**Latest oncology clinical development updates**

**Wednesday, February 19, 2025**

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## OTW News Highlights this week

- Positive Interim Analysis in Ongoing SurVaxM Clinical Trial Announced
- FAILED TRIAL: Ph 3 RELATIVITY-098 trial of Opdualag™ (nivolumab and relatlimab-rmbw) in adjuvant, stage III-IV melanoma did not meet its primary endpoint of RFS
- ASCO GU 2025: PADCEV + KEYTRUDA Show Long-Term Efficacy in 1L Treatment of Locally Advanced or Metastatic Urothelial Cancer
- Linvoseltamab BLA Accepted for FDA Review for the Treatment of R/R Multiple Myeloma; PDUFA: 10Jul2025
- IDEAYA Announces Further Gilead Sciences Clinical Study Collaboration Evaluating Combination of Trodelvy and IDE397 in MTAP-Deletion NSCLC
- IMFINZI perioperative regimen improved EFS and OS across MIBC patients regardless of cPR status in post-hoc exploratory analysis of NIAGARA Ph 3 trial
- FDA Fast Track Designation for CUSP06 for the Treatment of Platinum-Resistant Ovarian Cancer


U.S. FDA Approves ADCETRIS Combination Regimen for the treatment of R/R DLBCL

“Each year, more than 3,500 patients in the U.S. with this aggressive form of non-Hodgkin lymphoma experience treatment failure or relapse after two prior lines of therapy,” said Roger Dansey, M.D., Chief Oncology Officer, Pfizer. “Today’s approval further reinforces the important role of ADCETRIS as an existing standard of care with overall survival improvement shown for certain types of lymphomas, ...

Read more Drug Approvals


Fast Track Designation granted from the U.S. FDA for Amezalpat to Treat Patients with HCC

“We are thrilled to receive Fast Track designation from the FDA,” said Sam Whiting, M.D., Ph.D., chief medical officer and head of R&D of Tempest. “This designation, following the Orphan Drug designation granted last month, reinforces the promise of amezalpat as a potential treatment option for patients affected by HCC. We look forward to working closely with the FDA and ...

[Orphan Drug Designation granted to OPN-6602 for Multiple Myeloma]

"We are pleased to have received ODD for OPN-6602 for the treatment of multiple myeloma, a further validation of the drug's therapeutic potential in patients with this disease who have limited treatment options once they have relapsed," said Gideon Bollag, PhD, chief scientific officer.

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[Positive Topline Results for Breyanzi® (lisocabtagene maraleucel) in Adult Patients with R/R MZL Announced]

"Marginal zone lymphoma is a slow-growing cancer that, for many, has a favorable prognosis. But for those patients who relapse or become refractory, the disease can be quite aggressive, and there is a need for new effective and tolerable treatment options to address this unmet critical need," said Rosanna Ricafort, vice president, head of Late Development Program Leadership, Hematology and ...

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[Frontline Triple Drug Therapy with Tuspetinib Achieves Notable Responses in Newly Diagnosed AML Patients in Ph 1/2 TUSCANY Trial]

"These are very promising early results from the TUSCANY trial of TUS+VEN+AZA and the first indicators of the safety and efficacy we expected to see in newly diagnosed AML patients," said Rafael Bejar, M.D., Ph.D., Chief Medical Officer of Aptose. "To achieve a complete remission (CR) in Cycle 1 in a subject harboring a TP53 mutation – one of the ...

Read more Trial Results


Ph 2 opened in High Dose Cohort of INKmune™ Trial in Prostate Cancer

“INKmune™ can be given to men with mCRPC in an out-patient setting and so far has an exemplary safety profile,” said RJ Tesi, MD CEO of INmune. “Data from the low dose cohort has shown immunologic effects of INKmune™ therapy. The higher dose cohorts will help us understand the therapeutic benefits of INKmune™ therapy in treating men with mCRPC.”

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Dosing of Cohort A patients in the ACHIEVE Ph 2B trial of TCB008 concluded

"This early safety and efficacy data, obtained in patients with significant unmet clinical need, reiterates our confidence in our lead candidate, TCB008," said Bryan Kobel, CEO of TC BioPharm. "We're seeing the expedited delivery of data, six months after study re-initiation, signalling a positive safety and efficacy profile for TCB008. This data will shape our approach to clinical development as ...

Read more Trial Status


Hoth Therapeutics Partners with OnTargetx R&D to Advance Research for Cancer fighting HT-KIT Cancer Therapeutic

"This partnership is instrumental in our efforts to advance HT-KIT, a promising therapeutic aimed at targeting c-Kit in cancer treatments," said Robb Knie , CEO at Hoth Therapeutics. "We are committed to driving innovative solutions that can transform patient care."

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AbbVie and Xilio Therapeutics Announce Collaboration and Option Agreement to Develop Novel Tumor-Activated Immunotherapies

"AbbVie is committed to expanding our R&D efforts in oncology. This includes investigation of novel immunotherapy approaches that aim to generate improved next-generation cancer treatments for patients in need," said Theodora S. Ross, M.D., Ph.D., vice president, early oncology research and development, AbbVie. "This partnership with the Xilio team further exemplifies our commitment."

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**Editor's Desk**

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