MedNess Newsletter June 28, 2023

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MedNess News Highlights this week

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Drug Approvals

FDA Grants Full Approval For Blincyto To Treat MRD-Positive B-Cell Precursor Acute Lymphoblastic Leukemia

"We are pleased the FDA has granted full approval for BLINCYTO, the first FDA-approved CD19-directed CD3 T-cell engager BiTE® immunotherapy and the first to be FDA-approved for MRD in 2018," said David M. Reese, M.D., executive vice president of Research and Development at Amgen. "Today's full approval underscores the clinical benefit of BLINCYTO for people living with B-ALL, and we look forward to exploring how we can continue to make a significant impact for these patients."

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TALZENNA in Combination with XTANDI Receives U.S. FDA Approval for adult patients with HRR-mutated mCRPC

“Despite treatment advancement in metastatic castration-resistant prostate cancer, the disease can progress quickly, and many patients may only receive one line of therapy. Therefore, new first-line treatment options are needed to reduce the risk of disease progression or death. For patients with mCRPC harboring HRR genetic alterations, outcomes are even worse,” said Neeraj Agarwal, M.D., FASCO, Professor and Presidential Endowed Chair of Cancer Research at Huntsman Cancer Institute, University of Utah, and global lead investigator for TALAPRO-2. “The FDA’s approval of the talazoparib and enzalutamide combination is based on the findings from the pivotal TALAPRO-2 study, which demonstrated statistically significant and clinically meaningful reductions in the risk of progression or death among HRR gene-mutated tumors in patients with metastatic castration-resistant prostate cancer. It represents a treatment option deserving of excitement and attention.”

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Regulatory news

CHMP Positive Opinion for Trodelvy in Pre-Treated HR+/HER2- Metastatic Breast Cancer

“This positive opinion from the Committee confirms the clinical benefit and value of sacituzumab govitecan in pre-treated HR+/HER2- metastatic breast cancer and is a positive step toward bringing this treatment option to patients in Europe,” said Dr. Javier Cortes, Head of the International Breast Cancer Center, in Madrid and Barcelona, Spain. “Too many people living with pre-treated HR+/HER2- metastatic breast cancer are without treatment options after their cancer progresses, and this positive opinion is a significant step forward for patients and their loved ones across Europe.”

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FDA Orphan Drug Designation for ERAS-801 for the Treatment of Malignant Glioma

"GBM is an aggressive malignancy afflicting approximately 37,000 patients annually in the United States and Europe. Currently approved EGFR inhibitors are limited by insufficient CNS penetration to treat GBM and minimal activity against GBM-specific EGFR amplifications, mutations, and other molecular alterations, which contribute to high rates of relapse and a five-year survival rate below 10%," said Jonathan E. Lim, M.D., Erasca's chairman, CEO, and co-founder. "Receiving ODD recognizes both the importance of innovation for patients with GBM and the therapeutic potential of ERAS-801 to provide a targeted treatment option for these patients, who have a poor prognosis. This ODD follows the earlier Fast Track Designation granted to ERAS-801 by the FDA and underscores the urgency of finding new treatments for this patient population. The broad activity against both oncogenic and wildtype EGFR, high CNS penetration, and demonstrated ability to improve outcomes in over 90% of diverse EGFR-driven patient-derived glioma models support the potential for ERAS-801 to overcome current challenges with existing therapies. We anticipate reporting initial monotherapy data for ERAS-801 from the Phase 1 THUNDERBBOLT-1 trial in patients with recurrent GBM in the second half of 2023."

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Trial Results

Ongoing Double-Digit ORR observed for Single Agent Envafolimab in the ENVASARC Phase 2 Pivotal Trial

"We are pleased with the single agent activity of envafolimab that continues to generate a double-digit ORR, as well as the safety data showing envafolimab is well tolerated," said James Freddo, M.D., TRACON's Chief Medical Officer. "We believe the current response rate indicates that we remain on track to achieve the primary endpoint of the study of a minimum 11.25% objective response rate. We remain excited by the emerging data and for envafolimab's potential to become a differentiated treatment for sarcoma patients."

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FAILED TRIAL: Ph 3 KEYNOTE-585 Trial in GEJ Adenocarcinoma didn't meet primary endpoint of EFS

"While a statistically significant improvement in pathological complete response was observed in this study, we are disappointed that the KEYTRUDA regimen did not significantly improve event-free survival, a result that underscores the challenges in treating locally advanced resectable gastric cancer," said Dr. Scot Ebbinghaus, vice president, global clinical development, Merck Research Laboratories. "Innovative research in earlier stages of cancer is critical to help patients achieve better outcomes, and our efforts continue in earnest. We are grateful to the patients and investigators for their participation in this study."

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Trial Results

Trial Status

First Patient dosed in Ph 1 Study of Cancer Vaccine CVGBM for Surgically Resected Glioblastoma

"We are excited to enter the execution phase of our cancer vaccine development strategy with a study that is designed to establish proof-of-principle for our advanced second-generation mRNA backbone in oncology," said Dr. Myriam Mendila, Chief Development Officer of CureVac. "We will use the study data to evaluate the ability of our second-generation mRNA back-bone to raise strong tumor-directed immune responses and provide a firm foundation to further advance our oncology pipeline based on our potent vaccine platform and an unparalleled framework for antigen discovery."

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First Patients Dosed in Ph 2 Liver Cancer Trial of TTI-101

“Enthusiasm for our HCC study continues to expand with recently presented clinical data demonstrating TTI-101 monotherapy has robust efficacy in heavily pretreated patients with HCC, published preclinical work highlighting TTI-101’s synergy with immunotherapy, and the FDA’s Fast-Track Designation for TTI-101 in HCC,” said Imran Alibhai, PhD, CEO of Tvardi Therapeutics. “This is the second of three Phase 2 trials Tvardi has initiated to address diseases driven by STAT3.”

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Business News

NEOGAP acquires TCER Oncology AB, strengthening its position in personalised immunotherapy

“We are delighted to acquire the remaining shares in TCER Oncology and extend a warm welcome to Rolf Kiessling and Stina Wickström as valued shareholders in NEOGAP. This acquisition marks an important milestone, fortifying our standing in personalised immunotherapy. It allows us to expand our patent portfolio and pipeline of potential drug candidates while further developing our innovations in the field. We look forward to continuing to drive progress and deliver groundbreaking scientific breakthroughs in cancer treatment,” says Samuel Svensson, CEO of NEOGAP.

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