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MedNess (Onco-This-Week)

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October 25, 2023

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Natera’s evolution in molecular diagnostics

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MedNess Diagnostics

Natera’s evolution in molecular diagnostics

Natera’s success traces to pioneering research isolating and analyzing fetal DNA fragments circulating in a pregnant woman’s bloodstream. Natera capitalized on the emerging space of non-invasive prenatal tests (NIPT) with products such as Panorama that represented a major advance over risky amniocentesis procedures used for definitive diagnosis. Commencing its journey in the NIPT space as the fourth company to enter the U.S. market, Natera swiftly ascended to leading position in test volumes in the 2010s. The proficiency with cfDNA thus achieved positioned Natera advantageously for liquid biopsy-based cancer testing. Natera’s strategic approach initially addressed early detection by focusing on minimal residual disease (MRD) monitoring post-treatment. In 2017, Natera introduced Signatera—a pioneering NGS based ctDNA test designed to identify and trace residual disease following cancer therapy. This innovative test employed patient-optimized assays and boasted impressive sensitivity. Originally introduced solely for research objectives, Signatera was made available as a Laboratory-Developed Test (LDT) for clinical utilization starting in 2019. Preliminary retrospective data underscored its performance capabilities. Signatera’s analysis is customized to patient-specific clonal cancer mutations, tailored on the basis of unique mutational signature from the tumor tissue. It detects ctDNA at remarkably low levels, identifying mutations at allele frequencies as low as 0.01% in the blood. By tracking ctDNA changes over time, it furnishes insights into treatment efficacy and recurrence risk. Natera witnessed escalating momentum in oncology testing, with a 150 percent YoY increase with over 190,000 tests conducted in 2022. Though women’s health products still drive most of Natera’s revenue, with 20% YoY growth reported in 2022, cancer diagnostics contribute significantly to assay volume upticks, totaling over 2 million tests. Signatera’s personalized and comprehensive approach currently extends across a spectrum of malignancies as well as immunotherapy response monitoring. Clinical trials such as CIRCULATE, BESPOKE, DARE, and Galaxy— and an expanding body of peer-reviewed publications demonstrate its ability to detect residual disease months ahead of conventional diagnostics, bolstering its robust evidential foundation. Key FDA endorsements, including multiple breakthrough device designations since 2019, and growing Medicare coverage have further cemented its trajectory. Signatera’s roadmap encompasses FDA approval as a companion diagnostic, with PMA submitted in October 2023, and expanded Phase III clinical trials. Natera’s other oncology offerings include the tissue-based Altera for therapy guidance and Empower, a liquid assay for hereditary cancers. Natera’s growth strategy has also involved constructive collaborations with the competition such as the FoundationOneTracker launched in 2023. It integrates insights from FoundationOneCDx, the tissue based comprehensive genomic profiling test from Foundation Medicine with Natera’s customized ctDNA analysis to monitor treatment response, especially with immunotherapies. In an exciting development in 2022, Natera announced strategic expansion into early cancer diagnostics and screening. Building on its demonstrated proficiency in MRD monitoring and with exclusive access to a bank of prospectively collected CRC samples at the Aarhus University, Natera is developing and validating cancer screening products, and is poised to push boundaries in this emerging space.

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Drug Approvals

FDA Approves KEYTRUDA for Treatment of Patients With Resectable (T≥4 cm or N+) NSCLC in Combination With Chemo as Neoadjuvant Treatment, Then Continued as a Single Agent as Adjuvant Treatment After Surgery

“There remains a need for treatment options to improve outcomes for patients with earlier stages of non-small cell lung cancer,” said Dr. Heather Wakelee, principal investigator for KEYNOTE-671, thoracic medical oncologist and professor of medicine at Stanford University and past president of the International Association for the Study of Lung Cancer (IASLC). “This important milestone has the potential to change the current treatment paradigm for resectable non-small cell lung cancer that is greater than four centimeters or has lymph node involvement, by offering an immunotherapy-based regimen that has demonstrated statistically significant improvements in overall survival and event-free survival compared to a placebo and chemotherapy regimen.”

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Regulatory news

Tagrisso plus chemo granted Priority Review in the US for patients with EGFR-mutated advanced NSCLC

Susan Galbraith, Executive Vice President, Oncology R&D, AstraZeneca, said: "The FLAURA2 results reinforce Tagrisso as a backbone of standard of care in 1st-line EGFR-mutated non-small cell lung cancer, providing patients with an additional nine months of median progression-free survival when combined with chemotherapy. This option is particularly important for patients with a poorer prognosis such as those with brain metastases. We look forward to working with the FDA on an accelerated timeline to bring this treatment regimen to patients as quickly as possible."

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Positive CHMP opinion recommending approval of Jemperli (dostarlimab) + chemo as 1L treatment for dMMR/MSI-H primary advanced or recurrent endometrial cancer

Hesham Abdullah, Senior Vice President, Global Head Oncology, R&D, GSK, said: "We are pleased with this positive CHMP opinion and the potential for dostarlimab with chemotherapy to treat patients with this very challenging form of endometrial cancer. If approved, dostarlimab plus chemotherapy will be the first new treatment option in decades for these patients in the European Union, offering long-awaited new hope for improved long-term outcomes. This opinion further reinforces our confidence in dostarlimab's important role in the immuno-oncology treatment landscape."

