MedNess Newsletter May 31, 2023

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MedNess News Highlights this week

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Drug Approvals

EPKINLY (epcoritamab-bysp) Approved by FDA to Treat Adult Patients with R/R DLBCL

"DLBCL is an aggressive cancer type that can rapidly progress and resist treatment. The FDA approval of EPKINLY represents a new treatment mechanism of action for third line DLBCL patients. As a non-chemotherapy, single-agent treatment for DLBCL patients, we hope that EPKINLY can effectively treat this aggressive cancer type and can be used for patient care quickly and in an off the shelf form for physicians," said Thomas Hudson, M.D., senior vice president, research and development, chief scientific officer, AbbVie. "The approval is just the first step, with our partner Genmab, towards a shared goal of developing a core therapy for patients with B-cell malignancies."

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VANFLYTA First FLT3 Inhibitor Approved in Japan for Patients with Newly Diagnosed FLT3-ITD Positive AML

"Patients with newly diagnosed FLT3-ITD positive acute myeloid leukemia now will have the opportunity to receive targeted therapy with VANFLYTA," said Wataru Takasaki, PhD, Executive Officer, Head of R&D Division in Japan, Daiichi Sankyo. "VANFLYTA is the only medicine developed and approved specifically for treatment of newly diagnosed FLT3-ITD positive AML in Japan and has demonstrated improved overall survival for this patient population."

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Drug Approvals

Regulatory news

FDA Orphan Drug Designation Granted to Rucosopasem for Pancreatic Cancer

"Orphan drug designation for rucosopasem highlights the urgent need for more treatment options to extend survival in patients with pancreatic cancer, which is the fourth leading cause of cancer death in the U.S.," said Mel Sorensen, M.D., Galera's President and CEO. "Following our announcement of encouraging survival results from our pilot proof-of-concept trial in patients with LAPC in 2021, we initiated the GRECO-2 trial, which is currently enrolling. We believe rucosopasem has the potential to improve the efficacy of SBRT for pancreatic cancer, and we anticipate topline data from GRECO-2 by the end of next year."

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NDA for Fruquintinib for Treatment of Previously Treated mCRC Granted Priority Review; PDUFA: Nov 2023

"We are confident that fruquintinib has the potential to transform the treatment landscape for those living with previously treated metastatic colorectal cancer, as demonstrated by its strong clinical profile," said Awny Farajallah, M.D., head of Global Medical Affairs Oncology at Takeda. "There are significant needs for patients with this disease in the U.S., and we believe fruquintinib has the potential to address these needs regardless of patients' biomarker status. We look forward to continuing conversations with the FDA with the goal to make this therapy available to patients as soon as possible."

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Trial Results

KEYTRUDA + LENVIMA Demonstrates Long-Term, Durable Survival Benefit Versus Sunitinib as 1L Treatment for Patients With Advanced RCC

"KEYTRUDA plus LENVIMA continues to demonstrate durable clinical benefit as a first-line treatment for patients with advanced renal cell carcinoma, as shown by the clinically meaningful improvement in overall survival sustained with four years of follow up," said Dr. Thomas Hutson, DO, Pharm.D., FACP, Director of the Urologic Oncology Program and Co-chair of the Urologic Cancer Research and Treatment Center, Texas Oncology at Baylor Sammons Cancer Center. "Furthermore, these data also showed clinically meaningful improvements in median PFS and ORR compared to sunitinib. These findings reinforce the important role of KEYTRUDA plus LENVIMA as a first-line standard of care treatment option for patients with advanced renal cell carcinoma."

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IMFINZI + LYNPARZA and IMFINZI alone both significantly improved PFS in advanced endometrial cancer when added to chemotherapy

Shannon N. Westin, Professor of Gynecologic Oncology and Reproductive Medicine at the University of Texas MD Anderson Cancer Center, and principal investigator of the DUO-E trial, said: "These exciting data demonstrate durvalumab immunotherapy can significantly delay disease progression for patients with endometrial cancer and the addition of the PARP inhibitor olaparib can improve the benefit further. These combinations could provide physicians with new treatment approaches to improve outcomes for patients."

