Latest oncology clinical development updates

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OTW News Highlights this week

- AbCellera Expands Collaboration with AbbVie to Develop Novel T-Cell Engagers for Oncology
- FDA Clears 225Ac-Satoreotide Ph 1/2 Clinical Study in Patients with SCLC or Merkel Cell Carcinoma
- FDA Approves Lumakras® (Sotorasib) + Vectibix® (Panitumumab) For Chemorefractory KRAS G12C-Mutated Metastatic CRC
- Simnova and Orna Expand Strategic Partnership to Include BCMA-Targeted RNA Therapeutics
- Positive Topline Results for TIVDAK in the China Subpopulation of the Global Ph 3 innovaTV 301 Trial in Patients with Recurrent/Metastatic Cervical Cancer Announced
- NDA initiated with US FDA for TAR-200 for patients with BCG-unresponsive high-risk NMIBC
- Calquence plus chemoimmunotherapy approved in the US for patients with previously untreated mantle cell lymphoma

European Commission expands Jemperli (dostarlimab) plus chemotherapy approval to all adult patients with primary advanced or recurrent endometrial cancer

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: “For the first time, all patients with primary advanced or recurrent endometrial cancer in the EU have an approved immuno-oncology-based treatment that has shown a statistically significant and clinically meaningful overall survival benefit. We’re proud Jemperli continues to redefine the treatment landscape for patients.”

Datroway (datopotamab deruxtecan) approved in the US for patients with previously treated metastatic HR+ve, HER2-neg breast cancer

Dave Fredrickson, Executive Vice President, Oncology Haematology Business Unit, AstraZeneca, said: “With this first approval of Datroway in the US, we continue to deliver on our ambition for antibody drug conjugates to improve upon and replace conventional chemotherapy for the treatment of multiple cancers. We are proud to bring Datroway to people living with metastatic HR-positive, HER2-negative breast cancer, and ...

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NMPA Approves IND for HLX43 in Combination with Serplulimab

“Shanghai Henlius Biotech announced that the investigational new drug (IND) application for a phase 1b/2 clinical trial of HLX43 for Injection, the antibody-drug conjugate (ADC) product that developed by the company based on the collaboration with MediLink Therapeutics, in combination with the company's independently developed innovative anti-PD-1 monoclonal antibody (mAb) HANSIZHUANG (serplulimab), has been approved by the China National Medical ...

FDA IND Clearance Receives to Initiate Clinical Testing of R-5780 in Cancer

“The FDA's clearance for R-5780 is a testament to the innovation and dedication of our team at Rise Therapeutics driving novel immunotherapies forward into human proof-of-concept” states Christian Furlan Freguia, Senior Vice President of Research at Rise Therapeutics. “R-5780 represents a pioneering approach that leverages the power of gut-regulated immune pathways to enhance the effectiveness of immune checkpoint inhibitors... We ...

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[HyBryte™ Expanded Treatment Continues to Demonstrate Positive Outcomes in Early-Stage CTCL]

"The complete response rate, consistent treatment response and safety profile across multiple clinical studies to date with HyBryte™ has been exciting to see," noted Dr. Kim, Principal Investigator of the IIS and Lead Investigator of the FLASH2 study. "In the first Phase 3 FLASH study, HyBryte™ was shown to be efficacious with a benign safety profile compared to the current ...

[UGN-102 Achieves 82.3% Duration of Response at 12 Months for LG-IR-NMIBC]

“These data from the ENVISION trial provide compelling evidence that treatment with UGN-102 achieves a clinically meaningful complete response rate and also demonstrates remarkable durability in patients with LG-IR-NMIBC,” said Sandip Prasad, MD, M.Phil., Director of Genitourinary Surgical Oncology at Morristown Medical Center/Atlantic Health System, NJ, and Principal Investigator of the ENVISION trial. “The long-term results, with 82.3% duration of ...

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European Clinical Trial Sites opened and Initial Dosing of Cohort 4 completed for PAS-004 Ph 1 trial

Dr. Tiago Reis Marques, Chief Executive Officer of Pasithea stated, “We are pleased to be working with Arensia in Eastern Europe, allowing PAS-004 to be tested in patients with tumor types more sensitive to single agent MEK treatment or patients who have previously failed first-generation MEK inhibitors.”

Read more Trial Status

ArsenalBio and BMS Achieve Milestone for AB-4000 Series to Advance Next-Gen T Cell Therapies for Solid Tumors

“This milestone underscores the confidence Bristol Myers Squibb has in ArsenalBio’s programmable T cell platform and our shared vision to develop transformative cell therapies for solid tumors,” said Ken Drazan, M.D., ArsenalBio’s Chairman and CEO. “Our collaboration provides increasing opportunities to address the multifactorial challenge of treating solid tumors through programmable cell engineering. We look forward to continuing our work ...

A2 Biotherapeutics Closes $80 Million Series C Financing to Advance Precision Cell Therapies Using Proprietary Tmod Technology Platform

“We are excited by the initial clinical data from our lead programs, which we believe validates our proprietary logic-gate technology approach to solid tumor cancers,” said Jim Robinson, chief executive officer of A2 Bio. “This funding will enable us to continue ongoing clinical development of our CAR-T cell therapies as well as fund the potential next phase of development.”

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Editor's Desk

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