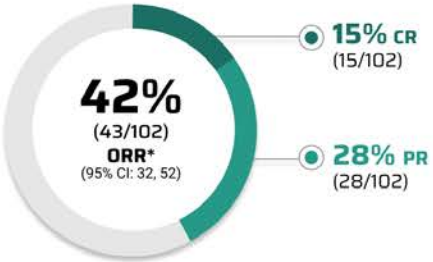
RYBREVANT Faspro™
(amivantamab and hyaluronidase-lpuj)
Subcutaneous injection | 160 mg/2,000 units per mL

NOW APPROVED in R/M HNSCC

The first and only subcutaneous dual-targeted therapy for adults with R/M HNSCC[1,2]

who progressed on or after platinum-based chemotherapy and an anti–PD-(L)1 antibody

Overall response rate[1,3]



Duration of response[1,3]

56% (24/43) of responders maintained their **response for** **≥6** months†

Duration of response ranged from 1.4+ to 19.7+ months
"+" indicates ongoing response.

Not indicated as a treatment for patients with OPSCC that is HPV-associated (ie, by p16 IHC).[1]
This indication is approved under accelerated approval. Continued approval for this indication may be contingent on confirmatory trial(s).[1]

Study design: The multi-cohort, multicenter, open-label, ongoing phase 1b/2 OrigAMI-4 trial (N=102) evaluated the efficacy and safety of subcutaneous RYBREVANT *FASPRO* in patients with previously treated R/M HNSCC who have received platinum-based chemotherapy and an anti–PD-(L)1 antibody. Patients were excluded from the trial if they had OPSCC that was HPV-associated (ie, by p16 IHC). **Primary endpoint:** ORR; secondary endpoint: DOR, both per BICR.[1,3]

*BICR-assessed confirmed ORR per RECIST v1.1 was 42% (95% CI: 32, 52).[1]
†DOR was assessed by BICR per RECIST v1.1.[1]

BICR, blinded independent central review; CI, confidence interval; CR, complete response; DOR, duration of response; HPV, human papillomavirus; IHC, immunohistochemistry; OPSCC, oropharyngeal squamous cell carcinoma; ORR, overall response rate; PD-(L)1, programmed cell death (ligand) protein 1; PR, partial response; RECIST, Response Evaluation Criteria in Solid Tumors; R/M HNSCC, recurrent or metastatic head and neck squamous cell carcinoma.

INDICATION

RYBREVANT *FASPRO* is indicated as a single agent for the treatment of adult patients with recurrent or metastatic HNSCC whose disease has progressed on or after platinum-based chemotherapy and an anti-PD-(L)1 antibody.

- Limitations of use: RYBREVANT *FASPRO* is not indicated as a treatment for patients with OPSCC that is HPV-associated (i.e., by p16 IHC).
- This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

RYBREVANT *FASPRO* is contraindicated in patients with known hypersensitivity to hyaluronidase or to any of its excipients.

WARNINGS AND PRECAUTIONS include: Hypersensitivity & ARRs, ILD/Pneumonitis, Dermatologic Adverse Reactions, Ocular Toxicity and Embryo-Fetal Toxicity.

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*For adults with R/M HNSCC with disease progression on or after platinum-based chemotherapy and an anti–PD-(L)1 antibody**

Well-established safety: The majority of ARs were grades 1–2[1,3]

ARs (≥10%) in patients in OrigAMI-4[1†]

Adverse reaction	RYBREVANT *FASPRO* (N=102)	
	All grades (%)	Grades 3–4 (%)
Skin and subcutaneous tissue disorders		
Rash‡	79	13
Nail toxicity‡	35	2
Dry skin‡	16	0
Pruritus	15	2
General disorders and administration site conditions		
Fatigue‡	39	3.9
Edema‡	28	1
Gastrointestinal disorders		
Stomatitis‡	32	2.9
Nausea	17	0
Diarrhea	16	0
Constipation	10	0
Injury, poisoning, and procedural complications		
Administration-related reactions	15	0
Metabolism and nutrition disorders		
Decreased appetite	15	0
Infections and infestations		
Pneumonia‡	14	6
Nervous system disorders		
Dizziness‡	14	2
Eye disorders		
Ocular toxicity‡	13	1

- **Serious ARs** occurred in 39% of patients. Serious ARs in ≥2% of patients included pneumonia (8%), hemorrhage (4.9%), dysphagia (2.9%), pneumothorax (2.9%), anemia (2%), dyspnea (2%), fatigue (2%), hepatic enzyme increased (2%), and ILD/pneumonitis (2%)[1]
- **Fatal ARs** occurred in 6% of patients including sudden death (2%), myocardial ischemia, tumor hemorrhage, aspiration pneumonia, and ILD/pneumonitis (1%, 1 patient each)[1]
- **The most common ARs** (≥20%) were rash, fatigue, nail toxicity, stomatitis, and edema[1]
- **Clinically relevant ARs** (<10%) in patients were vomiting, cough, hypotension, muscle spasms, aspiration, ILD/pneumonitis, skin ulcer, and local injection site reactions[1]
- **The most common grade 3 or 4 laboratory abnormalities** (≥2%) were decreased lymphocytes, decreased potassium, decreased hemoglobin, increased alanine aminotransferase, decreased albumin, decreased sodium, increased aspartate aminotransferase, and decreased white blood cells[1]

