Rybrevant + Lazcluze OK’d for EGFR-mutated NSCLC

written by CAP TODAY
October 10, 2024

October 2024—Johnson & Johnson announced Food and Drug Administration approval of Rybrevant (amivantamab-vmjw) plus Lazcluze (lazertinib) for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test.

Rybrevant plus Lazcluze is the first multitargeted, chemotherapy-free combination regimen with demonstrated superiority versus osimertinib approved for the first-line treatment of patients with EGFR-mutated NSCLC. Rybrevant is an EGFR- and MET-directed bispecific antibody that engages the immune system. Lazcluze is a highly selective, brain-penetrant, third-generation oral EGFR tyrosine kinase inhibitor. Rybrevant plus Lazcluze is the only multitargeted regimen targeting both the common EGFR mutations directly.

The FDA approval is based on positive results from the phase three MARIPOSA study, which showed Rybrevant plus Lazcluze reduced the risk of disease progression or death by 30 percent compared to osimertinib (median progression-free survival, 23.7 versus 16.6 months) in the first-line treatment of patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations. The median duration of response was nine months longer versus osimertinib (25.8 versus 16.7 months), a secondary endpoint of the study.

Johnson & Johnson, 800-526-7736