PUBLIC RECORDS / WORKED EXAMPLE

Rybrevant Faspro and the survival claim

Product diligence

Prepared by Dossier Editorial | November 8, 2026

EVIDENCE SOURCES	EVIDENCE CHECKED	PUBLISHER INSTITUTIONS
8	2026-11-08	3

SECTIONS	READER QUESTIONS	REVIEW SCOPE
7	3	Public records

EVIDENCE CHECKED	2026-11-08
EDITION	1 | Public-source research
ARTICLE	dossierplus.ai/blog/rybrevant-faspro-accelerated-approval-survival-evidence

IMPORTANT USE NOTE

Dossier Editorial prepared this public-record walkthrough with AI assistance. It illustrates how to check a regulatory claim for a diligence brief. It offers no individual treatment advice.

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PART 01

The decision in brief

The November 5 approval establishes a specific use for Rybrevant Faspro based on tumor response. Whether the treatment helps patients live longer than an alternative remains open. The original study reported median overall survival of 12.5 months in the treated cohort. It had no randomized comparison group for measuring how much survival the treatment added.

Publication date: November 8, 2026. Historical event dates are identified separately. This PDF and the article use the same structured source selection and findings.

PART 02

What can a reviewer put in a briefing?

A reviewer is asked to sign off on the sentence “Rybrevant Faspro helps people with head and neck cancer live longer.” The FDA’s decision supports narrower wording. In 102 patients included in its efficacy analysis, independent reviewers confirmed tumor responses in 42%. Among those who responded, 56% had a response lasting at least six months. [S1] [S2]

The study investigators also reported survival for the treated group. To support a claim that this therapy extends life, the reviewer would need a credible comparison with an alternative in the relevant population. FDA lists an ongoing confirmatory requirement. Keep the survival-benefit claim open while recording the approval and observed responses as supported. [S3] [S4] [S5]

PART 03

Match the drug, indication and study

The product is subcutaneous Rybrevant Faspro, amivantamab and hyaluronidase-lpuj. FDA’s Drugs@FDA record identifies Janssen Biotech, Inc., biologics license application 761433 and supplement 2. The original product approval dates to December 17, 2025. November 5, 2026 is the date of the new head and neck indication. [S1] [S7]

Section 1.5 covers single-agent use in adults whose recurrent or metastatic head and neck squamous cell carcinoma progressed during or after platinum chemotherapy and treatment with an anti-PD-(L)1 antibody. The label excludes HPV-associated oropharyngeal squamous cell carcinoma, identified by p16 testing. That limitation concerns a particular tumor site and HPV status. Preserve it when shortening the indication. [S1] [S2]

PART 04

Trace the claim through three dated records

PUBLIC RECORD	WHAT CHANGED	WHAT IT SUPPORTS
May 31, 2026 · OrigAMI-4 paper	Investigators published results from cohort 1, including response and observed survival.	A dated observation about patients who received the drug. [S3]

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PUBLIC RECORD	WHAT CHANGED	WHAT IT SUPPORTS
Nov 3, 2026 · OrigAMI-5 registry update	The sponsor listed the randomized phase 3 study as recruiting. It specifies overall survival and objective response among its primary outcomes.	A plan for a comparison. The registry showed no posted results at this check. [S4]
Nov 5, 2026 · FDA supplement 2	FDA granted accelerated approval for the specified use. The revised label identifies the response measures underlying the decision.	An authorized indication and its supporting evidence. [S1] [S2] [S7]

PART 05

Read the denominator before repeating the number

Table 29 on page 58 of the label reports a confirmed response rate of 42%, with a 95% confidence interval of 32% to 52%. The denominator is 102 patients in the primary efficacy population. The 56% figure answers a second question about how long responses lasted among responders. Using all 102 as the denominator for both percentages changes the claim. [S1] [S2]

The original paper reports another response estimate, 47%, from the treating investigators' assessments. FDA used the 42% estimate from blinded independent central review. Keep the assessment method with each figure. In the same paper, median overall survival was 12.5 months, with a 95% confidence interval of 10.2 to 16.8 months. Estimating months gained requires survival data from an appropriate comparison group. [S1] [S3]

FDA's news release compared the observed response rate with roughly 20% or less associated with existing therapies. OrigAMI-4 cohort 1 received amivantamab. There was no concurrent randomized comparator in that cohort. The release provides context for the response rate. A reviewer who converts it into a survival comparison changes both the endpoint and the study design. [S2] [S3] [S6]

PART 06

Which record can support the proposed sentence?

1. DOES THE CLAIM ADDRESS THIS EXACT USE OF THE DRUG?

- If established: Match supplement 2 and section 1.5. Record prior therapies, the tumor site and the HPV-related limitation.
- If unresolved: Identify the correct product, cancer and line of therapy before using figures from a similarly named record.

2. DOES THE SENTENCE DESCRIBE TUMOR RESPONSE?

- If established: Use Table 29 and name the assessor. Identify the 102-patient group for response rate and the responders for response duration.
- If unresolved: Write down the claimed outcome and locate evidence that measured it.

