Latest oncology clinical development updates

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OTW News Highlights this week

- FDA accepts sBLA for Opdivo + Yervoy for Patients with Unresectable or Metastatic MSI-H or MRD CRC
- FDA clears IND application for LTZ-301 to treat R/R NHL
- Eikon Therapeutics Secures $350.7 Million Series D to Advance Clinical-Stage Programs and Future Pipeline
- First New Subject Dosed in Ph 2 Study of Ampligen and Imfinzi Combination Therapy for Late-Stage Pancreatic Cancer
- Positive Final Survival Data from Ph 2 Clinical Trial of CAN-2409 in Non-Metastatic Pancreatic Cancer Announced
- FDA Fast Track Designation for PYX-201 Monotherapy in Patients with Recurrent or Metastatic Head and Neck Cancer
- Medigene and EpimAb Biotherapeutics Enter into a Co-Development Partnership for TCR-Guided T Cell Engagers
- Further development of PD-1xCTLA-4 bispecific antibody vudalimab paused

- Camizestrant demonstrated highly statistically significant improvement in PFS in 1L advanced HR+ve breast cancer with an emergent ESR1 tumour mutation in SERENA-6 Ph 3 trial
- FDA Grants Priority Review to KEYTRUDA + SOC as Perioperative Treatment for Resectable Locally Advanced SCCHN; PDUFA: Jun 23, 2025

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Odronextamab BLA Accepted for FDA Review for the Treatment of R/R Follicular Lymphoma

“FDA has accepted for review the resubmission of the BLA for odronextamab in R/R follicular lymphoma (FL) after two or more lines of systemic therapy. The target action date for the FDA decision is July 30, 2025. Acceptance of the BLA resubmission follows the achievement of an FDA-mandated enrollment target for the Phase 3 confirmatory trial in R/R FL (OLYMPIA-1). ...

FDA RMAT Designation for CAR-NK in Treatment of Multiply Relapsed Locally Advanced or Metastatic Pancreatic Cancer

“RMAT designation for ANKTIVA combined with NK cells was applied for by the Founder in the initial 2017 IND. With the clinical results of the QUILT trials across multiple tumor types from 2017 to 2024, validating the hypothesis that high-dose chemotherapy and radiation induces lymphopenia and can be reversed by ANKTIVA together with off-the-shelf CAR-NK cells (PD-L1 t-haNK) resulting in ...

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Promising Survival Observations in mTNBC Patients Treated with Leronlimab Announced

Dr. Jacob Lalezari, CEO of CytoDyn, added: “These provocative observations of improved survival in patients with mTNBC and prior treatment failure in the metastatic setting, including reported clearance of disease in a group of long-term survivors, provides early clinical evidence of leronlimab’s potential impact in the treatment of TNBC and other solid tumors. I expect the Company’s oncology efforts to ...

GEMSTONE-303 article published in JAMA, highlighting efficacy of sugemalimab + CAPOX vs placebo + CAPOX as 1L treatment for patients with unresectable locally advanced/metastatic G/GEJ adenocarcinoma with PD-L1 CPS ≥5

Dr. Jason Yang, CEO, President of R&D, and Executive Director at CStone, stated: "We are honored to see the GEMSTONE-303 study results published in JAMA. This study

establishes sugemalimab in combination with chemotherapy as the new standard first-line treatment for patients with PD-L1 CPS ≥5 G/GEJ adenocarcinoma. To date, sugemalimab has been approved for five indications in China. Internationally, we ...

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First Dose Cohort in STARLIGHT-1 Trial Completed and Approval Received to Initiate Higher Dose Cohort

“The safety and early efficacy data from the first dose cohort are encouraging. We look forward to evaluating the higher dose cohort to further understand the potential of EB103 as a transformative therapy for patients with relapsed/refractory B-cell NHL.” said Cheng Liu, Ph.D., President and CEO of Estrella Immunopharma.

1L STK11M NSCLC study discontinued

“It is, of course, disappointing and unexpected that we are now discontinuing the study. I would like to extend my gratitude to the patients and investigators who participated in our study for this particularly difficult-to-treat patient group, as well as to our team members who have worked tirelessly on this effort”, stated Olav Hellebø, Chief Executive Officer of BerGenBio. “We ...

Read more Trial Status

Swarm Oncology Ltd. and Cellex Cell Professionals GmbH Announce Strategic Partnership to Advance Swarm's Innovative T Cell Therapies for Solid Cancers

Martin Olin, CEO of Swarm, said: "Swarm's mission is to transform immunotherapy by overcoming its limitations and driving solid cancers into long-term remission. With Cellex's deep expertise in cell collection, therapy manufacturing, and regulatory compliance, we can ensure a seamless, high-quality manufacturing process and advance clinical development, bringing life-changing treatments to patients with the reliability and scale they need."

Ryvu Therapeutics announces strategic reorganization to extend the cash runway for the development of RVU120

Paweł Przewięźlikowski, Chief Executive Officer and the largest shareholder of Ryvu said: "We remain focused on advancing our first-in-class clinical blood cancer program RVU120, as well as promising early-stage assets. Considering our cash position, revenue projections, cost structure and the demanding market environment, we decided to optimize expenses so that the company has sufficient cash runway to generate key data for RVU120 and ...

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