

FDA approves targeted therapy for subset of NSCLC

May 28, 2021—The U.S. Food and Drug Administration approved [Janssen Pharmaceutical](#)'s Rybrevant (amivantamab-vmjw) as the first treatment for adult patients with non-small cell lung cancer whose tumors have epidermal growth factor receptor exon 20 insertion mutations. The FDA also approved Guardant Health's Guardant360 CDx as a companion diagnostic for Rybrevant.

Researchers evaluated Rybrevant's efficacy in a study of 81 patients with non-small cell lung cancer and EGFR exon 20 insertion mutations whose disease had progressed on or after platinum-based chemotherapy. In the trial population in which all patients received Rybrevant, 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.

Rybrevant received priority review and breakthrough therapy designation for this indication.