MedNess Newsletter April 12, 2023

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MedNess News Highlights this week

FDA Approves KEYTRUDA + Padcev combination for 1L Treatment of Certain Patients With Locally Advanced or Metastatic Urothelial Cancer

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Drug Approvals

FDA Approves KEYTRUDA + Padcev combination for 1L Treatment of Certain Patients With Locally Advanced or Metastatic Urothelial Cancer

"This approval is a major milestone in the treatment of patients with locally advanced or metastatic urothelial carcinoma because it is the first approved combination of an immunotherapy and an antibody-drug conjugate for these patients," said Dr. Eliav Barr, senior vice president, head of global clinical development and chief medical officer, Merck Research Laboratories. "This expands the use of KEYTRUDA-based regimens to more patients with advanced urothelial carcinoma and demonstrates the value of collaboration in creating new combination approaches for patients in need of more options."

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Drug Approvals

Regulatory news

IMBRUVICA's U.S. Accelerated Approvals for Mantle Cell Lymphoma and Marginal Zone Lymphoma Indications to be voluntarily withdrawn

"We fully support the FDA accelerated approval pathway, which patients rely on for timely access to promising treatments that may improve or extend their lives. While withdrawing these indications was a difficult decision, we remain confident in the benefit/risk profile of IMBRUVICA in its approved indications and are committed to its continued development," said Craig Tendler, M.D., Vice President, Late Development and Global Medical Affairs, Janssen Research & Development, LLC. "IMBRUVICA has transformed how patients with B-cell malignancies are treated and is the most comprehensively studied and prescribed therapy in its class."

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mRNA-4157/V940 (mRNA Cancer Vaccine + KEYTRUDA) Receives PRIME Scheme Designation from the EMA for Adjuvant Treatment of Patients with High-Risk Stage III/IV Melanoma Following Complete Resection

"Prime scheme designation for mRNA-4157/V940 in combination with KEYTRUDA highlights the potential promise of individualized cancer treatments in a population with limited alternatives," said Stephen Hoge, M.D., Moderna's President. "There is a high unmet need for therapies in melanoma, as it can be a life-threatening condition where available therapies may not be sufficiently effective in a significant proportion of patients."

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Trial Results

Clinical Data of KEYNOTE-695 Trial of TAVO™-EP + KEYTRUDA in Patients with Advanced Melanoma Refractory to anti-PD-1 Treatment announced

"Treatment of patients with anti-PD-1 refractory melanoma remains difficult with limited success for immune checkpoint inhibitor combinations and exploratory therapeutic approaches. It is disappointing that review by blinded central readers did not confirm the previously reported results by investigator assessment of the KEYNOTE-695 Phase 2 clinical trial in this patient population. However, we remain optimistic that the observed long duration of response and overall survival of 22.7 months in this heavily pre-treated patient population, together with previously reported preliminary results from Dr. Tarhini's IST in the neoadjuvant melanoma setting, provide rationale for further development of TAVO™-EP in combination with anti-PD-1 therapy. We plan to discuss these data and a draft protocol for TAVO™-EP in combination with pembrolizumab for a randomized Phase 2 trial in the neoadjuvant setting at the upcoming meeting with the FDA to potentially initiate the trial in the second half of 2023," said Robert Arch, Ph.D., Chief Executive Officer of OncoSec. "I want to thank all patients who participated in the KEYNOTE-695 trial, the clinical teams who conducted this trial, and everybody at OncoSec who remain focused on developing TAVO™-EP as a novel intratumoral treatment approach for cancer patients with unmet medical needs."

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Lynparza and Imfinzi combination improved PFS in newly diagnosed patients with advanced ovarian cancer without tumour BRCA mutations in DUO-O Ph 3 trial

Philipp Harter, Director, Department of Gynaecology and Gynaecologic Oncology, Evangelische Kliniken Essen-Mitte, Germany and principal investigator for the trial, said: "DUO-O showcases the power of academia and industry collaboration in advancing new treatment combinations for patients with ovarian cancer. I'm grateful for the academic cooperative study groups and patients around the world that made this trial possible and look forward to sharing the results with the clinical community."

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Trial Results

Trial Status

First Subject Dosed in Ph 1 KisMET-01 Clinical Trial of MYTX-011 for the Treatment of NSCLC

“Today’s announcement of our first subject dosed represents a significant step towards increasing the number of lung cancer patients eligible for treatment using ADCs, including those whose cancers express moderate cMET levels,” said Brian Fiske, PhD, Chief Scientific Officer and Co-Founder at Mythic Therapeutics. “At Mythic, we are focused on our vision of unlocking the full potential of MYTX-011 as well as our broader pipeline of ADCs incorporating FateControl™ technology, which represents a fundamentally new paradigm for ADC therapies.”

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First Two US Clinical Investigator Sites for AVA6000 Ph 1 Clinical Study Opened

Neil Bell, Chief Development Officer for Avacta Therapeutics, commented: “This timely opening of these two key US sites, under the expert direction of Dr Tap and Professor Cranmer, is a major milestone in Avacta’s entry strategy into the US with our promising AVA6000 pre|CISION™ lead programme. We share with our US colleagues a clear vision to transform treatment outcomes for patients, and we look forward to working together as we continue to build the clinical evidence base for the safety and tolerability of AVA6000, in addition to the significant tumour-targeting potential of the pre|CISION™ platform.”

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Trial Statuses

Business News

Biotheryx Announces Research Collaboration and License Agreement with Incyte for Discovery of Targeted Protein Degraders for Novel Oncology Targets

"We are pleased to embark on this collaboration with Incyte to identify targeted protein degraders for novel oncology targets. Biotheryx and Incyte share a commitment to finding new, transformative treatment options for people living with cancer," said Philippe Drouet, President and Chief Executive Officer of Biotheryx. "Our PRODEGY platform is designed to increase efficiency in degrader discovery and design, enabling the development of therapies for previously undruggable targets. We look forward to leveraging this differentiated approach in our collaboration with Incyte and in the continued advancement of our pipeline of first-in-class, next generation bifunctional degraders and molecular glues for the treatment of cancers and inflammatory disease."

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Scorpion Therapeutics and Pierre Fabre to Co-Develop and Commercialize STX-721 and STX-241 for Patients with EGFR Mutant NSCLC

"Our mission is to develop the next generation of transformational therapies and to deliver them to patients worldwide," said Axel Hoos, M.D., Ph.D., Chief Executive Officer of Scorpion. "Pierre Fabre is the ideal partner to accelerate this vision; a global pharmaceutical company with a robust clinical and commercial footprint in Europe and Asia, and a track record of successfully partnering with biotechnology companies to develop and provide access to innovative cancer medicines. This partnership should help to expand the reach of our EGFR targeting programs, allowing us to help patients who urgently need these treatments, including in markets such as China, where nearly 50% percent of all cases of NSCLC are expected to be EGFR-mutant by 20301.

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