Latest oncology clinical development updates

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OTW News Highlights this week

- Ph 1 SB101 Trial expanded to Evaluate Combination of SON-1010 with Trabectedin in Certain Sarcomas
- New Real-World DOR Data for JELMYTO Reports 68% RFS at Three Years in Patients with Low-Grade Upper Tract Urothelial Cancer (LG-UTUC)
- Global Ph 3 Trial of ASP-1929 Photoimmunotherapy in Combination with Pembrolizumab for 1L Recurrent Head and Neck Cancer initiated
- ASCO GI 2025: Positive Updated Data from ASPEN-06 Ph 2 Trial of Evorpacept in Patients with HER2-Positive Gastric Cancer presented
- IDMC recommends continuation of Ph 3 REGAL Trial of GPS in AML
- FAILED TRIAL: Ph 3 LEAP-015 Trial of KEYTRUDA + LENVIMA in Combination with Chemo in Patients with Certain Types of Gastroesophageal Adenocarcinoma did not meet co-primary endpoint of OS
- FDA feedback provided on potential ELI-002 Ph 3 study design, including dose, schedule, patient population and primary endpoint analysis

Tagitanlimab Approved by NMPA in Combination with Cisplatin and Gemcitabine For the 1L Treatment of Patients with recurrent or metastatic NPC

Dr. Micheal Ge, CEO of Kelun-Biotech said, “We are pleased that the second indication of our self-developed PD-L1 monoclonal antibody was successfully approved for marketing and demonstrated statistically significant and clinically meaningful improvements in PFS. For domestic NPC patients, Tagitanlimab has realized a breakthrough in therapeutic coverage and innovation from the backline to the frontline, which once again strongly validates ...

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BLA accepted, Priority Review granted for RP1 for the Treatment of Advanced Melanoma

“There are limited treatment options and a significant unmet need for patients with advanced melanoma who previously received an anti-PD-1 containing regimen,” said Sushil Patel, Ph.D., Chief Executive Officer, Replimune. “The BLA acceptance is an important milestone for Replimune, and we look forward to working closely with the FDA on the review of our application.”

[Orphan Drug Designation from the U.S. FDA for ZL-1310 (DLL3 ADC) for the Treatment of SCLC]

“Receiving an Orphan Drug Designation for ZL-1310 recognizes its potential to treat patients with SCLC. These patients have an urgent need for innovative treatment options with improved efficacy, safety and ready access in tertiary care and community settings,” said Rafael G. Amado, M.D., President, Head of Global Research and Development, Zai Lab. “ZL-1310 has demonstrated promising objective response rates and ...

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[Ph 2b Trial of OST-HER2 Achieves Primary Endpoint with Statistical Significance in the Prevention of Recurrent, Fully Resected, Lung Metastatic Osteosarcoma]

“We are extremely pleased with these results of our Phase 2b clinical trial because they show that OST-HER2-treated patients achieved the primary endpoint of 12-month EFS in a statistically significantly higher ratio than comparable historical controls, in addition to increasing the likelihood of 1-year and 2-year survival as compared with comparable historical controls,” commented Dr. Robert Petit, Chief Medical & ...

[ASCO GI 2025: Encouraging Results from Ph 1b/2 STELLAR-001 Trial of Zanzalintinib +/- Immune Checkpoint Inhibitor in Metastatic CRC announced]

“This cohort of the STELLAR-001 trial was designed to inform the contribution of atezolizumab to zanzalintinib in patients with previously treated metastatic colorectal cancer,” said Amy Peterson, M.D., Executive Vice President, Product Development & Medical Affairs, and Chief Medical Officer, Exelixis. “Data from this randomized expansion cohort reaffirms our decision to initiate STELLAR-303 evaluating zanzalintinib in combination with atezolizumab compared ...

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First patient dosed with KJ-C2320

“CARsgen Therapeutics Holdings Limited, a company focused on innovative CAR T-cell therapies for the treatment of hematologic malignancies and solid tumors, announces that KJ-C2320, an allogeneic CAR T-cell therapy targeting CD38, has administered the first dose to a patient in an investigator-initiated trial (IIT). KJ-C2320 is developed based on CARsgen’s THANK-uCAR® platform. An investigator-initiated trial is ongoing in China to ...

Patient Enrollment milestone reached for Ph 2 Trial of Ropidoxuridine for Treatment of Patients with GBM

“Enrollment into the trial is ahead of our expectations,” commented Shuttle Pharma’s CEO and Chairman, Anatoly Dritschilo, M.D. “I am grateful to the teams at each of these nationally recognized cancer centers for their participation in the trial as we look to develop radiation sensitizers to increase cancer cure rates, prolong patient survival and improve quality of life for patients ...

Read more Trial Status

AbbVie and Neomorph Announce Collaboration to Develop Molecular Glue Degraders for Oncology and Immunology

"At Neomorph, we have spent years building a unique molecular glue platform with broad coverage of the proteome," said Phil Chamberlain, DPhil, Co-Founder, President, and Chief Executive Officer of Neomorph. "We are thrilled to partner with AbbVie, a global leader in delivering transformative medicines in oncology and immunology, as we aim to tackle some of the most challenging and valuable ...

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Editor's Desk

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