INTRODUCTION

Perampanel is a once-daily anti-seizure medication (ASM) for the treatment of seizures (GTCS) and generalized tonic-clonic seizures (GTCS).

• In the US, perampanel is approved as monotherapy and adjunctive therapy for FOS (with or without focal to bilateral tonic-clonic seizures) in patients aged > 12 years, and for adjunctive treatment of GTCs in patients aged > 12 years.

METHODS

Study design and endpoints

The design of Study 332 has been previously published.

• Identify patients aged ≥ 12 years with intractable generalized epilepsy and uncontrolled GTCS.

• Treat patients with adjunctive perampanel (target dose: 8 mg/day) for 17 weeks in a Double Blind Treatment Period (mean ± 1 week).

• Safety was assessed in the Safety Analysis Set (all patients who received ≥1 dose of study drug and had any post-baseline safety data), and included monitoring of treatment-emergent adverse events (TEAEs).

ABSTRACT DESCRIPTION

This poster presents a post hoc analysis of time to first seizure event following administration of placebo or perampanel 8 mg/day in patients aged ≥ 12 years with uncontrolled GTCS during the Double Blind Treatment Period in Study 332 using the Kaplan-Meier method.

Primary efficacy endpoints

An a priori reported, secondary perampanel 8 mg/day effect on median percent reduction in GTCS during maintenance compared to placebo (P = 0.0018; Figure 1A). For all seizure types, median percent reductions in seizure frequency were also significantly greater with perampanel 8 mg/day compared with placebo (P < 0.0025; Figure 2A).

For all seizures, 50% responder rates were numerically higher with perampanel 8 mg/day compared with placebo (P < 0.0025; Figure 2B). Adjunctive perampanel 8 mg/day was also associated with a longer time to first seizure of any type compared with placebo (P = 0.0001; Figure 1B).

OUTCOMES

Patients

Of the 165 patients included in the Safety Analysis Set (placebo, n=82; perampanel, n=81), 82 patients in the Full Analysis Set (placebo, n=81; perampanel, n=80).

ABSTRACT DESCRIPTION

Time to first seizure analysis

This poster presents a post hoc analysis of time to first seizure event following administration of placebo or perampanel 8 mg/day in patients aged ≥ 12 years with uncontrolled GTCS during the Double Blind Treatment Period in Study 332 using the Kaplan-Meier method.

Summary statistics were determined without taking into account any censoring.

Time to first seizure analysis

The most common concomitant ASMs received during baseline were sodium valproate (18.3%), levetiracetam (21.6%), and topiramate (23.5%).

Time to first seizure analysis

Safety outcomes

Safety data have been published previously for Study 332; however, TEAEs were reported by 83.7% of patients receiving perampanel 8 mg/day and 71.5% of patients receiving placebo (Table 3).

No patients discontinued treatment because of a TEAE. In patients receiving perampanel 8 mg/day, 20% had serious TEAEs (11.7%) and 8% had TEAEs leading to discontinuation of perampanel treatment.

DISCLOSURES

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INTRODUCTION

• Determining whether the use of perampanel 8 mg/day leads to the attainment of first seizure event in patients with GTCS and patients with any seizure type when compared with placebo.

• Treatment with adjunctive perampanel 8 mg/day prolonged the time to first GTCS (45.3 days) or any type of seizure (31.2 days) in patients aged > 12 years with GTCs compared with placebo.

• Adjunctive perampanel doses of 8 mg/day have been previously shown to be generally well tolerated in patients with GTCs.

• These data are consistent with the primary efficacy endpoints of Study 332 and further support the efficacy of perampanel 8 mg/day for the treatment of GTCs.

BIBLIOGRAPHY

Conclusions

1. A special one-page presentation of this poster is also available by email or at the following website: http://www.fycompa.com

2. For any questions about this poster, please email or call Tia Brooks at tia.brooks@eisai.com or 925-677-7277.

CONCLUSION

1. Food and Drug Administration (FDA). Fycompa® Prescribing Information, February 2021. Available at: https://www.fycompa.com/-/media/Files/Fycompa/PDFs/Fycompa_PI.pdf


5. These data further support the efficacy of perampanel 8 mg/day for the treatment of GTCs.

6. Certain trade names, corporate/organizational names, or specific devices and/or products are used solely for the purpose of providing specific information and do not imply approval or endorsement of the use of the identified product(s) or trade name(s) by the U.S. Food and Drug Administration.

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