vyepti™
(eptinezumab-jjmr)
100 mg/mL injection

THE FIRST AND ONLY INTRAVENOUS (IV) TREATMENT FOR MIGRAINE PREVENTION

## WHAT IS VYEPTI™ AND WHO IS IT FOR?

The U.S. Food and Drug Administration (FDA) **approved VYEPTI™ (eptinezumab-jjmr) [on Feb. 21, 2020]** for preventive treatment of migraine in adults.[1]

VYEPTI is the **first and only IV treatment** for prevention of migraine,[1] a highly symptomatic and debilitating neurological disease that affects **39 million people in the US** and **3x as many women as men**.[2, 3]

## HOW DOES VYEPTI WORK?

VYEPTI is administered every 3 months via a 30-minute infusion.[1] The recommended dosage of VYEPTI is 100 mg but some patients may benefit from a dosage of 300 mg. It was **developed to deliver 100% of the medication quickly into the bloodstream,** so it can work as soon as possible after administration. Patients will receive VYEPTI **at their doctors' office or at an infusion center**.

## WHAT IS VYEPTI CONNECT™?

VYEPTI CONNECT is an optional program that **provides support throughout the process of initiating treatment with VYEPTI**—from benefit investigation through appeal—as well as information about financial assistance that may be available for eligible patients. **Financial assistance is available for eligible commercially insured patients** through the VYEPTI Copay Assistance Program. Learn more about the program by calling 833-4-VYEPTI.

## WHAT CLINICAL DATA SUPPORTED THE U.S. FDA APPROVAL OF VYEPTI?

The Phase 3 clinical trial program for VYEPTI included two randomized, double-blind, placebo-controlled studies (PROMISE-1 and PROMISE-2) that assessed the safety and efficacy of VYEPTI in adults with episodic and chronic migraine, administered every 3 months via a 30-minute IV infusion.

In Phase 3 clinical trials:

- **VYEPTI demonstrated statistically significant and clinically meaningful decreases in monthly migraine days** (MMD) from baseline over months 1 to 3 compared to placebo, which were sustained over 6 months.[1]
- A treatment benefit over placebo was observed **for VYEPTI as early as day 1 post-infusion**, and the percentage of patients experiencing a migraine was lower for VYEPTI than with placebo for most of the first 7 days.[1]
- Following the first infusion, **higher percentages of patients treated with VYEPTI experienced at least 75% fewer migraine days** over months 1-3 as compared to placebo.[1]
- The most common adverse reactions (incidence ≥2% and 2% or greater than placebo) in the clinical trials for the preventive treatment of migraine were nasopharyngitis (stuffy nose and scratchy throat) and hypersensitivity (allergic reactions).[1]

## ABOUT LUNDBECK IN MIGRAINE

The U.S. FDA approval of VYEPTI represents the entrance of Lundbeck into the migraine space. **Lundbeck has a 70-year history in neuroscience research with products registered in more than 100 countries.** As the only global pharmaceutical company focused solely on diseases of the brain, Lundbeck has the expertise to **address unmet needs in brain disorders, including migraine**, along with the passion and dedication to have a meaningful impact on these patient communities.

**Please see Important Safety Information on page 3.**

Lundbeck

## ABOUT THE PROMISE CLINICAL TRIAL PROGRAM

The efficacy and safety of VYEPTI was demonstrated in two randomized, placebo-controlled, phase III clinical trials (PROMISE-1 in episodic migraine and PROMISE-2 in chronic migraine) both with 6-month double-blind periods.[1] In both studies, patients were randomized to receive placebo, VYEPTI 100 mg, or VYEPTI 300 mg.[1] The primary endpoint was the change from baseline in mean monthly migraine days (MMD) over months 1-3.[1] Patients were allowed to use concurrent acute migraine or headache medications, including migraine-specific medications (i.e., triptans, ergotamine derivatives), during the trial.[1] The study excluded patients with a history of cardiovascular disease (hypertension, ischemic heart disease), neurological disease, and cerebrovascular disease.[1] In PROMISE-2, the study population included patients with a dual diagnosis of chronic migraine and medication overuse headache attributable to acute medication overuse of triptans, ergotamine, or combination analgesics greater than 10 days per month.[1]