*Not indicated as a treatment for patients with OPSCC that is HPV-associated (ie, by p16 IHC).[1]
†With Q3W dosing.[1]
‡Grouped terms.[1]

AR, adverse reaction; HPV, human papillomavirus; IHC, immunohistochemistry; ILD, interstitial lung disease; OPSCC, oropharyngeal squamous cell carcinoma; PD-(L)1, programmed cell death (ligand) protein 1; Q3W, once every 3 weeks; R/M HNSCC, recurrent or metastatic head and neck squamous cell carcinoma.

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Prophylactic strategies are recommended to help reduce the risk and severity of dermatologic ARs[1]

Premedications

Glucocorticoid required prior to initial injection (week 1, day 1).*
Antihistamine and antipyretic required prior to each injection.

	Month 1	Month 2	Month 3	Month 4	Month 5
AT-HOME ORAL AND TOPICAL REGIMEN					
Medications	**Oral doxycycline or minocycline** 100 mg twice daily for first 3 months of treatment			**Topical clindamycin 1% lotion** on the scalp for next 9 months of treatment	
Daily skincare	**Ceramide-based skin moisturizer** on the face and body (except scalp)				
	Chlorhexidine 4% wash on the hands and feet (once daily)				
	Protective clothing and broad-spectrum UVA/UVB sunscreen. Limit sun exposure during and for 2 months after treatment				

Month = month of treatment with RYBREVANT *FASPRO*.

For more information, contact an Oncology Clinical Educator

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Please see section 2.5 of the Prescribing Information for RYBREVANT *FASPRO* for more detailed information.

*Glucocorticoid administration is also required upon reinitiation after prolonged dose interruptions, then as necessary; or at a subsequent dose in the event of an ARR.[1]

AR, adverse reaction; ARR, administration-related reaction; UVA, ultraviolet A; UVB, ultraviolet B.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Hypersensitivity and Administration-Related Reactions with RYBREVANT *FASPRO*

RYBREVANT *FASPRO* can cause hypersensitivity and administration-related reactions (ARR); signs and symptoms of ARR include dyspnea, flushing, fever, chills, chest discomfort, hypotension, and vomiting. The median time to ARR onset is approximately 2 hours.

In OrigAMI-4 (n=132), all Grade ARRs occurred in 16% of patients. All reactions were Grade 1 or 2. Of the patients who experienced ARRs, 91% occurred with the initial dose (Week 1, Day 1).

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83% of patients stayed on therapy without permanent discontinuation due to ARs[1]

- **Permanent discontinuation** of RYBREVANT *FASPRO* due to an AR occurred in **17%** of patients
- **Dose interruptions** of RYBREVANT *FASPRO* due to an AR occurred in **51%** of patients
- **Dose reductions** of RYBREVANT *FASPRO* due to an AR occurred in **23%** of patients

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AR, adverse reaction.

IMPORTANT SAFETY INFORMATION (cont'd)

Hypersensitivity and Administration-Related Reactions with RYBREVANT *FASPRO* (cont'd)

Premedicate with antihistamines, antipyretics, and glucocorticoids and administer RYBREVANT *FASPRO* as recommended. Monitor patients for any signs and symptoms of ARR during injection in a setting where cardiopulmonary resuscitation medication and equipment are available. For the first dose, monitor patients for hypersensitivity and ARRs for 2 to 4 hours following the end of injection. Interrupt injection if ARR is suspected. Resume treatment upon resolution of symptoms or permanently discontinue based on severity.

Interstitial Lung Disease/Pneumonitis

RYBREVANT *FASPRO* can cause severe and fatal interstitial lung disease (ILD)/pneumonitis.

In OrigAMI-4, ILD/pneumonitis occurred in 1.5% of patients, including one fatal case (0.8%). All of these patients permanently discontinued RYBREVANT *FASPRO* due to ILD/pneumonitis.

Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold RYBREVANT *FASPRO* in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.

Dermatologic Adverse Reactions

RYBREVANT *FASPRO* can cause severe rash including toxic epidermal necrolysis (TEN), dermatitis acneiform, pruritus and dry skin.

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> In OrigAMI-4 (n=132), all Grade ARRs occurred in 16% of patients. All reactions were Grade 1 or 2. Of the patients who experienced ARRs, 91% occurred with the initial dose (Week 1, Day 1).

