Latest oncology clinical development updates

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OTW News Highlights this week

- Positive Immune Response Data Announced from FLAMINGO-01 Ph 3 Trial
- Initial Data from Ph 3 Trial Demonstrating 75% CRR at 3 Months with nadofaragene firadenove) in BCG-unresponsive Japanese NMIBC Patients Announced
- Mosaic Therapeutics in-licenses two clinical-stage oncology programs from Astex Pharmaceuticals
- Second Interim Analysis of OBI-822 Ph 3 Trial Completed and Trial Termination announced
- Ivonescimab + Chemo combo yields Statistically Significant PFS vs. Tislelizumab + Chemo in Chinese Patients with 1L Squamous NSCLC in HARMONi-6 Study
- CHMP Positive Opinion for Zanidatamab for the Treatment of Advanced HER2-Positive Biliary Tract Cancer
- FDA approves penpulimab-kcqx + chemo combo for 1L NPC and monotherapy in 2L+ NPC
- Halozyme Sues Merck for Patent Infringement over SC Keytruda Formulation
- Strategic Pipeline Prioritization Announced with Focus on CB-010 and CB-011 Oncology Programs

- Sasanlimab Combination Significantly Improves EFS in BCG-Naïve, High-Risk NMIBC, but misses OS endpoint
- FDA clears IND application for VS-7375, Enabling Ph 1/2a Trial in Advanced Solid Tumors
- NMPA approves Orelabrutinib for the 1L Treatment of CLL/SLL in China

OTW News Highlights this week

MHRA grants conditional marketing authorisation for AUCATZYL (obecabtagene autoleucel) for the treatment of adult patients with R/R B-ALL

“Continuing our momentum, this MHRA license is a significant milestone for Autolus as a company. With our scientific expertise, operations and manufacturing based in the UK, this is an important achievement for our company,” said Dr. Christian Itin, Chief Executive Officer of Autolus. “We want to thank all the patients and investigators at the UK trial centres for their contributions ...

Ivonescimab Receives NMPA Approval for 1L Treatment of PD-L1-Positive NSCLC, Based on Ph 3 Trial Demonstrating Superior Efficacy Over Keytruda

Dr. Xia Yu, Founder, Chairwoman, President, and CEO of Akeso, commented: "We are thrilled to announce the approval of ivonescimab as a first-line treatment for PD-L1-positive NSCLC, a major breakthrough in cancer immunotherapy. This milestone is a result of the dedication of investigators, participants, and patients, and we sincerely thank all of them. We also appreciate the regulatory authorities for ...

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EMA gives IMPD approval to initiate Ph 1 trial of OT-C001 + Rituximab in DLBCL patients

“We are delighted to have reached an important milestone of entering clinical development of OT-C001 following our strategic investments in Emercell since 2021," said Dr. C. Grace Yeh, Chairman and CEO of Onward Therapeutics,"This Phase 1 trial may validate Emercell’s patented platform technology for meaningful clinical outcomes. Along with the continued optimization of industrial manufacturing, these efforts will strengthen our ...

EMA granted orphan drug status to AB8939 for the treatment of AML

Professor Olivier Hermine, President of AB Science's Scientific Committee, member of the French Academy of Sciences and Head of the Hematology Department at Necker Hospital, commented: "This designation testifies to the potential of AB8939 for the treatment of AML. Indeed, AB8939 has shown activity as a monotherapy on Ara-C-resistant patient lines, including in unfavorable genetic situations (MECOM, TP53 mutations) that ...

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Positive Interim Ph 2 Results for NP137 in combination with anti-PD(L)1 Announced

“These interim results mark a major milestone in our mission to develop drugs that overcome therapy resistance”, said Patrick Mehlen, CEO of NETRIS Pharma. “We are excited by the potential of NP137 to restore patients sensitivity to immunotherapy-based treatments and to deliver a new treatment solution for patients with limited options”.

Positive Interim Results Demonstrating Durable Responses in Ongoing Ph 2 ADVANCED-2 Trial of TARA-002 in Patients with NMIBC Announced

“For patients with high-risk NMIBC, there are few effective and durable therapies available other than radical cystectomy, which we know is quite difficult for patients to tolerate,” said Tom Jayram, M.D., Director of the Advanced Therapeutics Center at Urology Associates, and ADVANCED-2 study investigator. “TARA-002 has shown impressive efficacy, safety profile, and 12-month durability in its Phase 2 trial. In ...

