Put It on the Board, 5/18

FDA approves osimertinib for NSCLC, nivolumab + ipilimumab for RCC

The FDA on April 18 approved osimertinib (Tagrisso, AstraZeneca) for the first-line treatment of patients with metastatic non-small cell lung cancer whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.

Two days earlier it approved nivolumab and ipilimumab (Opdivo and Yervoy, Bristol-Myers Squibb) in combination for the treatment of intermediate- or poor-risk advanced renal cell carcinoma.

Approval of osimertinib was based on a multicenter, international, randomized, double-blind, active-controlled trial (FLAURA) conducted in 556 patients with EGFR exon 19 deletion or exon 21 L858R mutation-positive unresectable or metastatic NSCLC who had not received previous systemic treatment for advanced disease. Patients were randomized (1:1) to receive osimertinib 80 mg orally once daily or standard-of-care treatment of gefitinib 250 mg or erlotinib 150 mg orally once daily. Of those randomized to standard-of-care treatment, 20 percent received osimertinib as the next line of antineoplastic therapy.

The estimated median progression-free survival was 18.9 months (95 percent CI: 15.2, 21.4) in the osimertinib arm and 10.2 months (95 percent CI: 9.6, 11.1) in the standard-of-care arm. The confirmed overall response rate was 77 percent for the osimertinib arm and 69 percent for the standard-of-care arm. The estimated median response durations for the osimertinib and standard-of-care arms were 17.6 and 9.6 months, respectively. At the time of the primary progression-free survival analysis, there were too few deaths to estimate or compare survival outcomes.

The approvals for nivolumab plus ipilimumab were based on CheckMate 214. Efficacy was evaluated in intermediate- or poor-risk patients (n=847). The trial demonstrated statistically significant improvements in overall survival and objective response rate for patients receiving the combination (n=425) compared with those receiving sunitinib (n=422). Estimated median overall survival was not estimable in the combination arm compared with 25.9 months in the sunitinib arm. The objective response rate was 41.6 percent (95 percent CI: 36.9, 46.5) for the combination versus 26.5 percent (95 percent CI: 22.4, 31) in the sunitinib arm ($P<0.0001$).
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FDA OKs ThinPrep Integrated Imager

The FDA has granted premarket approval for the Hologic ThinPrep Integrated Imager. The company says the Integrated Imager provides the power of ThinPrep computer-assisted imaging and the ease of dual slide review in a single, automated microscope.

“Approval of the ThinPrep Integrated Imager brings the benefits of ThinPrep automated Pap imaging to small- and mid-sized laboratories in the United States, and of course to their patients,” Tom West, president of Hologic’s diagnostic solutions division, said in a statement.

Integrated Imager is a combination of an imaging station and review scope in a single desktop system. Integrated Imager can also be used as a conventional microscope.

Hologic is launching the Compass Stainer in the United States in conjunction with the imager. It is a smaller-footprint automated stainer that can perform routine and special staining protocols. Hologic says it is an affordable solution for lower-volume laboratories that do not have the space for a larger, more expensive automated stainer.
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Qiagen launches AdnaTest liquid biopsy kits for prostate, lung cancer

Qiagen launched in April, at the American Association for Cancer Research annual meeting, two liquid biopsy panels to evaluate circulating tumor cells.

The AdnaTest ProstateCancerPanel AR-V7 Kit detects the androgen receptor splice variant 7 in CTCs of prostate tumor origin isolated from blood samples to investigate potential resistance to drugs for advanced prostate cancer. With an exclusive worldwide license from Johns Hopkins University for nucleic acid detection of the AR-V7 biomarker for diagnostic use, Qiagen is now launching the test for research use. Johns Hopkins researchers first highlighted the potential clinical relevance of AR-V7 in a 2014 article published in the *New England Journal of Medicine.* In the study, they used AdnaTest workflows for isolation, enrichment, and detection of the AR-V7 marker from CTCs in blood samples using reverse-transcription PCR.

