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Drug Approvals

FDA Approves WELIREG® (belzutifan) for the Treatment of Patients With Advanced Renal Cell Carcinoma (RCC) Following a PD-1 or PD-L1 Inhibitor and a VEGF-TKI

“Despite recent progress in the treatment of advanced RCC, there is yet to be an option specifically approved for patients whose disease progresses following a PD-1 or PD-L1 inhibitor and a TKI therapy,” said Dr. Toni K. Choueiri, LITESPARK-005 study chair, director, Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute…

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FDA Approves Expanded Indication for KEYTRUDA Plus Padcev for 1L Treatment of Adult Patients With Locally Advanced or Metastatic Urothelial Cancer

“Advanced bladder cancer is a common cause of cancer-related death,” said Dr. Thomas Powles, primary investigator of KEYNOTE-A39, professor of Genitourinary Oncology and director, Barts Cancer Center. “The overall survival benefit seen in the KEYNOTE-A39 trial demonstrates the potential for KEYTRUDA in combination with enfortumab vedotin to impact the first-line…

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Drug Approvals

Regulatory News

Orphan Drug Designation Granted by the U.S. FDA to Nana-val for the Treatment of Nasopharyngeal Carcinoma

“This orphan drug designation highlights the urgent need for new targeted treatment options for patients with rare diseases such as nasopharyngeal carcinoma, which is highly associated with EBV,” said Mark Rothera, President and Chief Executive Officer of Viracta. “We are encouraged by the interim data from the Phase 1b/2 study…

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FDA grants priority review for tarlatamab in SCLC

“The FDA’s Priority Review designation for this application underscores the urgency to provide new treatment options for patients with advanced SCLC who have progressed following treatment with platinum-based chemotherapy,” said David M. Reese, M.D., executive vice president of Research and Development at Amgen. “While first-line treatments often show strong responses,…

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Trial Results

FAILED TRIAL: RELATIVITY-123 Trial Evaluating the Fixed-Dose Combination of Nivolumab and Relatlimab in Patients with Previously Treated MSS CRC unlikely to meet primary endpoint, to be discontinued

“Metastatic colorectal cancer is a challenging cancer to treat with high unmet needs. Though there have been advances in treating patients with microsatellite instability-high (MSI-H)/deficient mismatch repair (dMMR) colorectal cancers, patients with microsatellite stable (MSS) tumors continue to have limited treatment options in later lines of therapy. While we know…

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mRNA-4157 (V940) + KEYTRUDA Combination Demonstrated Continued Improvement in RFS and DMFS in Patients with High-Risk Stage III/IV Melanoma Following Complete Resection Versus KEYTRUDA At Three Years

“As we continue to follow participants in the KEYNOTE-942/mRNA-4157-P201 study, we are excited to see such a robust clinical benefit with mRNA-4157 (V940) as adjuvant treatment in combination with KEYTRUDA in people with resected high-risk melanoma,” said Kyle Holen, M.D., Moderna’s Senior Vice President and Head of Development, Therapeutics and…

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Trial Status

Ph 3 INTerpath-002 Study of V940 (mRNA-4157) – KEYTRUDA combination for Adjuvant Treatment of Patients with Certain Types of Resected NSCLC

“As lung cancer is the leading cause of cancer death worldwide, there is a need for continued scientific advancements to help fight this disease at earlier stages when patients have the best chance for better outcomes,” said Dr. Marjorie Green, senior vice president and head of late-stage oncology, global clinical…

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First Patient Dosed in Phase 2b Clinical Trial of Samuraciclib in Combination with Fulvestrant in Patients with Advanced HR+, HER2- Breast Cancer

“We continue to make great progress in evaluating the combination of samuraciclib and fulvestrant with the dosing of the first patient in the Phase 2b study,” said Tim Pearson, Chief Executive Officer of Carrick Therapeutics. “There is a large unmet need in treatment for women with HR+, HER2- breast cancer,…

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Conference Coverage

CONFERENCE COVERAGE: American Society of Hematology (ASH) Annual Meeting 2023

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Business News

Agenus to Receive $25 Million Milestone Payment from Bristol Myers Squibb for TIGIT-CD96 Bispecific Program

“The start of the phase 2 portion of the dose expansion study marks an exciting milestone for this differentiated anti-TIGIT program and an important step in potentially delivering a meaningful new option for cancer patients,” said Chief Executive Officer, Garo Armen, Ph.D. “Similar to our lead program botensilimab, we engineered…

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SystImmune and Bristol Myers Squibb Announce a Global Strategic Collaboration Agreement for the Development and Commercialization of BL-B01D1

“Recent BL-B01D1 trials have shown broad potential across different solid tumors as well as a manageable safety profile,” said Dr. Yi Zhu, Chief Executive Officer at SystImmune. “We have long admired Bristol Myers Squibb’s global clinical development and commercialization capabilities in oncology, and this strategic collaboration is an exciting step…

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