

Rybrevant approved for some non-small cell lung cancer patients

26 May 2021



Rybrevant (amivantamab-vmjw) was approved for adults with non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, the U.S. Food and Drug Administration announced Friday.

The Guardant360 CDx (Guardant Health Inc.) liquid biopsy test was also approved as a companion diagnostic for use with Rybrevant.

The approval of Rybrevant was based on efficacy data from the ongoing Phase 1 CHRYSALIS study, a multicenter, open-label, [clinical study](#) of 81 patients with non-[small cell lung cancer](#) and EGFR exon 20 insertion mutations whose disease progressed with platinum-based chemotherapy. Depending on weight, patients received a dose of either 1,050 mg or 1,400 mg weekly for four weeks, with an initial dose as a split infusion in week 1 on days 1 and 2 and then administered every two weeks until disease progression or toxicity. Researchers observed a 40 percent response rate with Rybrevant, including 3.7

percent complete responses and 36 percent partial responses. Median response duration was 11.1 months, and 63 percent of patients had a response duration of six months or longer.

The most commonly reported [side effects](#) were rash, infusion-related reactions, skin infections around the fingernails or toenails, muscle and [joint pain](#), shortness of breath, nausea, fatigue, swelling in the lower legs or hands or face, sores in the mouth, cough, constipation, vomiting, and changes in certain blood tests. If patients develop symptoms of interstitial lung disease, the FDA notes that Rybrevant should be withheld, and it should be permanently discontinued if interstitial lung disease is confirmed. Patients taking Rybrevant should be advised to limit sun exposure during treatment and for two months following.

Approval of Rybrevant was granted to Janssen Pharmaceutical Companies of Johnson & Johnson.

More information: [More Information](#)

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