Latest oncology clinical development updates

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OTW News Highlights this week

- Boehringer Ingelheim broadens oncology portfolio with license for Synaffix's ADC technology
- Sasanlimab in Combination with BCG Improves EFS in Patients with BCG-Naïve, High-Risk NMIBC
- IND Clearance from FDA to Proceed with Ph 2 Study of TYRA-300 in NMIBC (SURF302)
- AbbVie and Simcere Zaiming Announce Partnership to Develop a Novel Trispecific Antibody Candidate in Multiple Myeloma
- Givastomig (CLDN18.2 x 4-1BB Bispecific Antibody) announced as Lead Clinical Program
- Adjuvant Libtayo® (cemiplimab) Significantly Improves DFS After Surgery in High-Risk CSCC in Ph 3 Trial
- Datopotamab deruxtecan granted Priority Review in the US for patients with previously treated advanced EGFR-mutated NSCLC

Read more Drug Approvals

FDA clears IND for Ph 1/2 clinical trial of REC-4539 in SCLC and MHRA clears IND for Ph 1 clinical trial of REC-3565 for B-cell malignancies

Chris Gibson, Ph.D., Co-Founder and CEO of Recursion said, “We are excited to add REC-4539 and REC-3565 to our clinical stage portfolio as we explore first- and best-in-class oncology medicines and build momentum and value through our pipeline. These are prime examples of how precision design, powered by the Recursion OS platform with advanced AI capabilities, enables us to identify ...

US FDA Breakthrough Therapy Designation Granted to Letetresgene Autoleucel (lete-cel) for Treatment of Myxoid/Round Cell Liposarcoma (MRCLS)

Adrian Rawcliffe, Adaptimmune's Chief Executive Office: "This designation by the FDA highlights the potential of lete-cel to address a critical need for new treatment options for patients with MRCLS. This is another important milestone in building out our sarcoma

franchise, as we aim to bring lete-cel to market in 2026 for the treatment of synovial sarcoma and MRCLS. We look ...

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Positive Update provided on Ph 2a Arm of IMM-1-104 in Combination with Modified FOLFIRINOX for 1L Pancreatic Cancer

“We are excited to report an updated ORR of 43% and DCR of 86% for IMM-1-104 in combination with modified gemcitabine/nab-paclitaxel in first-line pancreatic cancer patients. For reference, the benchmark reported for gemcitabine/nab-paclitaxel in this setting had an ORR of 23% and DCR of 48%. We look forward to reporting further data in the second quarter of 2025 and have ...

RYBREVANT® (amivantamab-vmjw) + LAZCLUZE™ (lazertinib) shows statistically significant and clinically meaningful improvement in OS versus osimertinib

“These new findings reinforce the clinically meaningful impact this chemotherapy-free regimen can have for patients worldwide with non-small cell lung cancer and represent the first overall survival benefit over the current standard of care,” said Yusri Elsayed, M.D., M.H.Sc., Ph.D., Global Therapeutic Area Head, Oncology, Johnson & Johnson Innovative Medicine. “With less than 20 percent of patients living beyond five ...

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Development plans of NY-500, an AI-Optimized PD-1 x VEGF Bifunctional Antibody, announced in multiple oncology indications

“We are excited to add a novel, AI-optimized PD-1 x VEGF therapeutic candidate to our pipeline of best-in-class bifunctional antibodies,” commented NAYA Biosciences President Dr. Daniel Teper. “NAYA’s bifunctional format has demonstrated the ability for synergistic dual-targeting activity, resulting in the potential to unlock clinical response in solid tumors. NY-500, our PD-1 x VEGF antibody, will target hepatocellular carcinoma (HCC) ...

Advancement of Ph 1 clinical programs, RP-1664 and RP-3467, to be continued

“While Lunre+Camo demonstrated positive results from our Phase 1 clinical trial, after careful consideration we have decided to progress this program into pivotal trials contingent on securing a strategic partner to fund further development. We are focused on achieving near-term inflection points for our Phase 1 clinical assets, RP-1664 and RP-3467, both of which have the potential to address significant ...

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Lilly to acquire Scorpion Therapeutics' mutant-selective PI3Kα inhibitor program

"PI3Kα mutations occur in a meaningful proportion of hormone-positive breast cancers, and there is significant unmet need for new treatment options that effectively and safely target this pathway," said Jacob Van Naarden, executive vice president and president of Lilly Oncology. "The selectivity profile of STX-478 has led to a differentiated clinical profile, enabling use in combinations with standard-of-care therapies to ...

Predictive Oncology Announces Agreement to be Acquired by Renovaro

“Since we initiated our formal review of strategic alternatives in mid-November, we have received significant inbound interest that has led to ongoing discussions and due diligence with several parties,” stated Raymond Vennare, Chairman and Chief Executive Officer of Predictive Oncology. “Through our discussions with Renovaro, we became increasingly compelled by the strategic potential of combining the Predictive’s AI-driven drug discovery ...

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