Read more Trial Results

First Patient Dosed in Ph 2 Trial of MB-105 in T-Cell Lymphoma patients

“This represents a significant milestone in advancing MB-105 as a potential treatment option for patients with T-cell lymphoma who currently face extremely limited therapeutic choices,” said Sarah Hein, Co-Founder and Chief Executive Officer of March Biosciences. “CAR-T therapies have revolutionized the treatment of B-cell lymphomas and leukemias but have not successfully addressed the rarer T-cell lymphomas and leukemias. We are ...

Sarah Cannon Research Institute at Colorado Blood Cancer Institute Announced as Key Clinical Trial Site for Ph 1 Trial of CER-1236 in AML

Chris Ehrlich, CERo Therapeutics CEO added, “CBCI is a world-renowned cancer center, and we believe their participation in our AML trial is continued validation of the scientific work performed to date with CER-1236. We look forward to announcing enrollment and initial dosing in the near term for this trial and to progress in launching our solid tumor study.”

Read more Trial Status

DAAN Biotherapeutics and GC Cell Sign Exclusive Technology Transfer Agreement for Tumor Antigen-Specific Antibody Sequence to Advance CAR-T and CAR-NK Cell Therapies

Byoung-Chul Cho, MD, the CEO of DAAN Biotherapeutics, stated, "We will continue to innovate our technologies to develop cancer treatments that will change the lives of patients."

Zelluna Reaches Major Milestone with Manufacturing Process Established in Preparation for Clinical Entry of TCR-NK Therapy ZI-MA4-1 Targeting Solid Tumours

"We are thrilled to have successfully locked down our TCR-NK cell therapy manufacturing process," said Namir Hassan, CEO of Zelluna. "This pivotal achievement not only demonstrates our capability to produce high-quality, scalable TCR-NK cell therapies, but also underscores our commitment to advancing next-generation immunotherapies that could transform the treatment of solid tumours and improve patient outcomes. This accomplishment is a ...

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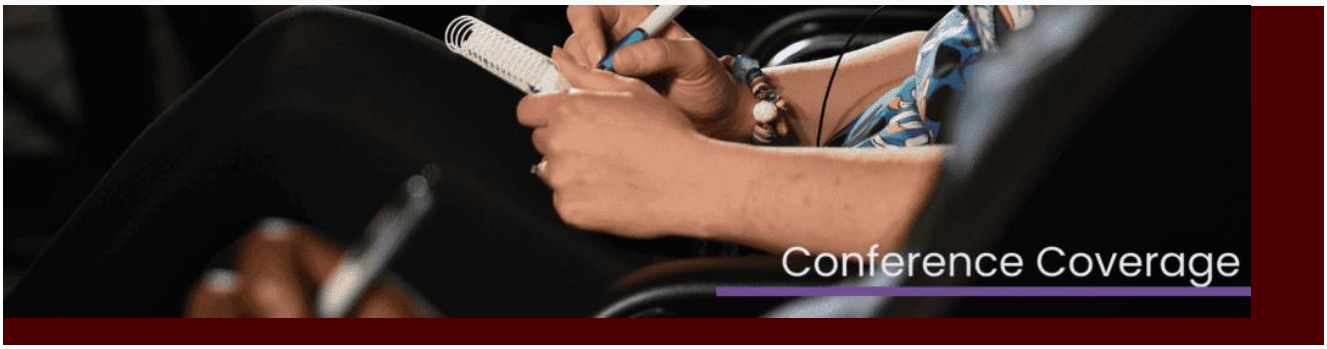

AACR 2025

ALX Oncology Announces Encouraging Final Results from Ph 1 Trial of Evorpacept + SOC Treatment in Patients with B-cell NHL Boehringer's new zongertinib data demonstrates durable and clinically meaningful results in patients with HER2 (ERBB2)-mutant advanced NSCLC Bolt Biotherapeutics Presents Results from the Phase 1 Dose-Escalation Clinical Study of BDC-3042 BriaCell Presents Survival and Clinical Benefit from Ph 2 of ...

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