

## 1 Category/product

<b>Category of application:</b>	Best pharmaceutical agent
<b>Drug name:</b>	RYBREVANT® (amivantamab-vmjw)
<b>Technical name:</b>	Amivantamab-vmjw
<b>Trade name:</b>	RYBREVANT®
<b>Date of US approval:</b>	May 21, 2021
<b>Date of EU approval:</b>	September 12, 2021
<b>Therapeutic categories:</b>	Oncology: non-small cell lung cancer (NSCLC)

**Indications:** RYBREVANT® is a bispecific epidermal growth factor receptor (EGFR)-directed and MET receptor-directed antibody approved in the United States for the treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion (ex20ins) mutations, as detected by a US Food and Drug Administration (FDA)-approved test, whose disease has progressed on or after platinum-based chemotherapy. This indication is approved under accelerated approval based on overall response rate (ORR) and duration of response (DOR). Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials.

As of June 30, 2022, RYBREVANT® is also approved in Brazil, Canada, the European Union, India, Lichtenstein, Mexico, South Korea, Switzerland, Taiwan, and the United Kingdom for use in adult patients with advanced NSCLC with activating EGFR exon 20 insertion mutations after failure of platinum-based therapy.