Premedicate with antihistamines, antipyretics, and glucocorticoids and administer RYBREVANT *FASPRO* as recommended. Monitor patients for any signs and symptoms of ARR during injection in a setting where cardiopulmonary resuscitation medication and equipment are available. For the first dose, monitor patients for hypersensitivity and ARRs for 2 to 4 hours following the end of injection. Interrupt injection if ARR is suspected. Resume treatment upon resolution of symptoms or permanently discontinue based on severity.

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Monitor patients for new or worsening symptoms indicative of ILD/pneumonitis (e.g., dyspnea, cough, fever). Immediately withhold RYBREVANT *FASPRO* in patients with suspected ILD/pneumonitis and permanently discontinue if ILD/pneumonitis is confirmed.

Dermatologic Adverse Reactions

RYBREVANT *FASPRO* can cause severe rash including toxic epidermal necrolysis (TEN), dermatitis acneiform, pruritus and dry skin.

> In OrigAMI-4, rash occurred in 81% of patients, including Grade 3 in 11% and Grade 4 in 0.8%. Rash led to a dose reduction in 11% of patients, and permanent discontinuation in 3% of patients.

When initiating treatment, prophylactic and concomitant medications are recommended to reduce the risk and severity of dermatologic adverse reactions. Instruct patients to limit sun exposure during and for 2 months after treatment. Advise patients to wear protective clothing and use broad spectrum UVA/UVB sunscreen.

If skin reactions develop, administer supportive care including topical corticosteroids and topical and/or oral antibiotics. For Grade 3 reactions, add oral steroids and consider dermatologic consultation. Promptly refer patients presenting with severe rash, atypical appearance or distribution, or lack of improvement within 2 weeks to a dermatologist. Withhold, reduce the dose, or permanently discontinue RYBREVANT *FASPRO* based on severity.

Important Safety Information continues on next page.

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IMPORTANT SAFETY INFORMATION (cont'd)

Ocular Toxicity

RYBREVANT *FASPRO* can cause ocular toxicity including keratitis, blepharitis, dry eye symptoms, conjunctival redness, blurred vision, visual impairment, ocular itching, eye pruritus and uveitis.

In OrigAMI-4, ocular toxicity occurred in 11% of patients, including 0.8% Grade 4. Keratitis occurred in one patient (0.8%).

Promptly refer patients presenting with new or worsening eye symptoms to an ophthalmologist. Withhold, dose reduce or permanently discontinue RYBREVANT *FASPRO* based on severity.

Embryo-Fetal Toxicity

RYBREVANT *FASPRO* can cause fetal harm when administered to a pregnant woman. Verify pregnancy status prior to initiating treatment. Advise pregnant women and females of reproductive potential of the potential risk to the fetus and to use effective contraception during treatment and for 3 months after the last dose of RYBREVANT *FASPRO*.

ADVERSE REACTIONS

In OrigAMI-4 (n=102), the most common adverse reactions (≥20%) were rash (79%), fatigue (39%), nail toxicity (35%), stomatitis (32%), and edema (28%). The most common Grade 3 or 4 laboratory abnormalities (≥2%) were decreased lymphocytes (26%), decreased potassium (9%), decreased hemoglobin (6%), increased alanine aminotransferase (4.9%), decreased albumin (4.9%), decreased sodium (4.9%), increased aspartate aminotransferase (3.9%) and decreased white blood cells (2%).

Serious adverse reactions occurred in 39% of patients. Serious adverse reactions in ≥2% of patients included pneumonia (8%), hemorrhage (4.9%), dysphagia (2.9%), pneumothorax (2.9%), anemia (2%), dyspnea (2%), fatigue (2%), hepatic enzyme increased (2%), and ILD/pneumonitis (2%). Fatal adverse reactions occurred in 6% of patients who received RYBREVANT *FASPRO* including sudden death (2%), myocardial ischemia, tumor hemorrhage, aspiration pneumonia, and ILD/pneumonitis (1%, 1 patient each).

Please read full Prescribing Information for RYBREVANT *FASPRO*.

cp-606849v1

References: 1. RYBREVANT *FASPRO* [Prescribing Information]. Horsham, PA: Janssen Biotech, Inc. **2.** National Cancer Institute. Drugs approved for head and neck cancer. Updated May 8, 2025. Accessed September 1, 2026. https://www.cancer.gov/about-cancer/treatment/drugs/head-neck **3.** Burtness B, Rosenberg AJ, Calderon B, et al; OrigAMI-4 Cohort 1 Investigators. Amivantamab in recurrent/metastatic head and neck squamous cell cancer after checkpoint inhibitor and chemotherapy: pivotal results from the phase Ib/II OrigAMI-4 study. *J Clin Oncol*. 2026:1-7. doi:10.1200/JCO-26-01042

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