INTRODUCTION

- Pimavanserin is a selective serotonin receptor-modulating agent with inverse agonist/antagonist activity, which may mitigate symptoms associated with neurodegenerative conditions.

- Pimavanserin is currently approved for treatment of agitation associated with Alzheimer's disease psychosis.

METHODS

- Due to differences in study designs across studies included in this analysis, safety was evaluated in the following way:
  - Pooled data were from 6 double-blind, placebo-controlled parallel-group studies of patients with NDD who received pimavanserin 34 mg (N=610) or placebo (N=610) once daily (Table 1).
  - Guidance for the patient population, including similar patient characteristics, was consistent across studies, along with similar recording of the AUCx (any usage of cADM) or requiring any usage of cADM for up to 3 months prior to baseline.

OBJECTIVE

- To describe the tolerability of cADM use in pimavanserin-treated patients with neuropsychiatric disease.

RESULTS

- Table 2 summarizes the TEAEs in the NDD pooled population by cADM use.
- Table 3 provides a list of cADMs used by 5% or more of NDD- or NVD-only patients.

CONCLUSIONS

- Patients with NDD receiving pimavanserin in clinical trials commonly received cADMs.
- This analysis is limited in that studies were not designed to statistically test differences between patients with and without cADM use.
- Across 9 clinical trials there was no evidence that pimavanserin use resulted in a worse TEAE or serious TEAE profile in NDD patients taking cADMs.

REFERENCES


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