### PROMISE-1

A total of 665 patients with episodic migraine were randomized to receive placebo (N=222), 100 mg VYEPTI (N=221), or 300 mg VYEPTI (N=222) every 3 months for 12 months.[1] Episodic migraine was defined as 4-14 headache days per month, of which at least 4 were migraine days.[1] The mean migraine frequency at baseline was approximately 8.6 migraine days per month and was similar across treatment groups.[1]

- Primary endpoint: Mean change from baseline in MMD with VYEPTI compared with placebo in months 1-3: -3.9 days for 100 mg (p=0.018), -4.3 MMD for 300 mg (p<0.001), and -3.2 days for placebo.
- Secondary endpoints:
  - Percent responders with at least 50 percent reduction in MMD in months 1-3 compared with placebo: 49.8 percent for 100 mg (nominal p-value=0.009), 56.3 percent for 300 mg (p<0.001), and 37.4 percent for placebo.[1]
  - Percent responders with at least 75 percent reduction in MMD in months 1-3: 22.2 percent for 100 mg (p=NS*), 29.7 percent for 300 mg (p<0.001), and 16.2 percent for placebo.[1]
  - Greater percentage of placebo-treated patients had migraine on most days during the first 7 days of treatment compared to VYEPTI-treated patients.[1]

### PROMISE-2

A total of 1,072 patients with chronic migraine were randomized to receive placebo (N=366), 100 mg VYEPTI (N=356), or 300 mg VYEPTI (N=350) every 3 months for 6 months.[1] Chronic migraine was defined as 15-26 headache days per month, of which at least 8 were migraine days.[1] Mean migraine frequency at baseline was approximately 16.1 migraine days per month and was similar across treatment groups.[1]

- Primary endpoint: Mean change from baseline in MMD compared with placebo in months 1-3: -7.7 days for 100 mg (p<0.001), -8.2 days for 300 mg (p<0.001), and -5.6 days for placebo.
- Secondary endpoints:
  - Percent responders with at least 50 percent reduction in MMD in months 1-3 compared with placebo: 57.6 percent for 100 mg (p<0.001), 61.4 percent for 300 mg (p<0.001), and 39.3 percent for placebo.[1]
  - Percent responders with at least 75 percent reduction in MMD in months 1-3: 26.7 percent for 100 mg (p≤0.001), 33.1 percent for 300 mg (p<0.001), and 15.0 percent for placebo.[1]
  - Greater percentage of placebo-treated patients had migraine on each individual day during the first 7 days of treatment compared to VYEPTI-treated patients.[1]

The safety of VYEPTI was evaluated in 2,076 patients with migraine who received at least one dose of VYEPTI.[1] The most common adverse reactions (≥2 percent and at least 2 percent or greater than placebo) in the clinical trials for the preventive treatment of migraine were nasopharyngitis and hypersensitivity.[1] In PROMISE-1 and PROMISE-2, 1.9 percent of patients treated with VYEPTI discontinued treatment due to adverse reactions.[1]

* NS = not statistically significant

**Please see Important Safety Information on page 3.**

## INDICATION AND IMPORTANT SAFETY INFORMATION

**Approved Use:**

- VYEPTI™ is a prescription medicine used for the preventive treatment of migraine in adults.

**Important Safety Information:**

- **Do not receive VYEPTI** if you have a known allergy to eptinezumab-jjmr or its ingredients.
- **VYEPTI may cause allergic reactions**. Call your healthcare provider or get emergency medical help right away if you have any symptoms of an allergic reaction: rash, swelling of your face, lips, tongue, or throat, if you have trouble breathing, hives or redness in your face.
- **Before starting VYEPTI**, tell your healthcare provider about all your medical conditions, including if you are pregnant or plan to become pregnant, or you are breastfeeding or plan to breastfeed.
- **Tell your healthcare provider** about all the medicines you take, including any prescription and over-the-counter medicines, vitamins, or herbal supplements
- **The most common side effects** of VYEPTI include stuffy nose and scratchy throat, and allergic reactions.
- These are not all the possible side effects of VYEPTI. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.
- **You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.**

**For more information, please see the Prescribing Information and Patient Information.**


**REFERENCES**

1. VYEPTI (eptinezumab) Full Prescribing Information
2. Lipton RB, et al. Migraine prevalence, disease burden, and the need for preventive therapy. Neurology 2007;68:343-349.
3. Migraine Research Foundation. Migraine Facts. Available at https://migraineresearchfoundation.org/about-migraine/migraine-facts/. Accessed February 19, 2020.



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