MedNess Newsletter January 11, 2023

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January 11, 2023

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MedNess News Highlights this week

BT8009 Gets FDA Fast Track Designation To Treat Urothelial Cancer

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Positive Top-line Results from Pivotal Ph 3 Trial of TAVT-45 for the Treatment of Metastatic Prostate Cancer Announced

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Enrollment Completed in the Global Registrational Ph 3 AXLerate-OC Trial for Platinum-Resistant Ovarian Cancer

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Triumvira Immunologics and Merck to Evaluate TAC01-HER2 Cell Therapy + KEYTRUDA® in Patients with HER2-positive Solid Tumors

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Regulatory news

BT8009 Gets FDA Fast Track Designation To Treat Urothelial Cancer

"FTD represents another positive step in the development of BT8009 and reflects the pressing need for a clinically meaningful, differentiated therapy compared to what is available for patients," said Kevin Lee, Ph.D., Chief Executive Officer. "We believe this designation is a valuable component of our future clinical and regulatory strategy as we work to align with the FDA to address the pressing unmet needs of people living with urothelial cancer."

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FDA Grants Priority Review to Glofitamab for People with Relapsed or Refractory Large B-Cell Lymphoma

"Unfortunately, people with relapsed or refractory large B-cell lymphoma have a poor prognosis and desperately need additional therapies that are immediately available at the time of relapse," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Even for patients whose cancer is rapidly progressing, glofitamab given for a fixed duration has shown impressive efficacy and long-term durability, with patients continuing to experience a complete remission after treatment has concluded."

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Regulatory News

Trial Results

Positive Top-line Results from Pivotal Ph 3 Trial of TAVT-45 for the Treatment of Metastatic Prostate Cancer Announced

“The positive results from the TAVT45C02 trial demonstrate that TAVT-45 may provide an easy-to-swallow alternative to Zytiga®, benefitting many patients with dysphagia or difficulty swallowing large tablets,” said Andreas Maetzel, M.D. Ph.D., chief medical officer of Tavanta Therapeutics. “Approximately 20 to 30 percent of cancer patients, including many patients with prostate cancer, have difficulty swallowing pills and capsules. We believe these patients may benefit from an alternate formulation like TAVT-45 that would allow them to take their much-needed medications in an easier-to-take formulation.”

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Pivotal LUNAR Study of TTFields + SoC in NSCLC Met Primary Overall Survival Endpoint

“We are pleased with the positive readout of the LUNAR study. Prior to LUNAR, the last phase 3 trial to lead to significant improvement in overall survival in late-stage, platinum-resistant non-small cell lung cancer was six years ago, underlining the difficulty in treating this disease,” said William Doyle, Novocure’s Executive Chairman. “We are also pleased by the profound performance of the TTFields together with immunotherapy, which has the potential to meaningfully extend patient survival beyond what was previously possible. I would like to thank our patients and investigators for their courage and dedication in completing LUNAR. And, I would like to thank Novocure’s employees for their unrelenting commitment to patients and their perseverance in propelling Novocure to this major milestone.”

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Trial Results

Trial Status

Enrollment Completed in the Global Registrational Ph 3 AXLerate-OC Trial for Platinum-Resistant Ovarian Cancer

“Completing enrollment of this pivotal study brings us closer to the day when batiraxcept potentially is available to patients,” said Scott Dove, Ph.D., Chief Operating Officer of Aravive. “Public reporting of topline data remains on track for mid-2023 and, if successful, are expected to support a Biologics License Application for PROC at the end of 2023. I would like to thank the patients enrolled in the trial, the clinical investigators, our CRO partners, and the Aravive team who worked tirelessly to advance the trial to this stage.”

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50% Enrollment completed in Randomised Ph IIb TACTI-003 Trial for 1L Head & Neck Cancer

Marc Voigt, CEO of Immutep stated: “We are pleased to reach this important milestone and extend our sincere appreciation to our investigators, clinical team, partners, and most importantly patients, that have participated in this study. As clinical evidence showing the compelling benefits of combining efti with immune checkpoint therapies such as pembrolizumab continues to grow, we are increasingly excited about efti’s potential to safely deliver superior clinical outcomes and meaningfully expand the population of cancer patients that respond to treatment.”

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Trial Statuses

Business News

Triumvira Immunologics and Merck to Evaluate TAC01-HER2 Cell Therapy + KEYTRUDA® in Patients with HER2-positive Solid Tumors

“We believe the addition of an immune checkpoint inhibitor, such as KEYTRUDA, to TAC01-HER2 will effectively release inhibitory PD-L1/PD1 signaling in T cells, potentially leading to improved and durable therapeutic responses, said Paul Lammers, M.D., M.Sc., Chief Executive Officer of Triumvira. We are pleased to work collaboratively with Merck to explore the potential of this approach to treat relapsed or refractory solid tumors and bring new drug therapies to patients who do not respond to existing treatments.”

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Nouscom and MSD to Evaluate NOUS-209 + KEYTRUDA® in a Ph 2 Randomized Trials in dMMR/MSI-High Metastatic Colorectal Cancer

Dr Marina Udier, Chief Executive Officer of Nouscom, added: “We are thrilled to collaborate with MSD, a global leader in immuno-oncology, and to work with their highly experienced and talented clinical development team, allowing us to accelerate the ongoing US and EU Phase 2 trial with NOUS-209. Based on our published and presented Phase 1 clinical data1,2 we see great potential of this combination approach in addressing the unmet medical need in these patients. We look forward to presenting preliminary data in 2023.”

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