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bite-size biopharma and medtech news

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MedNess News Highlights this week

European Commission approves Tecentriq SC, the EU's first PD-(L)1 cancer immunotherapy subcutaneous injection for multiple cancer types

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Submission of a Rolling NDA to the FDA for UGN-102 initiated

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FAILED TRIAL: Phase 3 EVOKE-01 study did not meet its primary endpoint of OS in previously treated metastatic NSCLC

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2023 Year-End Annamycin Clinical Trials Preliminary Data and 2024 Expectations for Multiple Data Readouts and Transition to Pivotal Phase 2B/3 announced

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Onco-This-Week

Drug Approvals

European Commission approves Tecentriq SC, the EU's first PD-(L)1 cancer immunotherapy subcutaneous injection for multiple cancer types

"We are pleased to introduce the first subcutaneous PD-L1 cancer immunotherapy in Europe," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Giving Tecentriq subcutaneously provides more flexibility to patients, while also helping to free up resources in constrained healthcare systems."

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Drug Approvals

Regulatory News

Submission of a Rolling NDA to the FDA for UGN-102 initiated

"The submission of the CMC portion of the NDA for UGN-102 marks a significant milestone for UroGen and underscores our dedication to advancing innovative therapies for the benefit of individuals grappling with low-grade, intermediate-risk non-muscle invasive bladder cancer," said Liz Barrett, President and CEO, UroGen. "We look forward to working…

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Positive CHMP Opinion for CAR T Cell Therapy Abecma (idecabtagene vicleucel) in Earlier Lines of Therapy for Triple-Class Exposed R/R Multiple Myeloma

“This positive CHMP opinion represents an important step toward bringing our potentially transformative first-in-class anti-BCMA CAR T cell therapy, Abecma, to more patients earlier in the multiple myeloma treatment paradigm to improve outcomes,” said Anne Kerber, M.D., senior vice president and head, Late Clinical Development, Hematology, Oncology, Cell Therapy (HOCT),…

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Fast Track Designation for Combination of Avutometinib and Sotorasib for the Treatment of KRAS G12C-Mutant NSCLC

“Receiving Fast Track Designation for the combination of avutometinib and sotorasib reinforces the importance of improving the depth of MAPK pathway inhibition to enhance tumor regression relative to KRAS G12C inhibition alone and the potential of the combination of avutometinib and sotorasib in KRAS G12C mutant locally advanced or metastatic…

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Orphan Drug Designation Granted to PTX-252 by U.S. FDA for the Treatment of Acute Myeloid Leukaemia (AML)

Stijn Van Rompay, Chief Executive Officer of Hyloris, commented: “Securing orphan drug designation for a product candidate incorporating a novel molecular entity, not yet approved by any regulatory agency, underscores our unwavering commitment to advancing the frontiers of scientific discovery within the repurposing space.”

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Regulatory News

Trial Results

FAILED TRIAL: Phase 3 EVOKE-01 study did not meet its primary endpoint of OS in previously treated metastatic NSCLC

“The totality of our data gives us continued confidence in Trodelvy’s potential in metastatic NSCLC, and in our broader lung cancer clinical development program,” said Merdad Parsey, MD, PhD, Chief Medical Officer, Gilead Sciences. “Treating metastatic NSCLC that has progressed on or after platinum-based chemotherapy presents significant challenges and the…

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Imfinzi plus transarterial chemoembolisation (TACE) and bevacizumab reduced the risk of disease progression or death by 23% vs. TACE in liver cancer eligible for embolisation

Bruno Sangro, MD, PhD, Director of the Liver Unit and Professor of Medicine at Clínica Universidad de Navarra, Pamplona, Spain and a lead investigator in the EMERALD-1 trial, said: “In this earlier liver cancer setting, embolisation alone has been the standard of care for more than 20 years, and rates…

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Clinical Response Update on AFM24-102 Trial in EGFR-wildtype Non-Small Cell Lung Cancer Provided

“We are encouraged by the responses in these patients who had all progressed on PD1 targeting therapy and made the strategic decision to expand this patient cohort,” said Dr. Andreas Harstrick, CMO and interim Chief Executive Officer of Affimed. “There is a significant unmet need for these patients who have…

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Trial Status

2023 Year-End Annamycin Clinical Trials Preliminary Data and 2024 Expectations for Multiple Data Readouts and Transition to Pivotal Phase 2B/3 announced

