Latest oncology clinical development updates

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OTW News Highlights this week

- Epsilogen Announces Acquisition of TigaTx, Inc. to Create Pan-Isotype Cancer Antibody Company
- First Patient Dosed in Ph 1/2 Study for KSQ-004EX in advanced solid tumors
- Positive OS in Cohort 3 from the Ongoing Ph 2 Trial of SLS009 in R/R AML Announced
- FDA clears IND application for ALX2004 for the treatment of EGFR-expressing solid tumors
- European Commission approves Columvi for R/R DLBCL not eligible for ASCT
- Solu Therapeutics Closes $41M Series A Financing and Announces First Patient Dosed in Ph 1 Trial of STX-0712 in Patients with CMML and Other Heme Malignancies
- Ph 3 AdvanTIG-302 trial unlikely to meet primary endpoint; Ociperlimab (BGB-A1217) Clinical Development Program to be discontinued
- Ph 3 DeLLphi-304 trial of IMDELLTRA (tarlatamab-dlle) in SCLC patients met its primary endpoint at a planned interim analysis

- NDA submitted to the US FDA for ziftomenib for the treatment of adult patients with R/R AML with a NPM 1 mutation
- US FDA Grants Full Approval of VITRAKVI (larotrectinib) for Adult and Pediatric Patients with NTRK Gene Fusion-Positive Solid Tumors

DATROWAY Approved in the EU for Patients with Previously Treated Metastatic HR+ve, HER2-neg Breast Cancer

"Treating metastatic HR positive, HER2 negative breast cancer presents challenges, particularly treatment resistance and disease progression that occur following endocrine-based therapy and initial chemotherapy," said Ken Keller, Global Head of Oncology Business, and President and CEO, Daiichi Sankyo, Inc. "DATROWAY represents the second antibody drug conjugate approved for breast cancer based on Daiichi Sankyo's DXd technology and the third medicine ...

FDA Approves Opdivo + Yervoy as a Treatment for Patients with 1L MSI-H or dMMR Unresectable or Metastatic CRC

"This approval marks our ninth indication for an Opdivo-based treatment in the gastrointestinal space. We are witnessing the transformative potential of dual immunotherapy in treating GI cancers," said Wendy Short Bartie, senior vice president of Oncology Commercialization at Bristol Myers Squibb. "People with MSI-H/dMMR metastatic colorectal cancer face high unmet need, and Opdivo plus Yervoy is an important new approach ...

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Ph 1/2a CTA Approval Granted to Evaluate ITOP1 in Early-Stage Esophageal Cancer

Dr Jonathan Kwok, Chief Executive Officer & Co-Founder at Infinitopes, commented: “We are delighted that we have advanced our lead vaccine candidate, ITOP1, from university research to a groundbreaking clinical programme in just over three years. This marks a major performance milestone for the company, bringing Infinitopes an important step closer to offering lifesaving solutions for patients with oesophageal and ...

FDA Clears Second IND Application to Initiate Ph 1 Trial of CER-1236 in Solid Tumors

“Of note, our team has been simultaneously progressing our Phase 1 AML trial in the U.S. Their incredible efforts cannot be under-emphasized, and I wish to convey my gratitude to our extremely competent and efficient team. We are looking forward to sharing progress on each of our two Phase 1 clinical trials in the near term,” added CERo CEO Chris ...

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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 …

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New clinical trial of GPC-100 (burixafor) planned in AML

“Exicure, Inc. is planning for a clinical trial in AML with GPC-100. The company believes that GPC-100, when paired with modern AML treatment regimens, can further improve outcomes in this high unmet need clinical indication. A Phase 1 chemosensitization study involving 15 patients with relapsed or refractory AML was previously conducted by Taigen, the original developer of GPC-100. In that …

[First Patient Enrolled in Ph 1b FORTRESS Trial of NG-350A in Patients with Locally Advanced Rectal Cancer]

"We have previously demonstrated that intravenously administered T-SIGn® therapeutics can reach both primary and metastatic tumor sites to drive local expression of immunotherapeutic payloads," said Oliver Rosen, MD, Akamis Bio's chief medical officer. "The results from prior clinical studies have provided what we believe is a clear roadmap for the design of the FORTRESS trial, where our aim is to ...

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[Scancell Holdings announces partnership with the NHS CVLP to fast-track access for NHS patients into the fourth cohort of the Ph 2 SCOPE study]

Phil L'Huillier, Chief Executive Officer, Scancell, commented: "We are delighted to announce our partnership with the CVLP. This partnership offers melanoma patients in the UK faster access to our developmental cancer vaccine, iSCIB1+, that we see is bringing long term immune control of the tumours to these advanced melanoma patients. It additionally underscores the potential benefit of iSCIB1+ to advanced ...

[OS Therapies Completes Acquisition of Advaxis Immunotherapies Clinical, Pre-clinical and IP Assets from Ayala Pharmaceuticals]

"We are thrilled to have now consolidated all of the intellectual property for the listeria cancer immunotherapy platform into OS Therapies, positioning us to fully expand it in the

years ahead and improve the standard of care across cancer treatment in the years ahead," said Paul Romness, CEO of OS Therapies. "We now have late-stage, mid-stage and early-stage cancer immunotherapy ...

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