previously treated mantle cell lymphoma

Dave Fredrickson, Executive Vice President, Oncology Business Unit, AstraZeneca, said: "This approval for Calquence offers people living with mantle cell lymphoma in China an effective and tolerable new treatment option to help control their disease. As the first approval in China for Calquence, it is also an exciting step forward for AstraZeneca in blood cancers, enabling us to help more patients across the globe gain access to innovative treatments."

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Retifanlimab Receives Accelerated FDA Approval for Merkel Cell Carcinoma

“More than a third of patients with MCC present with regional or distant metastases, which are associated with high rates of mortality,” said Dr. Shailender Bhatia, University of Washington and Fred Hutchinson Cancer Center. “The approval of Zynyz offers healthcare providers another first-line treatment option against MCC that can result in durable responses in patients with metastatic disease, and I look forward to having Zynyz in our treatment portfolio for these difficult-to-treat patients.”

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Drug Approvals

Regulatory news

FDA Orphan Drug Designation for FORE8394 for the Treatment of Primary Brain and CNS Malignancies

“The receipt of Orphan Drug Designation is another important regulatory achievement that reinforces the FDA’s recognition of the potential of FORE8394 to improve clinical outcomes in patients with BRAF-altered brain tumors,” said Stacie Shepherd, M.D., Ph.D., Chief Medical Officer of Fore Biotherapeutics. “This designation will help us continue to expedite the development of our novel BRAF inhibitor, and we look forward to working closely with the global investigator community supporting FORTE and to advancing the development of FORE8394 for patients in need.”

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BLA Submission for Lifileucel in Advanced Melanoma completed

Frederick Vogt, Ph.D., J.D., Interim President and Chief Executive Officer of Iovance, stated, "Completing our BLA submission for lifileucel is a critical step forward in our journey to deliver the first individualized, one-time cell therapy for a solid tumor. I would like to acknowledge the patients and physicians who participated in the C-144-01 clinical trial and the FDA review team for their commitment and support, as well as our internal team for their tremendous effort in completing the first BLA submission for Iovance. Our preparations for commercialization remain on track to support a launch later this year. We look forward to continued collaboration with the FDA as they review this new class of treatment for advanced melanoma patients with limited options."

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Trial Results

Results from INNATE Phase 2 Trial of JTX-8064 and Pimivalimab Demonstrate Deep and Durable Responses in Platinum Resistant Ovarian Cancer

"Following this analysis, we are pleased to see these results demonstrating deep and durable responses in patients, including those with a PD-L1 score of 0%, on a very well tolerated regimen. These results lead us to believe that there is a potential for meaningful clinical benefit with this combination in patients with few durable therapeutic options," said Richard Murray, Ph.D., chief executive officer and president of Jounce Therapeutics. "Tumor reduction was observed at 9 weeks in all the responding patients in the ovarian cancer cohort of the INNATE trial, but most did not achieve a PR until week 18, which delayed our ability to assess efficacy in this cohort. Platinum resistant ovarian cancer is a patient population with significant unmet need and progressive disease is often associated with debilitating symptoms."

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FAILED TRIAL: Ph 2 KeyVibe-002 Trial of MK-7684A (Vibostolimab + Pembrolizumab) in Previously Treated NSCLC patients did not meet primary PFS endpoint

“Through different approaches, such as novel combinations and coformulations, we hope to build on the foundation of KEYTRUDA to help even more patients with cancer,” said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. “We are grateful to the patients and investigators for their participation in this study evaluating MK-7684A in a heavily pre-treated group of patients, and look forward to additional data from the continuation of the blinded arms of KeyVibe-002. Based on responses we have seen in the signal-finding Phase 1/2 program to date, we are moving forward with our comprehensive research program evaluating MK-7684A across a wide range of cancers, including lung, other solid tumors and blood cancers.”

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Trial Results

Trial Status

Open-Label Arm of Ph 2 KeyVibe-002 Trial of MK-7684A (Coformulation of Vibostolimab and Keytruda) to continue in Previously Treated mNSCLC Patients

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Ph 1b/2 Study initiated to Evaluate Pepinemab + Avelumab in 2L Metastatic Pancreatic Ductal Adenocarcinoma (PDAC) patients

Dr. Zauderer continued, “The hypothesis for evaluating pepinemab in combination with ICIs in PDAC is supported by a robust body of preclinical studies and human clinical data. These data suggest that treatment with the semaphorin 4D (SEMA4D) blocking antibody, pepinemab, may reverse immunosuppression to promote the infiltration and activation of dendritic cells and CD8+ cells into the TME, rendering “cold” tumors “hot” and leading to enhanced efficacy of ICIs such as avelumab.”

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Trial Statuses

Business News

Jounce Therapeutics Enters Into Agreement to Be Acquired by Concentra Biosciences for $1.85 in Cash per Share Plus Contingent Value Rights

Jounce Therapeutics, Inc., a clinical-stage company focused on the discovery and development of novel cancer immunotherapies and predictive biomarkers, today announced it has entered into a definitive merger agreement whereby Concentra Biosciences, LLC will acquire Jounce for $1.85 in cash per share plus a non-tradeable contingent value right (the "CVR"). The $1.85 per share upfront consideration represents a premium of approximately 75% to Jounce's closing share price immediately prior to the March 14, 2023 public disclosure of Concentra's acquisition proposal.

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BioNTech and OncoC4 Announce Strategic Collaboration to Co-Develop and Commercialize Novel Checkpoint Antibody in Multiple Solid Tumor Indications

"Despite being a prime target for more than a decade, we believe that targeting CTLA-4 has not reached its full potential in cancer immunotherapy," said Prof. Ugur Sahin, M.D., Chief Executive Officer and Co-Founder of BioNTech. "The data presented by OncoC4 on their ONC-392 antibody indicate a differentiated safety profile and encouraging clinical activity in various types of tumors. We believe that this antibody is a valuable addition to our immuno-oncology portfolio, whether used alone or in combination with our personalized immunotherapies."

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