



Latest oncology clinical development updates

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OTW News Highlights this week

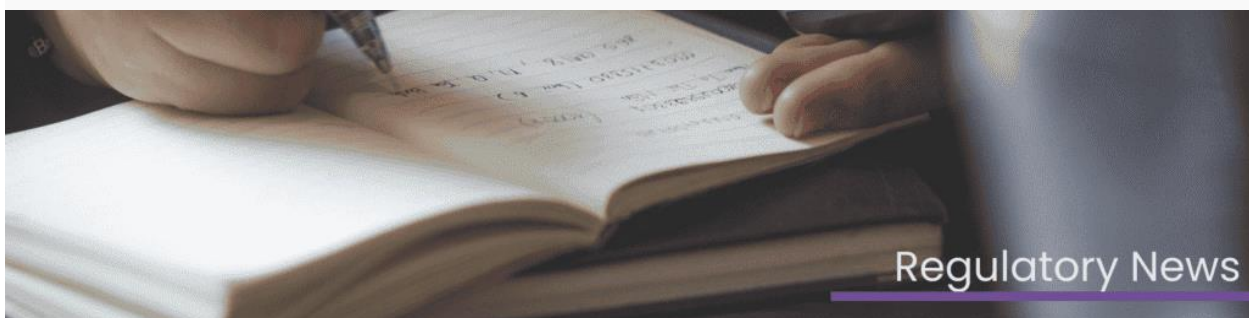
- [CHMP recommends EU label update for Phesgo to allow administration outside of clinical settings](#)
- [Sandoz enters global collaboration license agreement with Henlius to commercialize ipilimumab in multiple indications](#)
- [Plans for Ph 3 1L vepdegestrant combo trial with atirmociclib and Ph 3 2L combination trial with a CDK4/6 inhibitor shelved](#)
- [Ph 2/3 trial of 2L+ KN026 + chemo in HER2-positive gastric/GEJ cancer met the primary endpoint of PFS at interim analysis](#)
- [FDA clears IND application for LP-184 for Ph 1b/2 Trial in TNBC patients](#)
- [Concentra Biosciences to Acquire Kronos Bio](#)
- [CAPItello-280 Ph 3 trial of Truqap \(capivasertib\) + docetaxel and ADT in patients with metastatic CRPC to be discontinued](#)
- [Efti + KEYTRUDA Combo Drives Strong OS in Head and Neck Cancer with CPS <1](#)
- [FDA Fast Track Designation for INX-315 to Treat CCNE1-Amplified Platinum-Resistant/Refractory Ovarian Cancer](#)

- [Lynozyfic™ \(linvoseltamab\) Approved in the European Union for the Treatment of R/R Multiple Myeloma](#)

OTW News Highlights this week



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[FDA Feedback Provided to Enable Direct Ph 2 Trial for Gengleucel in MRD+ AML](#)

"We are thrilled with the FDA's guidance, which reflects the rigor of our clinical research and the significant therapeutic potential of Gengleucel, especially in targeting minimal residual disease," said Kevin Koh, CEO of Ingenium Therapeutics. "Launching our U.S. Phase 2 trial at premier cancer centers marks a major milestone in our mission to deliver novel immunotherapies to AML patients with ...

[Zurletrectinib Receives Priority Review from China's NMPA](#)

Dr. Jasmine Cui, the co-founder, chairwoman and CEO of InnoCare, said, “We are delighted that zurletrectinib has been granted priority review. Zurletrectinib has demonstrated outstanding efficacy and a favorable safety profile. We anticipate it will provide better treatment options for eligible patients with solid tumors earlier.”

