MedNess Newsletter September 14, 2023

From MedNess <newsletter@medness.org>

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MedNess (Onco-This-Week)

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Calquence approved in China for chronic lymphocytic leukaemia

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U.S. FDA Fast Track Designation for vididencel in Acute Myeloid Leukemia (AML)

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TIVDAK® (tisotumab vedotin-tftv) Met its Primary Endpoint of Improved OS in Patients with Recurrent or Metastatic Cervical Cancer Compared to Chemotherapy

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Drug Approvals

Calquence approved in China for chronic lymphocytic leukaemia

Professor Li Jianyong, Director of Haematology, People's Hospital of Jiangsu Province, and Leader of China CLL Working Group, said: "Many people living with chronic lymphocytic leukaemia experience relapse and need additional treatment options to help manage their disease. I'm delighted that with this approval patients now have access to an established treatment that has already demonstrated effectiveness in many patients across the globe."

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Drug Approvals

Regulatory news

U.S. FDA Fast Track Designation for vididencel in Acute Myeloid Leukemia (AML)

"As part of the preparations for continued clinical development of vididencel in AML, we continue to strengthen the program in all product-relevant aspects, including on the regulatory front," commented Jeroen Rovers, MD PhD, Chief Medical Officer of Mendus. "The Fast Track Designation granted by the FDA adds substantial regulatory value to the vididencel program in the most important healthcare market worldwide. As Mendus advances vididencel into the next phase of clinical development in AML maintenance, the Fast Track Designation will allow the Company to engage more frequently with the FDA to optimally align its development plan."

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MAA submitted to the EMA for Approval of Erdafitinib in Patients with Locally Advanced or Metastatic Urothelial Cancer with Susceptible FGFR Alterations

“For patients with advanced UC, including FGFR-driven tumours, outcomes remain poor and treatment options are limited; therefore, there is a need for novel, targeted therapies,” said Martin Vogel, EMEA Therapeutic Area Lead Oncology, Janssen-Cilag GmbH. “We are excited by the prospect of bringing innovative, personalised approaches to market for patients as we work towards our wider goal of making this complex disease a more manageable and ultimately curable condition.”

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Trial Results

TIVDAK® (tisotumab vedotin-tftv) Met its Primary Endpoint of Improved OS in Patients with Recurrent or Metastatic Cervical Cancer Compared to Chemotherapy

“TIVDAK is the only U.S. Food and Drug Administration-approved therapy in second-line recurrent or metastatic cervical cancer regardless of biomarker status, tumor histology and prior therapy,” said Roger Dansey, M.D., President of Research and Development and Chief Medical Officer at Seagen. “Demonstrating a survival benefit with the results of innovaTV 301 is a critical milestone in our efforts to ensure more adults living with advanced cervical cancer have an approved treatment option.”

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Phase 3 MARIPOSA-2 Study Meets Dual Primary Endpoint Resulting in Improvement in PFS for RYBREVANT® (amivantamab-vmjw) + Chemo +/- Lazertinib vs chemo Alone in Patients with EGFR-Mutated NSCLC after Disease Progression on Osimertinib

“MARIPOSA-2 provides the first Phase 3 study data of RYBREVANT-based regimens in the broader EGFR-mutated non-small cell lung cancer population,” said Peter Lebowitz, M.D., Ph.D., Global Therapeutic Area Head, Oncology, Janssen Research & Development, LLC. “The study builds on the significant innovation of RYBREVANT, a first-in-class bispecific antibody targeting two major oncogenic driver pathways, with clinically meaningful results that may change the treatment paradigm.”

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Trial Results

Trial Status

First Patient Dosed in Phase 1/2 Trial of BEAM-201 in Relapsed, Refractory T-ALL/T-LL

"As the first patient dosed with a Beam therapeutic candidate and the first patient in the U.S. to receive a base editing therapeutic, this represents a major milestone for the company, the scientists that made this possible, and the patients we hope to serve," said John Evans, chief executive officer of Beam. "We believe that the full therapeutic potential of CAR-T therapies, including the ability to utilize an allogeneic source of T cells, will only be unlocked through higher levels of cellular engineering enabled by multiple simultaneous genetic edits. Base editing is especially well-suited to this challenge, as it is designed to deliver highly efficient multiplex edits in cells without the double stranded breaks that can lead to frequent chromosomal rearrangements and loss of cell viability. BEAM-201, to our knowledge the first quadruplex-edited cell therapy candidate in clinical development, is an allogeneic CAR-T cell investigational therapy with the potential to make a substantial impact for patients diagnosed with challenging T-cell cancers who have limited treatment options."

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Trial Statuses

Business News

KSQ Therapeutics and CTMC Announce Strategic Collaboration to Accelerate the Development of Novel Engineered Tumor Infiltrating Lymphocyte (eTIL) Therapies for the Treatment of Solid Tumors

"Our eTIL programs – which edit the SOCS1 and Regnase-1 genes – have the potential to be firstand best-in-class cell therapies for cancer treatment. As our eTIL programs move through INDenabling studies, our partnership with CTMC will have us ready to manufacture KSQ-001EX and KSQ-004EX for clinical studies," said Qasim Rizvi, Chief Executive Officer of KSQ. "We believe our eTIL programs have the potential to address the significant unmet need in the solid tumor space."

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Portage Biotech announces collaboration with Merck to evaluate two next-generation adenosine antagonists in combination with Keytruda® in solid tumors

"We are excited to initiate another collaboration with longstanding immunotherapy leader, Merck, to further explore the potential benefits of combining checkpoint blockade with PORT-6 and PORT-7," said Dr. Ian Walters, Chief Executive Officer of Portage Biotech. "Our suite of potentially best-in-class adenosine antagonists are designed to act on multiple immune cell types for potentially more robust immunological effect and have been demonstrated preclinically to be more selective, more potent and more durable than other adenosine antagonists in development. We look forward to expanding this collaboration, evaluating our adenosine antagonists and continuing our mission to offer transformational therapies for patients in need."

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