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Regulatory News

Trial Results

Ph 3 CheckMate-67T Trial of Subcutaneous Nivolumab (nivolumab and hyaluronidase) Meets Co-Primary Endpoints in Advanced or Metastatic ccRCC

“Intravenous Opdivo has helped transform the treatment of several solid tumor types over the past decade, but there remains a need for additional administration options to address treatment burden on patients and improve efficiencies in healthcare systems,” said Gina Fusaro, Ph.D., vice president, global program lead, Bristol Myers Squibb. “We are delighted that the results of CheckMate -67T demonstrate that subcutaneous nivolumab delivers noninferior pharmacokinetics, in addition to objective response rate and safety data consistent with IV Opdivo. We believe this new option, given as a single injection administered in less than five minutes, could transform the treatment experience for both patients and physicians.”

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New Data Demonstrating Superiority of TPST-1120 Arm Across Multiple Study Endpoints in Randomized First-Line HCC Study Released

“This comprehensive analysis of more mature clinical data shows an even greater benefit than the earlier interim analysis of the TPST-1120 triplet therapy over standard of care alone, both for the entire study population and in subpopulations of patients, the latter of which was predicted by TPST-1120’s proposed mechanism of action,” said Stephen Brady, president and chief executive officer of Tempest. “First-line HCC remains an indication with substantial opportunity to improve patient outcomes and, based upon these data, we are excited about the opportunity to move TPST-1120 into a pivotal study. Given these new data and the Phase 1 evidence of activity beyond HCC, we look forward to advancing discussions with potential partners who share our vision for TPST-1120.”

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Trial Results

Trial Status

First Patient Dosed in the Registrational Phase III Study of Olverembatinib in Treatment-Naïve Patients with Ph+ ALL

Prof. Weili Zhao, Vice President of Shanghai Jiaotong University School of Medicine Affiliated Ruijin Hospital and Director of Shanghai Institute of Hematology, commented, "Ph+ ALL used to be the most high-risk and difficult-to-treat subtype of leukemia and the introduction of TKIs has resulted in improved prognosis to patients with this condition. However, clinicians face the pressing question of which TKI offers the best efficacy and safety. We hope HQP1351AG301, a clinical study evaluating olverembatinib, a China-developed next-generation TKI, can provide an answer to those important questions."

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First Patient Cohort dosed in Ovarian Cancer CER-T Clinical Trial

Dr. Amit Kumar, Chairman and CEO of Anixa Biosciences, stated, "We are pleased with the positive safety data from the first cohort and look forward to advancing to the next higher dose cohort. We hope to continue observing good safety results as we continue to increase dosage, and eventually objective efficacy data."

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Trial Statuses

Conference Coverage: ESMO 2023

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Business News

Daiichi Sankyo and Merck Announce Global Development and Commercialization Collaboration for Three Daiichi Sankyo DXd ADCs

“The promising results from clinical trials of patritumab deruxtecan, ifinatamab deruxtecan and raludotatug deruxtecan continue to demonstrate the broad applicability of Daiichi Sankyo’s DXd ADC technology across multiple targets, with each of these medicines having the potential to change clinical practice as has been already seen with ENHERTU®,” said Sunao Manabe, Representative Director, Executive Chairperson and CEO, Daiichi Sankyo Company, Limited. “As Daiichi Sankyo continues its transformation into a global oncology leader by increasingly building our infrastructure and talent, we recognize that a collaboration with Merck, a company with remarkable oncology experience and strong in-house development capabilities and resources, will help us deliver on our obligation to deliver these potential new DXd ADCs to more patients as quickly as possible.”

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Ascentage Pharma and AstraZeneca Enter into Clinical Collaboration on the Registrational Phase III Study of Bcl-2 Inhibitor Lisaftoclax in Combination with BTK Inhibitor Acalabrutinib in Patients with First-Line CLL/SLL

Dr. Yifan Zhai, Chief Medical Officer of Ascentage Pharma, said, “Combining Bcl-2 inhibitors and BTK inhibitors as a therapeutic approach has long attracted interest from both the research community and the industry. The Bcl-2 inhibitor lisaftoclax is a key drug candidate in Ascentage Pharma’s apoptosis-targeted pipeline. Results from the global Phase II study of lisaftoclax combined with acalabrutinib show that the combination regimen holds the promise as a patient-centric treatment strategy with enormous therapeutic potential. The clinical management of CLL/SLL overseas has already entered an era that is free of chemotherapies, and patients in China also desperately need a safer and more effective Bcl-2 inhibitor that can be combined with BTK inhibitors. Fulfilling our mission of addressing unmet clinical needs in China and around the world, we will work closely with AstraZeneca to actively advance this clinical development program of lisaftoclax and try to bring the drug to market as soon as possible for the benefit of more patients.”

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