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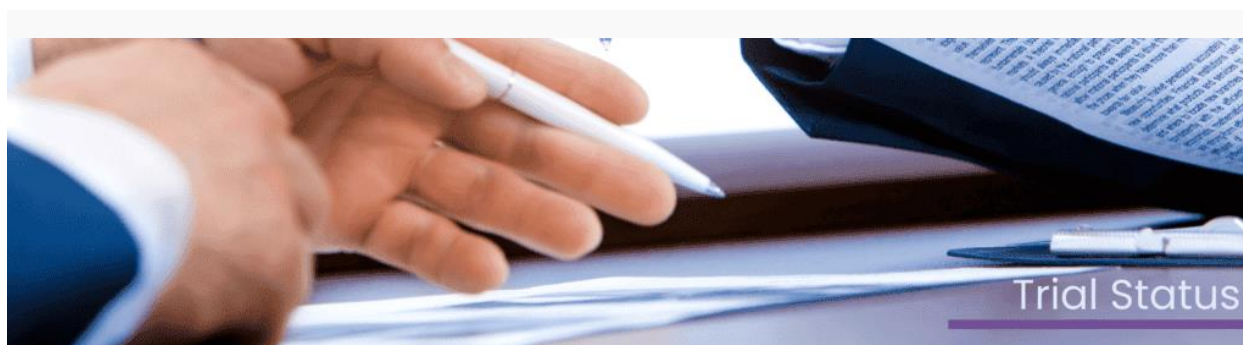
[Full Results Announced From Completed Ph 1 Study of JNJ-1900 \(NBTXR3\) in Pancreatic Cancer](#)

“Our collaboration with MD Anderson has always been driven by a shared commitment to exploring bold new approaches for patients with high unmet need,” said Louis Kayitalire, MD, Chief Medical Officer at Nanobiotix. “Given the extremely poor survival rates in LAPC and BRPC, the results from this Phase 1 study give us confidence in the potential of JNJ-1900 (NBTXR3) to ...

[CR achieved after 1 month of the in vivo CD19 CAR-T treatment, with durable response sustained over three months in R/R DLBCL patients](#)

Prof. Jia Wei , M.D., Ph.D., PI (principal investigator), Tongji Hospital Hematology Department (Wuhan) said "In this groundbreaking case, we observed the patient treated with Genocury's CD19 in vivo CAR-T achieved complete remission through 90-day follow-up - achieved without any lymphodepletion, which fundamentally challenges current cellular therapy dogma" said Dr. Jia Wei, "This therapy combines the benefits of autologous CAR-T ...

[Read more Trial Results](#)



[First patient enrolled in Ph 1 trial of AKIR001 in solid tumors](#)

“The launch of the clinical trial with AKIR001 marks the beginning of a new chapter for Akiram. Our vision has always been to develop a treatment that can offer new opportunities for patients with difficult-to-treat cancers, where treatment options are often limited. Seeing our drug candidate now being evaluated in collaboration with Karolinska University Hospital—one of Europe’s leading cancer centers—is ...

[Ph 1 study targeting GPC3 with 225Ac-GPC3 \(BAY 3547926\) in patients with advanced HCC initiated](#)

“Hepatocellular carcinoma continues to be a devastating disease for millions of patients and a pressing unmet need in cancer care. The launch of the Phase I trial using the 225Ac-GPC3 radionuclide therapy marks an important milestone in our commitment to develop new medicines targeting cancer cells with high effect size and precision to improve the lives of people living with ...

[Read more Trial Status](#)



[Repare Therapeutics Announces Out-Licensing of its Discovery Platforms to DCx Biotherapeutics](#)

“We have taken careful steps to evaluate all aspects of our business to ensure continued value generation, and this out-licensing agreement with DCx for our discovery platforms enables us to further focus on our clinical portfolio and drive cost reductions while maintaining an economic interest in the platform technologies we have developed,” said Steve Forte, President, Chief Executive Officer and ...

[VERAXA Biotech Enters Co-discovery Alliance with OmniAb for a Novel Bispecific ADC Program](#)

“This partnership brings together two highly complementary technologies to create a new class of bispecific ADCs,” commented Christoph Antz, Ph.D., CEO and Co-Founder of VERAXA. “Bispecific ADCs represent a powerful opportunity to address difficult-to-treat solid tumors, and this collaboration fits squarely within our mission to drive innovation through targeted partnerships. Strategic collaborations will continue to be a mainstay in VERAXA’s ...

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