MedNess Newsletter April 27, 2023

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Para sarah@medness.org

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MedNess News Highlights this week

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Positive Ph 3 Tislelizumab Trial in Advanced Gastric or GEJ Adenocarcinoma announced

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Coeptis Therapeutics Signs Agreement to Acquire Allogeneic Immuno-Oncology NK Platform in Phase 1 Clinical Trials from Deverra Therapeutics

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Drug Approvals

FDA approves Polivy in combination with R-CHP for people with certain types of 1L DLBCL

"It has been nearly 20 years since a new treatment option has become available to people newly diagnosed with diffuse large B-cell lymphoma," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Today's decision from the FDA to approve Polivy in combination with R-CHP in this setting brings a much-needed new treatment option which may improve outcomes and bring other benefits to many patients with this aggressive lymphoma."

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Drug Approvals

Regulatory news

Fast Track Designation for Botensilimab and Balstilimab in Colorectal Cancer

“We are pleased that the FDA has granted Fast Track designation for the combination of botensilimab with balstilimab in patients with non-MSI-H colorectal cancer, recognizing the high unmet medical need in this population,” said Dr. Steven O’Day, Chief Medical Officer of Agenus. “The Fast Track designation offers important benefits, including the potential eligibility for a Priority Review, and we will be working with the FDA and all key stakeholders to rapidly advance the botensilimab/balstilimab combination in colorectal cancer as well as other solid tumor indications.”

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Quizartinib NDA Review for Patients with Newly Diagnosed FLT3-ITD Positive AML Extended by FDA

“We are continuing to work with the FDA to facilitate completion of their review of the quizartinib new drug application in order to bring this important medicine to patients as soon as possible,” said Mark Rutstein, MD, Global Head, Oncology Clinical Development, Daiichi Sankyo. “Quizartinib was shown to improve overall survival when added to standard chemotherapy and continued as monotherapy and has potential to change the standard of care for patients with newly diagnosed FLT3-ITD positive AML.”

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Trial Results

Positive Ph 3 Tislelizumab Trial in Advanced Gastric or GEJ Adenocarcinoma announced

"At the recent ASCO GI meeting, we presented results from an interim analysis demonstrating a statistically significant and clinically meaningful improvement in overall survival in the high PD-L1 expression group in RATIONALE 305 and we are pleased that the final analysis demonstrated a significant survival benefit and consistent safety profile in the entire study population," said Mark Lanasa, M.D., Ph.D., Chief Medical Officer, Solid Tumors at BeiGene. "Gastric cancer is the fifth most common cancer globally, and the prognosis for patients with advanced or metastatic conditions remains inadequate; these data support tislelizumab combined with chemotherapy as a potential first-line treatment option for patients with locally advanced, unresectable or metastatic gastric or gastroesophageal junction cancer."

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Positive final results from Ph 2 trial of VB10.16 + atezolizumab in advanced cervical cancer announced

"We are extremely encouraged by the unprecedented data that indicates a doubling of the survival of PD-L1+ patients with advanced cervical cancer compared to treatment alternatives. Not only do we see patients on average live longer, but 7 of the 14 patients who received all treatments are still alive without signs of progression. This is a landmark day for VB10.16 and for Nykode's technology and we are excited to move the cancer vaccine forward towards the market for the benefit of patients," said Michael Engsig, Chief Executive Officer of Nykode Therapeutics.

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Trial Results

Trial Status

Independent Data Monitoring Committee Recommends Galinpepimut-S REGAL Trial to Continue as Planned

“This positive IDMC review marks another significant milestone in GPS development and builds on the favorable profile of our study drug, galinpepimut-S,” said Angelos Stergiou, MD, ScD h.c., President and Chief Executive Officer of SELLAS. “Enrollment continues in our global Phase 3 REGAL registrational study, which currently remains on track for interim analysis by the end of 2023 or early 2024.”

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CONFERENCE COVERAGE: American Association for Cancer Research (AACR) Annual Meeting 2023

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Business News

Coeptis Therapeutics Signs Agreement to Acquire Allogeneic Immuno-Oncology NK Platform in Phase 1 Clinical Trials from Deverra Therapeutics

"This transaction would greatly expand Coeptis' technology portfolio by incorporation of a cutting-edge allogeneic cell therapy platform with extensive safety and clinical data and align itself with leading experts in the field of cell and gene therapy," said Dave Mehalick, President and CEO of Coeptis Therapeutics. Mr. Mehalick continued, "The addition of these clinical and pre-clinical immune effector cell programs would significantly diversify our R&D capabilities and bring a clinical pipeline with multiple novel approaches to combination cellular immunotherapy approaches, not yet achieved by others. Importantly, the substantial capabilities of the allogeneic cell therapy platform would open new pathways for Coeptis to consider expanding its cell-based therapies beyond autologous CAR T. We are excited about the possibility of exploring the application of both the SNAP-CAR and GEAR technologies to allogeneic, off-the-shelf immune effector cells. The NK and macrophage (MAC) immune effector cell generation from Deverra's platform combined with Coeptis' target specific CARs has the potential to result in development of allogeneic NK and MAC cell therapies."

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Tubulis Announces Strategic License Agreement with Bristol Myers Squibb to Develop Next Generation ADCs for the Treatment of Cancer Patients

"This strategic agreement with Bristol Myers Squibb is an important validation of the potential of our approach in developing next-generation ADC-based therapeutics and our cutting-edge ADC conjugation technologies that accommodate advanced ADC design to tackle tumors with high-unmet medical need," said Dominik Schumacher, PhD, CEO and co-founder of Tubulis. "We are committed to transforming oncology treatment paradigms and to deliver better outcomes for cancer patients. Joining forces with BMS, a leading global oncology company, is a significant step toward achieving that goal."

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