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MedNess (Onco-This-Week)

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MedNess News Highlights this week

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MedNess Diagnostics

Cancer early diagnosis and liquid biopsies: Are We There Yet?

The field of liquid biopsy-based cancer diagnostics stands at an inflection point, primed to enable earlier detection, precise monitoring, and tailored cancer management. Myriad companies, predominantly startups but also including seasoned diagnostics players, are steering rapid innovations through blood tests that analyse circulating tumor DNA, cells, and other cancer biomarkers. Central to this transformation is circulating DNA, encompassing cell-free DNA (cfDNA), and its subset, circulating tumor DNA (ctDNA). This tandem has emerged as an unparalleled promise allied with the extraordinary strides in sequencing technologies. This multi-part series will chronicle the transformative thrusts of these diverse companies, explaining their distinguished histories, ground-breaking techniques, signature products, promising pipelines, and more. The companies take unique approaches yet share an overarching goal of early cancer detection. Their techniques leverage a diverse array of biomarkers, including genetic mutations, methylation markers, proteins, and inventive combinations thereof to discern cancer signals. Additionally, the burgeoning potential of machine learning algorithms to pinpoint subtle but indicative molecular patterns is gaining traction across the industry. Their offerings span early screening, residual disease tracking, and therapy selection. The series will also elucidate the field’s immense promise to profoundly impact patient outcomes through non-invasive assays that complement or even replace invasive tissue biopsies. However, liquid biopsy advances have also encountered unique challenges involving clinical adoption, reimbursement, regulatory approval, and alignment with therapeutics. The articles will investigate these hurdles and discuss how thoughtful research and flexible policies can pave the way for liquid biopsies to realize their paradigm-shifting potential. Overall, this series will illuminate the ground-breaking work of pioneering companies to transform cancer diagnostics with routine blood draws. Overview The landscape of in vitro diagnostics in cancer management stands on the precipice of transformation. It has long been evident that the most profound impact on cancer treatment lies in preemptive detection and intervention before clinical manifestation. Yet, in the absence of minimally intrusive and efficacious early screening techniques, this aspiration has remained mostly elusive. The tangible advantages of timely detection resonate in the statistics of the few malignancies to have recommended screening methods, such as breast, colorectal, lung, cervical, and prostate cancers. The last couple of decades have seen increasing recognition of assorted circulating agents as potential indicators of latent disease, ranging from DNA, proteins, metabolites, to membrane vesicles. Combining techniques for capturing and identifying these agents, with leveraging expansive datasets through data science, we are moving closer to the realization of the vision of early cancer diagnosis from routine blood samples. This progress is also giving rise to notable advancements and disruptions in the field of diagnostics. Central to this transformation is circulating DNA, encompassing cell-free DNA (cfDNA), and its subset, circulating tumor DNA (ctDNA). This tandem has emerged as an unparalleled promise allied with the extraordinary strides in sequencing technologies. The dividends of decades of foundational research in cancer genetics and epigenetics are also manifesting in the form of discernible epigenetic changes and fragmentation patterns that offer the prospect of

highly specific cancer characterization in combination with genetic alterations. Artificial intelligence (AI) also assumes significance, given importance of identifying health and disease related patterns with precision in the colossal datasets generated by these diagnostic methodologies. The merits of these assays extend beyond the early detection of nascent diseases across the diagnosis continuum, to encompass monitoring minimal residual disease (MRD), profiling tumors to tailor personalized therapies, and gauging treatment responses. The success of these will be pivotal in realizing the ambitious objectives of the Cancer Moonshot initiative. Launched in 2016 and revitalized in 2022 by President Biden, this initiative aspires to curtail cancer mortality rates by a 50% within the ensuing quarter-century.…

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Drug Approvals

Calquence approved in China for chronic lymphocytic leukaemia

Professor Li Jianyong, Director of Haematology, People's Hospital of Jiangsu Province, and Leader of China CLL Working Group, said: "Many people living with chronic lymphocytic leukaemia experience relapse and need additional treatment options to help manage their disease. I'm delighted that with this approval patients now have access to an established treatment that has already demonstrated effectiveness in many patients across the globe."

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Drug Approvals

Regulatory news

Quizartinib Recommended for Approval in EU by CHMP for Patients with Newly Diagnosed FLT3-ITD Positive AML

“Today’s positive CHMP opinion for quizartinib is an important step towards translating the clinical benefit observed in QuANTUM-First into an approved treatment option for patients in the EU with the difficult-totreat FLT3-ITD subtype of acute myeloid leukemia,” said Mark Rutstein, MD, Global Head, Oncology Clinical Development, Daiichi Sankyo. “If approved, quizartinib would be the first FLT3 inhibitor approved specifically for patients with newly diagnosed FLT3-ITD positive AML.”

