Latest oncology clinical development updates

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OTW News Highlights this week

- First Patient Dosed in Ph 3 MIRACLE Trial of Annamycin and Ara-C in R/R AML patients
- Patient with HPV+ HNSCC dosed in Ph 1 ACESOT-1051 Trial
- Edity Therapeutics Enters into a Strategic Co-Development Partnership with Aurigene Oncology to Advance a Novel Cell Therapy Program for Solid Tumors
- Clinical development program for ociperlimab (BGB-A1217) to be discontinued
- Tovecimig (CTX-009) Meets Primary Endpoint in Ph 2/3 Study in Patients with Biliary Tract Cancer
- FDA Clears IND Application for Ph 1 Clinical Trial of RB-164 for Hematologic and Solid Malignancies
- Imfinzi-based perioperative regimen approved in the EU for resectable NSCLC based on AEGEAN Ph 3 trial results

[European Commission approves SC RYBREVANT (amivantamab) for the treatment of patients with advanced EGFR-mutated NSCLC]

“The approval of subcutaneous amivantamab represents a welcome improvement of the treatment experience for both patients living with EGFR-mutated advanced non-small cell lung cancer and the healthcare professionals who support them,” said Henar Hevia, PhD., Senior Director, EMEA Therapeutic Area Lead, Oncology, Johnson & Johnson Innovative Medicine. “This advancement presents an important opportunity to reduce the treatment burden, improve quality ...

[Enhertu approved in the EU for patients with HR-positive, HER2-low or HER2-ultralow metastatic breast cancer following at least one endocrine therapy]

Dave Fredrickson, Executive Vice President, Oncology Haematology Business Unit, AstraZeneca, said: “Enhertu continues to open up new approaches to the diagnosis and treatment of patients with metastatic breast cancer. This approval underscores the importance of testing metastatic breast cancer tumours for any IHC staining to identify patients with HR-positive, HER2-low or HER2-ultralow disease who may be eligible for Enhertu once ...

[Read more Drug Approvals]

FDA clears IND application for CVHNLC targeting squamous NSCLC

“CVHNLC is our second oncology program to enter the clinical stage, highlighting the continued progress we are making with our mRNA-based precision immunotherapies. Importantly, we have been able to design CVHNLC using both known, shared tumor antigens and novel proprietary antigens discovered using our differentiated in-house technology platform,” said Dr. Alexander Zehnder, Chief Executive Officer of CureVac. “We are leveraging ...

FDA clears IND application for ALX2004 for the treatment of EGFR-expressing solid tumors

“Clinical advancement of our first ADC and the first drug candidate developed on our proprietary linker-payload platform is an important milestone in our mission to deliver breakthrough therapies that will help transform the future of cancer treatment,” said Jason Lettmann, Chief Executive Officer at ALX Oncology. “We meticulously designed all aspects of ALX2004 – the antibody backbone, linker and payload ...

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[Preliminary positive immune response data announced from Ph 3 clinical trial FLAMINGO-01 of GLSI-100]

CEO Snehal Patel commented, "With the preliminary analysis of open label data of the Phase III trial complete, we will continue to analyze the open label data, potentially leading to future publications. We will also try to improve the conduct and design of the study with the ultimate goal to reproduce the Phase IIb results, if possible, and to prepare ...

[SON-1010 Demonstrates a Strong Safety Profile in Combination with Atezolizumab for Treatment of Platinum-Resistant Ovarian Cancer]

“This topline safety data release from our atezolizumab combination program is another significant milestone for Sonnet’s clinical development,” concluded Raghu Rao, Sonnet’s Interim Chief Executive Officer. “Safety of this extended PK version of IL-12 has been within expected levels and the comparison with dosing in healthy volunteers provided strong evidence of tumor targeting and accumulation in humans. We have used ...

[Read more Trial Results]

[First Patient Dosed in ZOLAR Trial of TLX300-CDx in Advanced Soft Tissue Sarcoma]

Dr. David N. Cade, Telix Group Chief Medical Officer, added, “We are pleased that a first patient has been imaged in the first-in-human ZOLAR trial, which is designed to inform both the potential efficacy (dosimetry) and safety profile of this research candidate as a

therapeutic, based on a theranostic approach. We would like to thank Professor Hicks and his team ...

First Patient Dosed in Ph 1 Study of VVD-159642 for Treatment of Advanced Solid Tumors

“We’re excited to bring our fourth innovative oncology asset into the clinic, which not only represents continued validation of Vividion’s covalent-first chemoproteomics platform but also provides a potential new treatment option for patients with RAS-driven cancers,” said Aleksandra Rizo M.D., Ph.D., Chief Executive Officer of Vividion.

Read more Trial Status

Boehringer Ingelheim strengthens antibody-drug conjugate portfolio with new NBE Therapeutics R&D center in Basel

"This investment in a new, cutting-edge research center underscores our strong commitment to deliver breakthrough innovation to people living with cancer," said Jean Engela, CEO at NBE Therapeutics. "We are confident that this state-of-the-art building will enable our team of scientists to accelerate the development of next-generation ADCs, ultimately impacting the lives of patients battling cancer."

BORUZU, First Ready-to-Use Bortezomib Injection for Multiple Myeloma and Mantle Cell Lymphoma, launched

"As we advance our broader strategy to build a leading injectables portfolio with durable, high-impact complex products, we are excited to announce the U.S. launch of BORUZU™ in our oncology portfolio. This ready-to-use injectable marks a significant innovation for our customers by streamlining pharmacy preparation steps for clinicians while now carrying a unique J-code to facilitate reimbursement. Our commitment remains ...

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Managing Editors

- Shalini Roy Choudhury, PhD
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- Siftjit Kaur, PhD
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