MedNess Newsletter January 4, 2023

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MedNess

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January 4, 2023

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MedNess News Highlights this week

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AML and MDS

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Merck and Kelun-Biotech Announce Exclusive License and Collaboration Agreement for 7 Investigational ADC Candidates for the Treatment of Cancer

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Drug Approvals

FDA approved Lunsumio® (mosunetuzumab-axgb) for the treatment of adult patients with R/R follicular lymphoma

"This approval is a significant milestone for people with relapsed or refractory follicular lymphoma, who have had limited treatment options until now," said Elizabeth Budde, M.D., Ph.D., Haematologic Oncologist and Associate Professor, City of Hope Division of Lymphoma, Department of Hematology & Hematopoietic Cell Transplantation, and Lunsumio clinical trial investigator. "As a first-in-class T-cell engaging bispecific antibody that can be initiated in an outpatient setting, Lunsumio's high response rates and fixed-duration could change the way advanced follicular lymphoma is treated."

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Zynlonta® (loncastuximab tesirine) approved in the EU for the treatment of R/R DLBCL

“We are delighted by the European Commission’s approval of Zynlonta” said Anders Ullman, Head of Research & Development and Medical Affairs, Chief Medical Officer at Sobi. “We look forward to making Zynlonta available as a new treatment option to patients in the EU impacted by diffuse large B-cell lymphoma, a debilitating disease in haematology.”

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Drug Approvals

Regulatory news

BLA Review for Toripalimab as Treatment for Recurrent or Metastatic Nasopharyngeal Carcinoma (NPC) by FDA remains pending

“Although toripalimab’s BLA review process has been impacted by the COVID-19 pandemic, we believe the impact is temporary,” said Dr. Sheng Yao, Senior Vice President of Junshi Biosciences. “Together with our partner Coherus, we are working with the FDA to expedite the facility inspection so it may be conducted safely as soon as possible in order to provide NPC patients with a treatment that has been demonstrated to be safe and effective. Our production operations are well prepared for the inspection.”

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Adagrasib (KRAZATI™) Receives Breakthrough Therapy Designation from FDA for Patients with Advanced, KRAS-Mutated CRC

“KRASG12C-mutations occur in 3-4% of colorectal cancers and are associated with poor outcomes. Few effective treatment options exist for these patients,” said Alan Sandler, M.D., Chief Medical Officer. “We are encouraged by this data, particularly adagrasib in combination with cetuximab. With the BTD status, we look forward to working together with the FDA to potentially bring this treatment option to late-line KRASG12C-mutant CRC patients through the accelerated approval pathway.”

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Trial Results

mOS of 21 Months in Advanced, Refractory Cancer Patients observed in Ph 2 trial of PDS0101-based triple combination therapy in advanced HPV-positive cancers

"The expanded data continue to demonstrate the durability and tolerability of the PDS0101-based triple combination therapy in advanced HPV-positive cancers, an extremely challenging population of refractory and previously untreatable HPV-positive patients," stated Dr. Frank Bedu-Addo, President and Chief Executive Officer of PDS Biotech. "We are pleased to see the continued consistency in the data with each update and we look forward to meeting with the FDA to discuss the registrational pathway."

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Positive Topline Data in Ph 2 Pivotal HERIZON-BTC-01 Trial of Zanidatamab announced

"We are thrilled to report these positive topline data from the HERIZON-BTC-01 clinical trial, which further support the potential of zanidatamab as a new chemotherapy-free therapeutic option for HER2-amplified and expressing BTC. These data demonstrate that zanidatamab, as a single agent, improves on the current standard of care for patients in a difficult-to-treat disease who currently have a poor prognosis based on the limited treatment options currently available," said Neil Josephson, M.D., Chief Medical Officer at Zymeworks. "I want to thank all of the patients, their families and the investigators who participated in this important study."

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Trial Results

Trial Status

Patient dosing stopped in MGTA-117 Ph 1/2 Dose Escalation Clinical Trial in R/R AML and MDS

"Magenta Therapeutics today announces that, per the clinical trial protocol for the MGTA-117 Phase 1/2 Dose Escalation Clinical Trial in relapsed/refractory acute myeloid leukemia (AML) and myelodysplastic syndrome (MDS), it has stopped dosing participants at the Cohort 4 dosing level (0.13 mg/kg) and plans to dose additional participants at the Cohort 3 dosing level (0.08 mg/kg). In accordance with the clinical trial protocol and following the recommendation of the trial's safety Cohort Review Committee on December 19, 2022, Magenta plans to continue enrollment at the Cohort 3 dose level."

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First Patient Dosed in PRESERVE-004 Ph 2 Clinical Trial of ONC-392 + KEYTRUDA® in Patients with Platinum-Resistant Ovarian Cancer

"We are pleased to be making progress on our ONC-392 clinical program with the dosing of our first patient in the PRESERVE-004 trial in the combination arm with KEYTRUDA. We are hopeful these results will build on the promising responses we've seen with ONC-392 as monotherapy," said Pan Zheng, M.D., Ph.D. Chief Medical Officer and co-founder of OncoC4. Dr. Zhang further added, "We are grateful to our partners, Merck and the GOG Foundation for their support of the PRESERVE-004 trial. We look forward to providing additional data as they become available."

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Trial Statuses

Business News

Merck and Kelun-Biotech Announce Exclusive License and Collaboration Agreement for 7 Investigational ADC Candidates for the Treatment of Cancer

"Advances in ADC technologies are yielding a new generation of candidates designed to more precisely target and deliver potent anticancer agents to the tumor site," said Dr. Dean Y. Li, president, Merck Research Laboratories. "We

continue to augment our oncology pipeline and look forward to working with the Kelun-Biotech team to advance these candidates to the patients that need them."

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Kite To Acquire Tmunity Therapeutics To Pursue Next Generation CAR T-Cell Therapy Advancements In Cancer

"Kite has demonstrated an ability to globally scale cell therapy and address the unique challenges and opportunities that cell therapy represents, which are quite different in material ways than traditional pharmaceutical or biotech approaches," said Tmunity Founder Carl June, MD, who is also the Richard W. Vague Professor of Immunotherapy in Penn's Perelman School of Medicine and director of Penn's Center for Cellular Immunotherapies. "Kite's singular focus on cell therapy makes them unique and particularly nimble."

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