Latest oncology clinical development updates

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OTW News Highlights this week

- Orphan Drug Designation from the US FDA for Amezalpat to Treat Patients with HCC
- Innovent Enters into Exclusive Global License Agreement with Roche for Novel DLL3 Antibody Drug Conjugate
- Investigator-initiated trial (IIT) initiated in China for KJ-C2219 for the treatment of R/R B-NHL
- FDA Acceptance and Priority Review of NDA for Avutometinib + Defactinib for the Treatment of Recurrent KRAS Mutant Low-Grade Serous Ovarian Cancer Announced
- DATROWAY Approved in Japan for Patients with Previously Treated Unresectable or Recurrent HR+ve, HER2neg Breast Cancer

European Commission approves RYBREVANT (amivantamab) + LAZCLUZE (lazertinib) for the 1L treatment of patients with EGFR-mutated advanced NSCLC

“This approval marks significant progress for those living with the devastating impact of EGFR-mutated non-small cell lung cancer, who too often face a poor prognosis and limited treatment options,” said Henar Hevia, Ph.D., Senior Director, EMEA Therapeutic Area Lead, Oncology of Janssen-Cilag International NV, a Johnson & Johnson company. “The combination of amivantamab and lazertinib exemplifies the potential of targeted ...

China’s NMPA Approves VYLOYTM (zolbetuximab) for 1L Treatment of Advanced Gastric or GEJ Adenocarcinoma

Moitreyee Chatterjee-Kishore, Ph.D., M.B.A., Senior Vice President and Head of Immuno-Oncology Development, Astellas said, “Approximately 35% of Chinese patients with advanced and metastatic gastric and GEJ cancers have tumors that positively express CLDN18.2. By specifically targeting this biomarker with zolbetuximab we are able to stimulate selective cell death, reducing the overall number of CLDN18.2-positive cells in a tumor. The NMPA ...

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Update Provided on Paxalisib Regulatory Pathway Following Type C Meeting with FDA

"We appreciate the extensive and thoughtful feedback from the FDA, which provides us with added clarity with respect to paxalisib's potential registration pathway for the treatment of patients with NDU glioblastoma," commented Dr. John Friend, Kazia's CEO "We believe data from the GBM-AGILE trial, including the prespecified secondary endpoint, which demonstrated a 3.8-month OS improvement, provides evidence supporting a clinically ...

NDA submitted to US FDA for Accelerated Approval for Patients with Recurrent H3 K27M-Mutant Diffuse Glioma

“We also entered into a credit facility of up to $30 million with Silicon Valley Bank providing access to additional capital during this upcoming investment cycle and helping ensure dordaviprone availability to as many patients as possible, as quickly as possible, if approved. We are grateful to our partners at Silicon Valley Bank for their long-term support of Chimerix. This ...

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First Patient Dosed in First-in-Human Ph 1 Clinical Trial of HX044

"We are thrilled to see the first patient entered into clinical study, which marks a significant development milestone for this therapeutic candidate in our pipeline. This achievement demonstrated our strong R&D and clinical development capacity, and it reflects our commitment to addressing unmet medical needs for the patients. We will be working diligently to move this project forward", said Dr. ...

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Ikena Oncology and Inmagene Biopharmaceuticals Announce Agreement for Merger and Private Placement

“We are pleased to work with the Ikena team and multiple worldclass healthcare investors on this reverse merger and PIPE transaction. This is an important step for us to gain powerful resources to maximize the opportunities for IMG-007, a highly differentiated drug candidate with best-in-class potential,” commented Jonathan Wang, PhD, founder, Chairman and Chief Executive Officer of Inmagene. “We are ...

Galera Therapeutics completes acquisition of Nova Pharmaceuticals

“Dismutase Mimetics and NOS inhibitors involve complementary pathways that play important roles in cancer, in the tumor microenvironment, in resistance to conventional chemoradiotherapy and in immuno-oncology,” said Mel Sorensen, M.D., President & CEO of Galera. “Substantial mechanistic and preclinical rationale for both agents in solid tumors, especially in breast cancer, has been generated by the companies and their collaborators. Both ...

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Editor's Desk

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