Put It on the Board

FDA approves Rybrevant and Lumakras for NSCLC

July 2021—The FDA in May approved two new targeted therapies for non-small cell lung cancer.

One is Rybrevant (amivantamab-vmjw) for adult patients with NSCLC whose tumors have *EGFR* exon 20 insertion mutations. The other is Lumakras (sotorasib) for adult patients with NSCLC whose tumors have the *KRAS* G12C mutation and who have received at least one prior systemic therapy.

For Rybrevant, the FDA also approved Guardant Health's Guardant360 CDx as a companion diagnostic. For Lumakras, it approved the Qiagen Therascreen KRAS RGQ PCR kit and the Guardant360 CDx as companion diagnostics.

Researchers evaluated Rybrevant's efficacy in a study of 81 patients with NSCLC and *EGFR* exon 20 insertion mutations whose disease had progressed on or after chemotherapy. The overall response rate was 40 percent. The median duration of response was 11.1 months, with 63 percent of patients having a duration of response of six months or more.

The efficacy of Lumakras was evaluated in 124 patients with locally advanced or metastatic *KRAS* G12C-mutated NSCLC with disease progression after immune checkpoint inhibitor or chemotherapy or both. The objective response rate was 36 percent, and 58 percent of those patients had a duration of response of six months or longer.

CAP issues blue-top tube recommendations

The CAP on June 15 issued recommendations to guide laboratories in reducing the clinical impact of the shortage of 3.2 percent sodium citrate blue-top tubes, which is expected to persist until the end of this year.

One option is to validate or develop alternative sodium citrate tubes, but laboratories that do so must have a written procedure for this process, document training for it, and follow checklist requirement GEN.40942 (specimen container analytic interference) to ensure the change does not affect patient results.

Another is to use point-of-care testing devices, but laboratories must follow the manufacturer's instructions (COM.04250). If the laboratory uses the method outside of the intended use (i.e. monitoring of patients on warfarin), the test is then modified and the lab will need to perform a validation of test performance specifications as outlined in COM.40350 and ensure operators are qualified to perform high-complexity testing (GEN.54750).

The CAP, which reviewed the recommendations with FDA officials, provides recommendations also for ordering providers and for nurses and phlebotomists. Those recommendations, and the full list of recommendations for clinical laboratories, are at https://bit.ly/CAP_bluetop.

AMP recommends minimum set of PGx alleles for *CYP2D6* genotype testing

The Association for Molecular Pathology on June 9 released its consensus recommendations to aid in the design and validation of clinical *CYP2D6* assays, promote standardization of testing across different laboratories, and improve patient care.

The guideline, "Recommendations for Clinical *CYP2D6* Genotyping Allele Selection: A Joint Consensus Recommendation of the Association for Molecular Pathology, College of American Pathologists, Dutch Pharmacogenetics Working Group of the Royal Dutch Pharmacists Association, and European Society for Pharmacogenomics and Personalized Therapy," was published online ahead of publication in the *Journal of Molecular Diagnostics* (doi.org/10.1016/j.jmoldx.2021.05.013).

The latest *CYP2D6* report builds on the earlier recommendations for clinical genotyping of *CYP2C19*, *CYP2C9*, and genes important for warfarin testing. The recommendations should be implemented with other relevant clinical guidelines such as those issued by the Clinical Pharmacogenetics Implementation Consortium, Dutch Pharmacogenetics Working Group, Canadian Pharmacogenomics Network for Drug Safety, and American College of Medical Genetics and Genomics, which mostly focus on the interpretation of PGx test results and therapeutic recommendations for specific drug-gene pairs.

Grail presents PATHFINDER data, introduces Galleri

Grail presented on June 4 at the ASCO annual meeting the first results from the interventional PATHFINDER study evaluating Galleri, a multi-cancer early detection blood test. The company also announced that Galleri is now available in the U.S. by prescription.

PATHFINDER was designed to assess the implementation and performance of Galleri in a clinical care setting, evaluate the clinical care pathways following a signal-detected Galleri test result, and measure the time required to achieve diagnostic resolution.

The study analyzed 6,629 individuals ages 50 or older with no suspicion of active cancer. In the interim analysis, an earlier version of Galleri accurately detected 29 cancers across 13 types: breast, colon and rectum, head and neck, liver and bile duct, lung, lymphoid leukemia, lymphoma, ovary, pancreas, plasma cell neoplasm, prostate, small intestine, and Waldenstrom macroglobulinemia. Of the new cancers detected, nine of 23 were localized (stage I–II), and more than half (13/23) were detected before distant metastases (stage I–III). Final results are expected in the first half of next year.

Latest on COVID-19

Editor’s note: See captodayonline.com for news on SARS-CoV-2 tests (Coronavirus News). A list of FDA EUAs for COVID-19 can be found at https://j.mp/covid-19-EUA.