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Trial Results

Trial Status

Enrollment completed in Immune Checkpoint Inhibitor Naïve Arm of VERSATILE-002 Phase 2 Clinical Trial in Advanced HPV16 Positive Head and Neck Cancer

"Completing enrollment in the ICI naïve arm is an important milestone in the VERSATILE-002 Phase 2 trial and the ongoing development of PDS0101 in combination with KEYTRUDA® as a potential treatment for recurrent and/or metastatic HPV16-positive head and neck cancer," said Dr. Lauren V. Wood, Chief Medical Officer of PDS Biotech. "HPV-driven HNSCC is a growing problem, and there is a large unmet medical need to develop an HPV-targeted immunotherapy. Preliminary data reported at ASCO 2022 and highlighted at our October 2022 Head and Neck Cancer KOL Roundtable suggest that PDS0101 in combination with KEYTRUDA® may lead to improved outcomes in ICI naïve, recurrent or metastatic HNSCC patients. We now look forward to reporting updated data from the VERSATILE-002 trial at ASCO 2023 as the next step towards a planned global confirmatory randomized, controlled trial investigating the combination of PDS0101 and KEYTRUDA® in this same patient population."

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First Patient dosed in AIPAC-003 Phase II/III Trial for Metastatic Breast Cancer

Immutep CSO, Prof Frédéric Triebel said: "Commencing patient dosing for our AIPAC-003 trial of efti is a significant milestone for Immutep. Our aim is to improve clinical outcomes, focusing on a robust primary endpoint later in the phase III, overall survival, for patients with standard-of-care chemotherapy. Our previous trial, AIPAC, showed encouraging efficacy and safety results, including a 2.9-month median overall survival benefit and statistically significant median overall survival improvements of between 4.2 to 19.6 months across three pre-specified subgroups. We look forward to seeing how 90mg efti dosing, along with same-day administration of efti plus paclitaxel until disease progression, may build upon these prior results."

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Trial Statuses

Conference Coverage: 2023

American Society of Clinical Oncology (ASCO) Annual Meeting

CONFERENCE COVERAGE: 2023 American Society of Clinical Oncology (ASCO) Annual Meeting

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Business News

Sony and Astellas Enter into Collaborative Research Agreement to Discover a Novel ADC Platform for the Oncology Field

"Sony's life science business has accumulated substantial knowledge in the field of cell analysis," said Katsunori Ogawa, Head of Life Science & Technology Business Unit at Sony Corporation. "Through this collaboration, Sony is striving to contribute to the medical and drug discovery fields and provide further social value by leveraging Sony's technological capabilities in the development of anti-cancer drugs therapy, which are expected to grow."

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IDEAYA Expands Clinical Trial Collaboration and Supply Agreements with Pfizer to Support Registrational Trial Evaluating Darovasertib and Crizotinib Combination in First-Line Metastatic Uveal Melanoma

“We are grateful to have Pfizer’s continued support – including their clinical expertise as a collaboration partner and with respect to drug supply, as we target initiation of our Phase 2/3 registrational trial in Q2 2023 for the darovasertib and crizotinib combination in first-line HLA-A2 negative MUM, with PFS as primary endpoint for potential accelerated approval. The efficacy we observed in our Phase 2 clinical trial for first-line metastatic uveal melanoma patients suggests compelling clinical efficacy and a potential paradigm shift for treating MUM patients,” said Dr. Darrin Beaupre, M.D., Ph.D., Chief Medical Officer, IDEAYA Biosciences.

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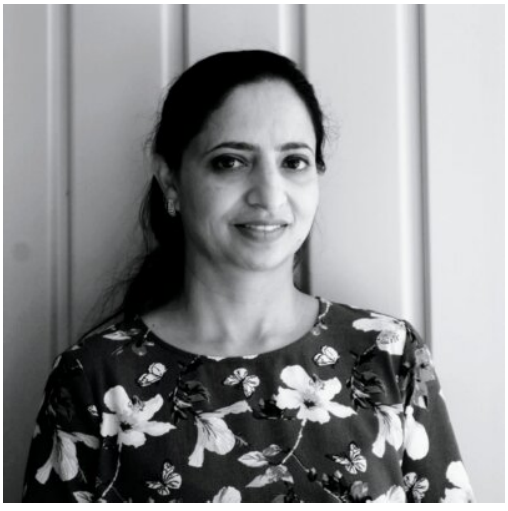

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