Latest oncology clinical development updates

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OTW News Highlights this week

- Nuvation Bio Announces EAP in the US for Taletrectinib in Advanced ROS1-positive NSCLC
- Primary Endpoint Met in Ph 2b Trial of Zipalertinib in Patients with NSCLC with EGFR Exon 20 Insertion Mutations Who Have Received Prior Therapy
- Imvax Announces Completion of $29 Million Financing and Confirms Timing for Topline Results of Ph 2b Trial of IGV-001 in Newly Diagnosed GBM
- BRAFTOVI Combination Regimen Significantly Improved PFS and OS in Ph 3 BREAKWATER Trial
- Imfinzi recommended for approval in the EU by CHMP for limited-stage SCLC
- Enhertu approved in the US for patients with HER2-low or HER2-ultralow metastatic breast cancer following disease progression after one or more endocrine therapies

NMPA approves Sarclisa + SOC VRd in China for patients with newly diagnosed multiple myeloma ineligible for transplant

Olivier Nataf, Global Head, Oncology, Sanofi commented, “When Sanofi entered China more than four decades ago, we did so with the intention of bringing potentially transformative therapies to Chinese patients. This approval, occurring just weeks after Sarclisa’s first in the country, represents tremendous progress towards advancing this mission. Now, patients with multiple myeloma and their providers have access to two ...

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FDA Orphan Drug Designation for MB-105 for T-Cell Lymphoma

“Beyond an important regulatory milestone, securing orphan drug designation for MB-105 from the FDA underscores the critical need for new therapeutic options for patients with T-cell lymphoma,” said Sarah Hein, Co-Founder and Chief Executive Officer of March Biosciences. “Currently, patients with treatment-resistant or recurrent T-cell cancers face an extremely poor prognosis. The MB-105 Phase 1 trial has shown promising safety ...

FDA Rare Pediatric Disease and Orphan Drug Designations for ST-01156

“SEED is rapidly transitioning into a clinical-stage company, with the planned IND filing in the next few months for ST-01156, our novel and potentially best-in-class RBM39 degrader. This marks a significant milestone in our four-year journey to bring innovative therapies to patients,” said Dr. Lan Huang, Co-Founder, Chairman, and CEO of SEED and BeyondSpring. “RBM39 is a validated target to ...

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Initial Clinical Data from Part B of the DeFianCe Study and Part C of the DisTinGuish Study of sirexatamab (DKN-01) Reported

"Data from Part B of the DeFianCe study closely mirror the findings from Part A, and together they demonstrate the potential of sirexatamab to provide a compelling treatment option for second-line CRC patients who do not benefit from current standard of care," said Cynthia Sirard, M.D., Chief Medical Officer of Leap. "Along with consistently achieving higher response rates than the ...

Positive Topline Results of Ph 3 COMPETE Trial with ITM-11 in Patients with Gr 1 or 2 Gastroenteropancreatic Neuroendocrine Tumors (GEP-NETs) announced

“We want to thank the patients, families and caregivers, and investigators for their commitment to and trust in this trial. People with GEP-NETs, whose journey from diagnosis to proper treatment can take years, remain in significant need of more robust, data-driven

treatment options to maximize outcomes. The successful COMPETE data support ITM-11's potential and we believe mark an important milestone ...

Read more Trial Results

FIRCE-1 Ph 2 Study of Firi-cel to Discontinue; Advances Remaining Programs While Evaluating Strategic Options

"We are disappointed with these unexpected results from our Phase 2 study. Durability of complete response is an important clinical goal for LBCL patients who are R/R to CD19 CAR T-cell therapy. Combined with a higher-than-expected occurrence and severity of IEC-HS, the data generated so far does not meet our expectations of a competitive benefit-risk profile for patients in the ...

Read more Trial Status

BioNTech Completes Acquisition of Biotheus

“BioNTech SE announced today the completion of the acquisition of Biotheus, a clinical-stage biotechnology company dedicated to the discovery and development of novel antibodies to address unmet medical needs of patients with oncological or inflammatory diseases. The acquisition was announced on November 2024 and builds on the successful collaboration on the late-stage clinical asset BNT327, an investigational bispecific antibody targeting ...

Lantheus to Acquire Evergreen Theragnostics for Upfront Payment of $250 Million

“As Lantheus continues to advance its industry leadership, this transaction, along with the agreement to acquire Life Molecular Imaging, enhances our operations across the radiopharmaceutical value chain,” said Brian Markison, CEO of Lantheus. “With Evergreen’s manufacturing and development capabilities, we become fully integrated and will ultimately make a difference in the lives of more patients. We are pleased to welcome ...

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