Latest oncology clinical development updates

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OTW News Highlights this week

- GSK completes acquisition of IDRx, Inc.
- Radiance Biopharma Enters Exclusive License For ROR-1 Targeted Antibody Drug Conjugate
- Positive Data from Ph 2a Trial of SLS009 and Zanubrutinib in DLBCL Announced
- Fast Track Designation from the US FDA for IBI363 in Squamous NSCLC
- FDA Authorizes ImmunityBio to Provide Recombinant BCG (rBCG) to Urologists to Address TICE® BCG Shortage
- Approval of Protocol Amendment for Ovarian Cancer CER-T Clinical Trial Announced
- Neoadjuvant Opdivo® + Chemo Demonstrate Statistically Significant and Clinically Meaningful OS in Resectable NSCLC
- Zongertinib receives Priority Review from US FDA for the treatment of HER2-mutant advanced NSCLC
- EMA approves WELIREG® (belzutifan) for advanced clear cell RCC that progressed following a PD(L)-1 inhibitor and at least two VEGF therapies

EPKINLY® (epcoritamab) Approved by Japan Ministry of Health, Labour and Welfare for Additional Indication as a Treatment for R/R Follicular Lymphoma

“In the treatment of follicular lymphoma, where options become limited with each relapse, there remains a high unmet need for third-line and subsequent therapies in the absence of a clear standard of care,” said Dr. Koji Izutsu, Head of the Department of Hematology, National Cancer Center Hospital, who served as the principal investigator of the Japanese Phase 1/2 clinical trial ...

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RZ-001 Gains Fast Track Status for HCC, Following GBM

Seong-wook Lee, CEO of Rznomics, stated, "This Fast Track designation reaffirms the potential of RZ-001 as an innovative cancer treatment. We are committed to accelerating clinical development to provide effective treatment options for patients suffering from difficult-to-treat cancers."

[AUTX-703 Granted Fast Track Designation by the FDA for R/R AML]

“We are gratified by the FDA’s recognition of AUTX-703’s potential as an important, novel treatment option for relapsed or refractory AML patients, a community that remains in desperate need of new therapies,” said Kate Yen, Ph.D., Founder and Chief Executive Officer of Auron. “The FDA Fast Track Designation underscores the urgent need for innovative treatments for these patients and this ...

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[Translational Data Announced from Ph 1/2 OVATION 2 Study of IMNN-001 in Advanced Ovarian Cancer]

“These new data from the OVATION 2 Study confirm what we saw in the Phase 1 study and build on the robust body of evidence supporting the safety and strong overall survival results achieved with IMNN-001. These data also give us new levels of insight confirming the potential of our TheraPlas technology platform,” said Stacy Lindborg, Ph.D., president and chief ...

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Go-ahead obtained to continue enrolling patients in its pancreatic cancer trial (GOBLET Cohort 5) after a positive safety review

“We’re hitting critical milestones that validate our progress and set the stage for what we believe will be an exciting year,” said Wayne Pisano, Interim CEO and Chair of Oncolytics’ Board of Directors. “With positive feedback from regulators in place, we’re advancing our pancreatic cancer study toward full enrollment, and our ASCO GI presentations highlighted pelareorep’s strong safety and efficacy …

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Epitopea Announces License and Research Collaboration Agreement with MSD to Identify CryptigenTM Tumor-Specific Antigens

“Epitopea has been at the forefront of identifying CryptigenTM TSAs, whose intratumor shared nature across patients has made them ideal targets for the development of off-the-shelf immunotherapies,” commented Alan C. Rigby, Epitopea’s CEO. “At Epitopea we continue to accelerate the development of our preclinical pipeline as we transition to a clinical-stage company on the ‘heels’ of our recent, oversubscribed, pre-Series …

Arcus Biosciences Retains Rights to Casdatifan and Announces Pricing of $150 Million Common Stock Offering

“We are thrilled to retain ownership of casdatifan, which has the potential to address a significant unmet need for patients with an estimated $5 billion market opportunity. Owning the rights to casdatifan represents a transformational change for Arcus, providing us with significant future strategic optionality,” said Terry Rosen, Ph.D., chief executive officer of Arcus. “Data just presented in an oral ...

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