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MedNess News Highlights this week

European Commission Approves KEYTRUDA + Chemotherapy for New 1L Indications in Advanced HER2-Negative Gastric or GEJ Adenocarcinoma in Tumors Expressing PD-L1 (CPS ≥1) and Advanced Biliary Tract Cancer

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Drug Approvals

European Commission Approves KEYTRUDA + Chemotherapy for New 1L Indications in Advanced HER2-Negative Gastric or GEJ Adenocarcinoma in Tumors Expressing PD-L1 (CPS ≥1) and Advanced Biliary Tract Cancer

“KEYTRUDA has shown its potential as an important treatment option in the EU across a number of gastrointestinal cancers, with seven indications based on data from our extensive clinical development program,” said Dr. Marjorie Green, senior vice president and head of late-stage oncology, global clinical development, Merck Research Laboratories. “With…

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U.S. FDA Approves Label Update For Yescarta CAR T-Cell Therapy To Include OS Data

“This U.S. label update for Yescarta is an important step to reinforce healthcare provider confidence to treat eligible patients with Yescarta, immediately following progression or relapse in large B-cell lymphoma,” said Frank Neumann, MD, PhD, Senior Vice President and Global Head of Clinical Development, Kite. “Our ZUMA-7 overall survival analysis…

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Drug Approvals

Regulatory News

FDA Issued New Postmarketing Requirement on sNDA seeking full approval of LUMAKRAS® (sotorasib)

“FDA has completed its review of the company’s supplemental New Drug Application seeking full approval of LUMAKRAS® (sotorasib). This review, which resulted in a Complete Response Letter, was based on the CodeBreaK 200 trial results for the treatment of adults with previously treated locally advanced or metastatic KRAS G12C-mutated non-small…

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FDA Clearance of Investigational New Drug Application for SC262 for Patients with Relapsed or Refractory B-cell Malignancies

“Patients who have failed a CD19-directed CAR T therapy represent a significant unmet need, and this population is growing as more patients receive these therapies,” said Doug Williams, PhD, Sana’s President of Research and Development. “SC262 represents an important potential option for these patients and is the next step in…

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Trial Results

Positive Topline Data Achieving Primary Endpoint in Pivotal Clinical Study of Iopofosine I 131 in Waldenstrom’s Macroglobulinemia Announced

“There is a critical need for new therapies with novel mechanisms of action to treat WM. There are no approved treatments for patients post BTKi therapy, where currently the expected response rate to salvage treatments is approximately 10%, and the expected duration of response in those patients is less than…

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Scemblix Shows Superior MMR Rates Vs. SoC TKIs In Phase III Trial For Newly Diagnosed Patients With CML

“We are very encouraged by these results given that a significant proportion of patients with newly diagnosed chronic myeloid leukemia, or CML, do not achieve their treatment goals,” said Prof. Tim Hughes, MD, South Australian Health & Medical Research Institute (SAHMRI). “There remains a significant need in first-line therapy of…

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Trial Status

Global Phase 3 studies started for bomedemstat (LSD1 inhibitor), nemtabrutinib (BTK inhibitor), MK-2870 (anti-TROP2 ADC) and MK-5684 (CYP11A1 inhibitor)

“These Phase 3 trial initiations for four of our investigational candidates represent a critical step forward in our efforts to advance potential treatment options for people with solid tumors and hematologic neoplasms and malignancies,” said Dr. Marjorie Green, senior vice president and head of oncology, global clinical development, Merck Research…

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Patients enrolled into the Third Dosing Cohort of Phase 1/2 Study of ONCT-534 for the Treatment of R/R Metastatic Castration-Resistant Prostate Cancer

“The ONCT-534-101 investigators are enthusiastic about this study, and we are excited about the enrollment and progress through the initial dosing levels. Reaching the third cohort represents an important milestone for the program, as we believe we are nearing potentially therapeutic doses that may benefit prostate cancer patients who have…

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Business News

Boehringer Ingelheim And 3T Biosciences Enter Into A Second Partnership To Develop Next-Generation Cancer Immunotherapies

“At Boehringer Ingelheim, we are committed to transforming patients’ lives. The initial success of our work with 3T gives us confidence that together we can and will expand and accelerate our pipeline of first-in-class T-cell based anti-cancer therapies,” said Lamine Mbow, Ph.D., Global Head of Cancer Immunology and Immune Modulation,…

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Orion and MSD Announce Initiation of Two Phase 3 Trials Evaluating ODM-208/MK5684 in Certain Patients with Metastatic Castration-Resistant Prostate Cancer

“The start of our co-development Phase 3 program with MSD provides exciting opportunities to evaluate the potential of ODM-208/MK5684 as a novel treatment of mCRPC, both in front-line and late-line patients, including those with and without androgen receptor ligand binding domain (AR LBD) mutations,” said Professor Outi Vaarala, Senior Vice…

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