“Over the course of 2023, we delivered on our promise for a year of important data from our Annamycin clinical development programs. We are well-positioned to continue building upon our encouraging growing body of preliminary clinical data and transition to pivotal Phase 2B/3 clinical trials by year-end 2024. We believe…

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First Patient Treated in the Phase 2a Trial of LSTA1 in Patients with Glioblastoma Multiforme

“We are very pleased to announce the first patient treated in this Phase 2a study evaluating LSTA1 in patients with newly diagnosed GBM, a very aggressive brain tumor that is often fatal. We hold great hopes for the benefits of LSTA1 in this indication based on preclinical evidence that demonstrates…

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IK-595 first cohort treated and cleared safety evaluation window

“We are laser focused on driving IK-930 and IK-595 forward in the next year to interpretable and clear data reads as we continue to build value for investors,” commented Mark Manfredi, Ph.D., Chief Executive Officer of Ikena. “Our extended team has achieved many significant milestones together, and IK-930 and IK-595’s…

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Business News

LAVA Therapeutics Announces Collaboration with Merck to Evaluate LAVA-1207 in Combination with KEYTRUDA

“We are excited to work with Merck & Co., Inc., Rahway, NJ, USA as we continue to unlock the therapeutic potential of LAVA-1207 and explore its potential capabilities in combination with KEYTRUDA®,” said Stephen Hurly, President and Chief Executive Officer, LAVA. “To date, LAVA-1207 has demonstrated a favorable safety profile…

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Inhibrx Announces Sale of INBRX-101 to Sanofi for an aggregate value of up to $2.2B

“Inhibrx and Sanofi announced that the companies have entered into a definitive agreement under which Aventis Inc., a Pennsylvania corporation (a subsidiary of Sanofi) will acquire all the assets and liabilities associated with INBRX-101, an optimized, recombinant alpha-1 antitrypsin (“AAT”) augmentation therapy currently in a registrational trial for the treatment…

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MaxCyte Signs Strategic Platform License with Imugene to Advance their Cancer Immunotherapy Programs

“By leveraging our scalable cell-engineering process and optimized clinical manufacturing workflow, Imugene is rapidly moving towards a potential Phase 2 registrational trial for azer-cel in cancer,” said Maher Masoud, President and CEO of MaxCyte. “Our technology has been integral to the manufacturing of the allogeneic T-cell immunotherapies and was efficiently…

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Business News

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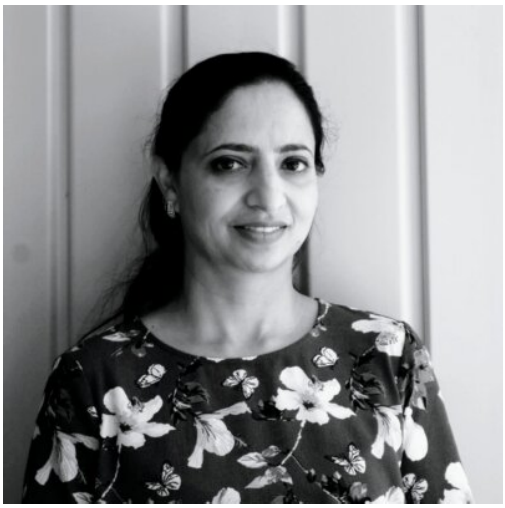

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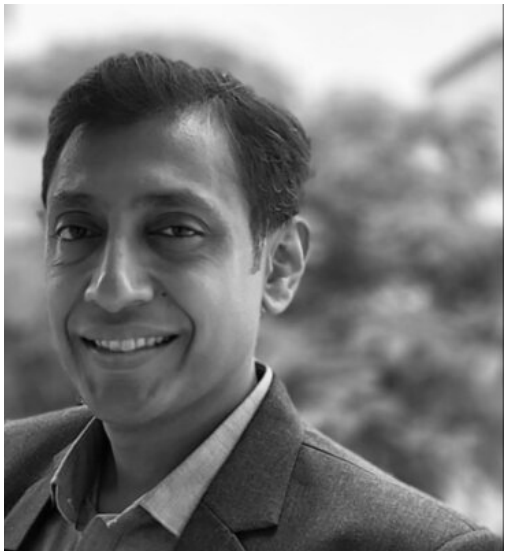

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