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Enhertu recommended for approval in the EU by CHMP for patients with HER2-mutant advanced NSCLC

Enhertu recommended for approval in the EU by CHMP for patients with HER2-mutant advanced NSCLC Susan Galbraith, Executive Vice President, Oncology R&D, AstraZeneca, said: “HER2-mutant non-small cell lung cancer is an aggressive form of lung cancer that often affects younger patients and has a poor prognosis, with limited approved therapies. This milestone recognises the unmet need in the European Union and if approved, Enhertu will provide the first targeted treatment option for these patients.”

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Regulatory News

Trial Results

Phase 2 EVOKE-02 Study Of Trodelvy + KEYTRUDA Demonstrates Promising Clinical Activity In 1L mNSCLC

"Patients with metastatic NSCLC continue to need novel treatment options. The data from the EVOKE-02 study gives us confidence in the clinical activity of sacituzumab govitecan in combination with pembrolizumab in first-line metastatic NSCLC patients," said Byoung Chul Cho, MD, PhD, Professor in the Division of Medical Oncology at Yonsei Cancer Center, Yonsei University College of Medicine. "The positive response rates and duration of response across patients treated with the combination shows promise compared with historical responses to anti-PD1 monotherapy in this setting.These data support further investigation of sacituzumab govitecan as a potential IO-combination option in first-line metastatic NSCLC."

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Datopotamab deruxtecan plus Imfinzi showed promising clinical activity in the 1L advanced NSCLC setting in TROPION-Lung04 Phase Ib trial

Cristian Massacesi, Chief Medical Officer and Oncology Chief Development Officer, AstraZeneca, said: "Following the positive high-level results of TROPION-Lung01, these initial TROPION-Lung04 results in the first-line setting reinforce our confidence in datopotamab deruxtecan as a potential treatment option for patients with advanced non-small cell lung cancer. Through our robust clinical programme we are eager to continue evaluating this TROP2-directed antibody drug conjugate in lung cancer across treatment settings, alone and in novel combinations."

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Trial Results

Trial Status

Patient Dosing with MT-302 initiated in Phase 1 Study for Advanced or Metastatic Epithelial Tumors

“Initiation of patient dosing with MT-302 is a major milestone for Myeloid in our effort to deliver better treatment options for patients living with solid tumors. We are leading the way with our proprietary approach to in vivo programming, including with many novel CAR constructs designed for selective expression in a wide range of immune cells,” said Daniel Getts, Ph.D., CEO of Myeloid. “By advancing MT-302 into the clinic, we are harnessing the power of the innate immune system to overcome many observed limitations of CAR-Ts for solid tumors. We look forward to advancing MT-302 in our Phase 1 study and demonstrating the potential of our innate immunity platform to program cells directly in vivo and drive better outcomes.”

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Clinical Hold Lift Plan of the HEMO-CAR-T IND is Accepted by FDA

Dr Vladislav Sandler, Chief Executive Officer, commented: “We are pleased that the FDA has agreed to our plan and preliminary test results to address their concerns regarding our HEMO-CAR-T IND application. We are now working hard to complete the schedule of work set out in the plan and to re-submit the IND as expeditiously as possible in order to move forward with clinical trials of HEMO-CAR-T.”

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Trial Statuses

Business News

Exelixis and Insilico Medicine Enter into Exclusive Global License Agreement for ISM3091

"ISM3091 represents a potentially best-in-class approach to inhibiting USP1, an important oncology target with broad applicability in BRCA-mutant tumors," said Dana Aftab, Ph.D., Executive Vice President, Discovery and Translational Research and Chief Scientific Officer, Exelixis. "We believe preclinical data on ISM3091's potent anti-tumor activity, tolerability, and pharmacokinetics set the compound apart from competing USP1 inhibitors and make it an important addition to Exelixis' growing clinical-stage pipeline. Following the FDA's clearance of Insilico's IND earlier this spring, we're looking forward to accelerating phase 1 trial enrollment."

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Ryvu Therapeutics' Global Licensee Menarini to Expand Development of MEN1703 (SEL24) with a New Study in Advanced Diffuse Large B-Cell Lymphoma (DLBCL)

"We are excited to begin this Phase II study with our partner Menarini to address the critical unmet need in DLBCL," said Pawel Przewiezlikowski, co-founder, largest shareholder, and CEO of Ryvu Therapeutics. "The extensive preclinical evidence of MEN1703 activity in multiple types of lymphomas sets a promising foundation for evaluating the molecule's potential in DLBCL, and we look forward to seeing this program continue to advance in the clinic."

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