Less-Buzzy JP Morgan Still Provides Insights Into Companies' Precision Medicine Plans

This year's JP Morgan Healthcare Conference highlighted companies' plans in the liquid biopsy, companion diagnostic, and precision oncology therapeutic spaces.

By Edward Winnick

AS THE HEALTHCARE market moves toward more personalized care, the number of companies elbowing into the precision medicine space has grown substantially in recent years. This is no more apparent than at the annual **JP Morgan Healthcare Conference**, which brings investors, Wall Street analysts, dealmakers, and other stakeholders involved in every facet of the healthcare industry to San Francisco to hear pitches from companies that run the gamut from biopharma, diagnostics, medical devices, and research tools to insurance, hospitals, and services. While the January event may not have quite the buzz as it had pre-pandemic, it remains a big draw for investors and a massive platform for companies looking to raise their profile within the investment community. For the GenomeWeb newsroom, it offers four days of insights into how the companies we cover view their markets currently and their plans for this year and beyond.

For the firms straddling the genomic research tools and clinical diagnostics markets, one area that has remained hot for development and investment is the liquid biopsy space. This was apparent at the conference, with **Guardant Health**, **Exact Sciences**, and **Myriad Genetics** all offering pipeline updates that could have substantial implications for the cancer testing market both near and long term.

Guardant Cofounder and Co-CEO Helmy Eltoukhy called the firm's so-called smart liquid biopsy system a "quantum leap forward." The platform combines liquid biopsy with new multimodal chemistry that allows visualization of genomics and epigenomics data simultaneously, making it 50 times more sensitive than the Guardant360 CDx platform and expanding the breadth of genomic data at the same cost of goods, he said. The upgrade to its currently

marketed tests will provide a "massive sensitivity boost" by looking at more than 1,000 biomarkers. The firm also plans to complete its US Food and Drug Administration premarket application for the Guardant Shield test for colorectal cancer screening in Q1 2023 and is targeting approval and launch of the test as an *in vitro* diagnostic in 2024.

Exact Sciences CEO Kevin Conroy noted that a blood-based multicancer early detection (MCED) assay the firm has been developing will take "a number of years" before it hits the market, though the firm is planning on seeking clearance through the FDA rather than offering it as a lab-developed test. Such a test would detect methylated DNA and protein targets and could be used for several cancers including esophageal, lung, liver, and ovarian, among others. It would potentially compete against a MCED test being developed by Guardant and Grail's Galleri, which is already in use. But all of these tests face questions about whether the value of pan-cancer screening outweighs its costs, and the field is wrestling with significant unknowns regarding clinical best practices, especially for cancer types without established screening paradigms and known follow-up procedures.

Myriad Genetics is targeting a launch in the second half of this year of its Precise Liquid molecular profile test, a 523-gene comprehensive genomic profiling test for therapy selection that could serve as a standalone product or as a reflex test if a solid tumor is insufficient, CEO Paul Diaz told conference attendees. That test follows the introduction last year of the firm's Precise Tumor, which is offered in collaboration with Intermountain Healthcare and looks at the same number of genes but includes RNA analysis to detect fusions in solid tumors.

In general, oncology testing is a key area of focus for firms involved in the precision medicine market, and beyond liquid biopsies, some firms at the conference were eager to discuss their efforts in developing companion diagnostics. One of those firms, **Invitae**, plans to "double down" on its oncology franchise, according to CEO Ken Knight, and make improvements to its oncology and pharmacogenomics offerings in predicting therapy response and disease recurrence and in identifying potentially dangerous drug-gene interactions.

One company to keep an eye on in the companion diagnostics space is **Akoya Biosciences**, a spatial proteomics tech firm founded in 2015 that is turning its eyes to the clinical market. The firm, which earlier this year formed an alliance with **Agilent Technologies** to develop workflows for multiplex assays that would be used as companion diagnostics, already has a CDx deal in place with **Acrivon Therapeutics** to develop such an assay for the firm's targeted DNA damage response inhibitor, ACR-368. CEO Brian McKelligon said at the JP Morgan event, "It's a first foray for Akoya into the clinical market, which many thought was much farther off."

