Latest oncology clinical development updates

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OTW News Highlights this week

- Ph 2 Trial evaluating the efficacy and safety of Lutetium (177Lu) rhPSMA-10.1 Injection initiated in metastatic CRPC
- Enhertu followed by THP before surgery showed statistically significant pCR improvement high-risk HER2-positive early-stage breast cancer patients in DESTINY-Breast11 Ph 3 trial
- IND Clearance obtained for Ph 1b/2 Trial of LP-184 + ICIs in NSCLC patients with KEAP1 and/or STK11 mutations and low PD-L1 expression
- First Patient Dosed in STARt-002 Trial of Invikafusp Alfa in Combination with Trodelvy® in Metastatic Breast Cancer
- Statistically Significant Topline Results from Global Ph 2 Trial of Elraglusib in 1L Treatment of Metastatic Pancreatic Cancer Announced
- Fast Track Designation for ADRX-0706 Nectin-4 ADC for the Treatment of Advanced Cervical Cancer
- FDA Approves the AVMAPKI™ FAKZYNJA™ Combination for KRAS-mutated Recurrent Low-Grade Serous Ovarian Cancer patients

OTW News Highlights this week

Calquence + chemo approved in the EU FOR 1L MCL

Dave Fredrickson, Executive Vice President, Oncology Haematology Business Unit, AstraZeneca, said: “Treatment with the Calquence combination in first-line mantle cell lymphoma demonstrated a significant improvement in progression free survival and a consistent safety profile for patients in the pivotal ECHO trial. As the first and only BTK inhibitor approved in this indication in the EU, we are proud to provide …

CHMP recommends EU label update for Phesgo to allow administration outside of clinical settings

"Between 2017 and 2023, the socioeconomic burden of HER2-positive breast cancer in ten major economies was nearly $590 billion, projected to increase to nearly $1,000 billion by 2032," said Levi Garraway, M.D., Ph.D., Roche’s Chief Medical Officer and Head of Global Product Development. “At-home treatment may help alleviate the pressure on healthcare systems through significant capacity savings. This aligns with …

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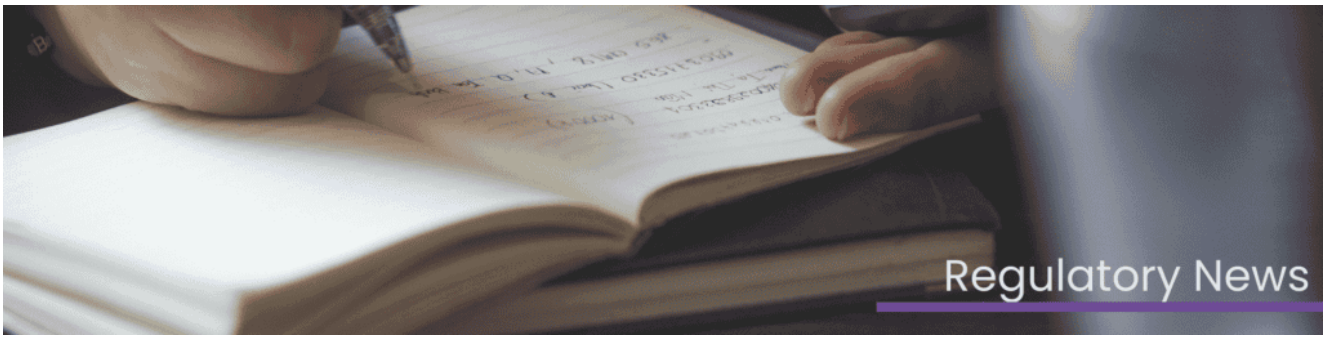

FDA Advisory Committee Announced for UGN-102 for Recurrent Low-Grade Intermediate-Risk NMIBC

“We are excited to discuss our data with the Advisory Committee and broader medical community as we continue our mission to bring innovative solutions to patients suffering from bladder cancer,” said Liz Barrett, President and Chief Executive Officer of UroGen. “We believe UGN-102 represents a meaningful advancement for patients facing the recurrent and challenging nature of LG-IR-NMIBC, and we look …

FDA lifts the clinical hold on IND applications for the EBVALLO™ (tabelecleucel) program

"We are very pleased to have addressed the FDA's questions, and this has enabled the FDA to lift the clinical holds," said Cokey Nguyen Ph.D., President and Chief Executive Officer of Atara. "We are working closely with our partner Pierre Fabre Laboratories and our clinical trial sites and anticipate resuming enrollment and treatment of patients as soon as possible."

Read more Regulatory News

Pivotal Revumenib Data in R/R mNPM1 AML published in the Journal Blood

"We are thrilled to publish the first positive pivotal dataset in patients with an NPM1 mutation, the most common genetic alteration observed in AML," said Neil Gallagher, M.D., Ph.D., President, Head of Research and Development at Syndax. "These important data support the safety and efficacy of revumenib in relapsed or refractory mNPM1 AML and serve as the foundation for the …

Primary Endpoints for Efficacy and Safety Achieved in VIRAGE Ph 2b Trial of VCN-01 with Gemcitabine/nab-Paclitaxel in 1L Metastatic Pancreatic Cancer Patients

"The exciting topline data from the VIRAGE Phase 2b trial demonstrate the potential opportunity for VCN-01 to benefit metastatic PDAC patients treated with gemcitabine/nab-paclitaxel SoC chemotherapy." said Steven A. Shallcross, Chief Executive Officer of Theriva Biologics. "The significantly reduced hazard ratios for survival parameters in the VCN-01 treatment group provide compelling evidence that VCN-01 in combination with gemcitabine/nab-paclitaxel may extend …

Read more Trial Results

Ph 1b Expansion Studies with JANX007 Initiated in Patients with Prostate Cancer

"Improved efficacy and durability of responses has been observed by other prostate cancer drugs and TCEs when moving into earlier lines of therapy. There are also indications that safety with TCEs improve in earlier lines of therapy where disease burden is lower. We believe that these observations, coupled with the data seen in our Phase 1a dose escalation in later …

Ph 2 Trial of OX-4224 initiated in NSCLC

"Launching this clinical trial is a key step toward fulfilling OmRx's mission of addressing global health disparities in cancer treatment," said Isy Goldwasser, CEO, OmRx. "Checkpoint inhibitor antibodies have revolutionized cancer care in high-income countries, but remain largely inaccessible to many patients globally. With OX-4224, we have the opportunity to bring the benefits of immunotherapy to many more people."

Read more Trial Status

Cellipont Bioservices and Optieum Biotechnologies Partner to Advance cGMP Manufacturing of CAR-T Therapy for Glioblastoma

Shun Nishioka, CEO of Optieum added, "At Optieum, we are committed to redefining the future of CAR-T therapy through relentless innovation and scientific rigor. Partnering with Cellipont's team of experts ensures that our groundbreaking therapies

are manufactured to the highest standards, accelerating our progress toward delivering next-generation therapies for glioblastoma and other solid tumors.”

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