The AdnaTest LungCancer Kit provides insight into the molecular mechanisms of lung cancer through highly specific selection of CTCs, including stem cell-like cells implicated in cancer growth and epithelial-mesenchymal transition. A proprietary set of antibodies provides sensitive detection of lung-cancer-associated targets through reverse-transcriptase PCR. The open system ensures flexibility for users to add the targets of interest.
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SeraCare NGS QC software integrated into Philips’ genomics platform

SeraCare Life Sciences has partnered with Navican, an Intermountain Healthcare company, and Royal Philips on the integration of SeraCare’s clinical NGS QC solution to support the rollout of Navican’s TheraMap Precision Cancer Care services. The integrated solution connects SeraCare’s iQ NGS QC Management software to the Philips IntelliSpace Genomics Platform to automate tracking of all genomics workflow QC parameters necessary for monitoring, trending, and reporting on the performance of the TheraMap clinical NGS assay.

SeraCare’s iQ NGS QC Management solution leverages a broad selection of quantitative multiplexed DNA and RNA reference materials with a QC tracking and reporting software solution.
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FDA approves Qiagen’s PartoSure

The FDA has approved Qiagen’s PartoSure, a test for assessing the risk of spontaneous preterm birth in patients with symptoms of preterm labor.

A noninvasive strip test that provides results in five or fewer minutes, PartoSure has been shown in published studies to have a higher positive predictive value for preterm birth compared with current diagnostic methods, while maintaining an equally high negative predictive value, according to Qiagen (Wing DA, et al. *Obstet Gynecol.* 2017;130[6]:1183–1191; Melchor JC, et al. *Ultrasound Obstet Gynecol.* March 26, 2018. doi:10.1002/uog.18892).

The test detects placental alpha microglobulin-1 (PAMG-1) in patients presenting with signs and symptoms of preterm labor.

Qiagen reports that the European Association of Perinatal Medicine's preterm labor and birth management guidelines identify PartoSure's PAMG-1 as the biomarker with the highest combination of negative and positive predictive values (Di Renzo GC, et al. *J Matern Fetal Neonatal Med.* 2017;30[17]:2011–2030).
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New ctDNA reference materials for NGS

SeraCare Life Sciences is adding ctDNA Complete and ctDNA Panels to its circulating tumor DNA portfolio of reference materials. These new materials expand the Seraseq product line to also cover copy number variations and accelerate single-gene and variant-focused testing.

Seraseq ctDNA Complete is an expert-curated content that adds broader coverage of all genomic events, including SNVs, indels, CNVs, and structural rearrangements. Seraseq ctDNA Panels are disease-focused, low-plex reference samples of clinically relevant driver mutations in oncogenes implicated in lung cancer. These include driver mutations in *EGFR* (T790M, L858R, exon 19 deletions, G719S), *KRAS* (G12D), and *BRAF* (V600E). These oncogenic mutations can be assayed at a limit of detection of 0.1 percent allele frequency against a background of well-characterized genomic background wild-type cell line.
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BioMérieux acquires Astute

BioMérieux has acquired Astute Medical, which developed the FDA-cleared Nephrocheck test for the early risk assessment of acute kidney injury. It is based on the level of two biomarkers, IGFBP-7 and TIMP-2.

Astute granted BioMérieux a license in 2015 to develop and market the Nephrocheck test for the Vidas automated immunoassay system. Since 2017, BioMérieux has been a licensed distributor with Astute for the Nephrocheck test on the Astute140 Meter in the U.S.
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Beckman launches DxH 900

Beckman Coulter released on May 1 the DxH 900 hematology analyzer. Foundational to the system, the company says, are its core technologies, including the enhanced Coulter Principle, VCS 360, and DataFusion.

The DxH 900 analyzer demonstrates 93 percent first-pass throughput, according to Beckman Coulter, providing accurate flagging and reducing the number of slide reviews.
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