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3. DOES THE SENTENCE CLAIM PATIENTS LIVED LONGER BECAUSE OF TREATMENT?

- If established: Look for a suitable comparison, the treatment regimens, the survival estimate and its uncertainty.
- If unresolved: An observed survival figure may be reported with its cohort and follow-up. Keep any comparison open.

4. HAS A LATER TRIAL OR FDA ACTION SETTLED THE QUESTION?

- If established: Check the results, the population and FDA's action for the same indication. Update only the claim that evidence supports.
- If unresolved: Record the trial identifier, status and next document needed.

PART 07

Build a reproducible Dossier record

- Start an indication record with the product name, BLA 761433, supplement 2 and decision date. Keep trial NCT06385080 (OrigAMI-4) and NCT07276399 (OrigAMI-5) as separate entries.
- Attach the prescribing information and the investigators' abstract. Add one row per number, with columns for endpoint, denominator, assessor, comparator and source location. A blank comparator field is meaningful in the survival row.
- Test the proposed briefing sentence against those rows. Record the supported wording, the open question and the document that could change it. Export the decision with its sources so the next reviewer can check each statement. [S1] [S2] [S3] [S4] [S7]

PART 08

What could change the survival finding?

FDA lists postmarketing requirement 5095-1 for OrigAMI-5 and gives May 31, 2029 as its original projected completion date. The trial registry separately estimates June 18, 2029 for primary completion. Those dates describe different fields and are projections. Check for posted results and an updated agency determination as they become available. [S4] [S5]

OrigAMI-5 studies first-line combination treatment in recurrent or metastatic disease. Its arms use different regimens from the previously treated, single-agent population in the approval evidence. Even when results arrive, record the population, comparison and endpoint before assigning the result to a claim about the approved use. [S1] [S4] [S5]

PART 09

Questions readers ask

DOES 42% MEAN THAT 42% OF PATIENTS LIVED LONGER?

The 42% measures confirmed tumor response in the efficacy group. A survival comparison requires data on time to death and a suitable comparator. The original paper's survival result describes the treated cohort. [S1] [S2] [S3]

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WAS THE SIX-MONTH FIGURE MEASURED IN ALL 102 PATIENTS?

The 56% refers to responders whose response lasted at least six months. The FDA decision identifies the denominator directly. Using 56% as a rate for every patient in the study would overstate the finding. [S1] [S2]

DOES THE VERIFIED-BENEFIT ENTRY FOR RYBREVANT SETTLE THIS QUESTION?

The similarly named entry in FDA's verified-benefit table concerns Rybrevant (amivantamab-vmjw) for a specific lung cancer indication. For Rybrevant Faspro's head and neck use, the relevant agency entry is the ongoing requirement for OrigAMI-5. [S2] [S5] [S8]

PART 10

Linked source register

Titles with a recorded URL link to that source. Entries without a URL identify retained material but do not open an original file. For any court or business record being used in litigation, obtain a certified copy directly from the clerk or filing authority and preserve the retrieval date.

S1 **FDA's November 5 oncology approval notice**
Regulatory decision summary. Anchor: Opening and Efficacy and Safety. Defines the approved population and identifies the denominator for response duration. · retrieved 2026-11-08

S2 **Rybrevant Faspro prescribing information, supplement 2**
FDA-approved product label. Anchor: Sections 1.5 and 14.5, Table 29, printed p. 58. Product-specific scope, efficacy population and assessment method. · retrieved 2026-11-08

S3 **OrigAMI-4 pivotal cohort results**
Original investigators' published abstract via NLM. Anchor: PMID 42218660, abstract Methods and Results, May 31, 2026. Reports the cohort survival estimate and both response assessments. The public XML contains the authors' abstract. · retrieved 2026-11-08

S4 **OrigAMI-5 randomized confirmatory study**
Sponsor-submitted ClinicalTrials.gov record. Anchor: NCT07276399, study design, outcome measures and dates. Registry update posted Nov 3. Recruiting, with no results posted when checked. · retrieved 2026-11-08

S5 **FDA ongoing cancer accelerated approvals**
Postmarketing requirements tracker. Anchor: Rybrevant Faspro, requirement 5095-1. Identifies the trial and the original projected completion date. · retrieved 2026-11-08

S6 **FDA's public announcement and treatment benchmark**
Agency news release. Anchor: Nov 5, trial results and comparison with available therapies. Supplies context for the response comparison in the announcement. · retrieved 2026-11-08

S7 **Drugs@FDA approval history for Rybrevant Faspro**
Regulatory application history. Anchor: BLA 761433, ORIG-1 and SUPPL-2 rows. Distinguishes the original product approval from the new indication. · retrieved 2026-11-08

S8 **FDA verified clinical benefit table**
Regulatory status register. Anchor: Rybrevant (amivantamab-vmjw), March 1, 2024 conversion. Different product and lung cancer indication. Match the entire row before using it. · retrieved 2026-11-08

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