There was plenty of other news in the first couple of months of the year regarding companion diagnostics with partnerships announced by **Foundation Medicine** with **Boehringer Ingelheim** for a biliary tract cancer drug; **Thermo Fisher Scientific** with **AstraZeneca** for non-small cell lung cancer drug Tagrisso (osimertinib); Guardant with AnHeart Therapeutics to develop and commercialize the Guardant360 CDx and Guardant360 TissueNext assays as companion diagnostics for the use of taletrectinib in adults with advanced or metastatic ROS1-positive non-small cell lung cancer; and

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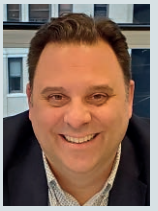
an announcement from **Roche** and **Janssen** that they would use multiple technologies, including immunohistochemistry, digital pathology, next-generation sequencing, PCR, and immunoassays, as companion diagnostics for unspecified targeted therapies.

In the precision oncology therapy space, there were several updates provided at the JP Morgan conference. While presentations from pharma bellwethers such as **Merck**, **Novartis**, **Bristol Myers Squibb**, and **Johnson & Johnson** were undoubtedly closely followed, a newer competitor, **Mirati Therapeutics**, has recently made waves. The firm gained FDA approval in late 2022 for its KRAS G12C inhibitor Krazati (adagrasib) in advanced or metastatic KRAS G12C-mutant non-small cell lung cancer. According to Mirati CEO David Meek, the firm's priority is to establish Krazati as a second-line, standard-of-care treatment for this subset of lung cancer patients, a setting where the new drug would compete with **Amgen**'s Lumakras (sotorasib). The firm also plans to initiate a Phase III study of Krazati as a monotherapy and in combination with Merck's Keytruda (pembrolizumab) in first-line KRAS G12C-mutant NSCLC, and it has several early-stage drug candidates in its pipeline, such as its KRAS G12D inhibitor MRTX1133 and SOS1 inhibitor MRTX0902.

In the CAR T space, eyes are on Janssen and **Legend Biotech**'s BCMA-directed CAR T-cell therapy Carvykti (ciltacabtagene autoleucel). The firms recently said they will unblind data from a Phase III trial comparing Carvykti against standard chemotherapy in multiple myeloma patients who have received one to three prior lines of therapy. The firms, which are codeveloping and co-commercializing Carvykti, said the trial has met its primary endpoint demonstrating that the drug improves progression-free survival versus chemo. The data could support the use of Carvykti as an earlier-line multiple myeloma treatment, providing oncologists with yet another new option – Bristol Myers Squibb's Abecma (idecabtagene vicleucel), a competitor to Carvykti, also recently showed it may benefit multiple myeloma patients as an earlier-line treatment.

Meanwhile, for the FDA it's been a busy start to the year in approving precision oncology drugs. Among those getting the nod were **Gilead Sciences**' Trop-2-directed antibody-drug conjugate Trodelvy (sacituzumab govitecan) for patients with previously treated, hormone receptor-positive, HER2-negative metastatic breast cancer; **Menarini**'s Orserdu (elacestrant) as a second-line treatment for estrogen receptor-positive HER2-negative advanced breast cancer harboring ESR1 mutations (along with the Guardant360 CDx as a blood-based assay for identifying patients with ESR1 mutations who are eligible for treatment); and **Seagen**'s Tukysa (tucatinib) in combination with **Genentech**'s Herceptin (trastuzumab) for patients with metastatic colorectal cancer whose tumors are RAS wild-type and HER2-positive and who have received prior chemotherapy. PMQ



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Edward is editor in chief of GenomeWeb. He's been with the company since 2004 serving as a reporter and editor before running GenomeWeb's daily news operations. Since being named editor in chief in 2013, he has led expansion of the newsroom and the launch of two additional news sites, 360Dx and Precision Oncology News, over the past six years. Prior to GenomeWeb, he served as executive editor of the Reuters Health Industry Briefing and worked as a reporter and editor for Windhover Information. Over the years he has covered almost every sector of the life sciences industry including biopharma, diagnostics, health services, insurance, and research tools. He is a graduate of the University of Connecticut and has an awesome Siberian Husky named Nigel.