



DeciBio Liquid Biopsy Weekly Digest

Jan 21st, 2021

There are quite a few interesting headlines released to start the year, although this can be expected with JPM and ASCO GI. Below are brief summaries of some of the major developments we noticed, but there are quite a few other headlines to peruse as well.

J.P. Morgan Health Care Conference Snapshot

- Natera laid out plans to expand the utility of Signatera through two primary avenues. IO therapy response monitoring is a new growth opportunity the company plans to enter this quarter and receive reimbursement for by the summer. The more direct growth route is by targeting additional indications for MRD under the umbrella LCD. Natera has already collected data for their MRD approach in lung, bladder, breast, and esophageal cancer with other indications on the horizon.
- GRAIL confirmed near-term launch intentions of their pan-cancer early detection assay, targeting Q2 2021 for the commercial launch of Galleri as an LDT. The 6.6k patient PATHFINDER study completed enrollment in Dec 2020 and is planned to readout mid-202; the data from this trial is intended to support the LDT launch. In addition, GRAIL announced partnerships with Amgen, AstraZeneca, and BMS to evaluate their platform for MRD detection in early-stage cancer. This move, combined with Illumina's efforts to grow into clinical genomic profiling, could enable GRAIL / Illumina to offer assays throughout a patient's journey (i.e., screening, therapy selection and monitoring). Currently, Guardant is the only other main player with established

efforts in offering comprehensive testing, but FMI and Predicine could follow suit.

- Adaptive Biotechnologies announced that Clonoseq will soon offer blood-based testing, which could double the market size of this assay.
- Exact Sciences announced an exclusive license to TGen's TARDIS technology. TARDIS is a sensitive personalized MRD approach capable of detecting minute amounts of ctDNA in a patient's blood and was [shown](#) to detect molecular response and residual disease during neoadjuvant breast cancer therapy. Exact also clarified that TAPS, an alternative to bisulfite conversion for methylation analysis that increases sensitivity and efficiency that would be built into the blood-based Cologuard 2.0, its pan-cancer early detection test, and potentially the MRD test along with TARDIS. Exact acquired this technology through Base Genomics, and it was previously unclear if they planned to license out or integrate this technology into their portfolio.

ASCO GI Snapshot

- Guardant announced a target launch date for Guardant Reveal (the commercial name of the LUNAR-1 assay) of Feb 2021. Guardant Reveal is the only liquid only (i.e. does not require an initial tissue sample) MRD assay and is being launched based on the data from the COBRA trial, which investigated Reveal's use in adjuvant therapy decision making for Stage II colon cancer. While Reveal is the only liquid only MRD assay, Guardant opted to focus on CRC mutation and methylation profiles and does not personalize the assay to patient-specific mutations, as Signatera does. Guardant also announced that ECLIPSE, the registrational trial for LUNAR-2, would complete enrollment in 2021.
- Freenome announced additional data from AI-EMERGE that demonstrated their multi-omic assay could detect advanced adenomas with a sensitivity of 41% and a specificity of 90%. This shows that a blood-based method has comparable performance to stool-based methods for advanced adenoma detection. It was also shown that their assay detected 2x more advanced adenomas compared to methylation only or single protein approaches.

Other interesting headlines included fundraising efforts by interesting early detection companies Delfi (\$100M) and Earli (\$40M), SOLVD's clinical study launch, CMS's final coverage decision for blood-based CRC screening, and the deal between VolitionRx and 4D Lifetec. Be sure to give those a scan!

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Market Highlights

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- [Genetron Health to Partner With Sino Biopharm Subsidiary to Comarket Liver Cancer Test in China](#) | 6 Jan 2021
- [SOLVD Health Prepares to Launch Clinical Study of Non-Invasive Colorectal Cancer Screening Test](#) | 6 Jan 2021
- [Stage Zero Life Sciences' Aristotle Cancer Screen Gets Set To Launch](#) | 10 Jan 2021
- [Resolution Bioscience Announces Companion Diagnostic Collaboration with Mirati Therapeutics](#) | 11 Jan 2021
- [GRAIL Announces MRD Collaborations with Amgen, AstraZeneca, and Bristol Myers Squibb](#) and [GRAIL Confirms Q2 2021 Introduction of Galleri](#) | 11 Jan 2021
- [Clinical Genomics Announces Nationwide Expansion of Patient Access to COLVERA](#) | 11 Jan 2021
- [Delfi Diagnostics Announces \\$100 Million Series A](#) | 12 Jan 2021
- [Earli Raises \\$40 Million Series A](#) | 12 Jan 2021
- [Natera to Present New Colorectal Cancer Data at the 2021 ASCO GI Symposium](#) | 12 Jan 2021
- [At JPM, Natera CEO Lays Out Growth Potential for NIPT, Transplant, Cancer Testing](#) | 13 Jan 2021
- [Strata Oncology Announces Personalized Recurrence Monitoring Trial](#) | 13 Jan 2021
- [Exact Sciences Licenses Targeted Digital Sequencing Method to Extend Leadership in Precision Oncology](#) | 13 Jan 2021
- [Guardant Health to Present Data at ASCO GI](#) | 14 Jan 2021
- [Freenome: Evaluation of a sensitive blood test for the detection of colorectal advanced adenomas in a prospective cohort using a multiomics approach](#) | 15 Jan 2021
- [Guardant Health and Vall d'Hebron Institute of Oncology Announce Partnership to Establish First Guardant-Based Liquid Biopsy Testing Service in Europe](#) | 18 Jan 2021
- [CMS Finalizes Blood-Based Colon Cancer Screening NCD with Non-Coverage for Epi ProColon](#) | 20 Jan 2021

Research Highlights

- [Pan-cancer circulating tumor DNA detection in over 10,000 Chinese patients](#) | 4 Jan 2021

- [Liquid Biopsy Predicts Colon Cancer Relapse Months Before CT](#) | 17 Jan 2021

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