



## Short Note on Pimavanserin in Alzheimer's Disease Psychosis

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### INTRODUCTION

More than 40 million people worldwide suffer from dementia. Managing symptoms is especially difficult if accompanied by psychosis. Although no drug has been approved by the US Food and Drug Administration (FDA) for psychosis in dementia patients, typical antipsychotics are used off-label in severe cases where non-pharmacological interventions have failed. However, the use of antipsychotics in elderly patients with dementia-related psychosis has been associated with side effects such as impaired motor function, cognitive impairment, cerebrovascular events, and an increased risk of death. The new antipsychotic drug pimavanserin was designated by the US FDA as a breakthrough therapy for the treatment of DRP in 2017. The pivotal phase III Harmony study found that pimavanserin reduced psychosis relapse by 2.8 times compared with placebo. This favorable result may pave the way for the approval of pimavanserin in the DRP.

### DESCRIPTION

In this review, we discuss the pharmacological activity, clinical efficacy and safety of pimavanserin as a novel atypical antipsychotic with the potential to address unmet needs in older adults with DRP. The US Food and Drug Administration (FDA) have yet to approve a drug to treat DRP. Given the severity and high prevalence of BPSD, as well as the lack of FDA approved pharmacological treatments, many off-label drug classes have been used to treat BPSD. Atypical antipsychotics such as aripiprazole, risperidone, olanzapine and quetiapine are the most widely used and effective drugs for this purpose. However, in elderly patients with DRP, the use of antipsychotics is associated with adverse reactions such as impaired motor function, cognitive impairment, cerebrovascular events, and an increased risk of death. This review focuses on pimavanserin, a novel antipsychotic drug that received FDA breakthrough ther-

apy designation in 2017 for the treatment of DRP. This designation means that the FDA will expedite its review and development. Cummings demonstrated the efficacy of pimavanserin in the treatment of hallucinations and delusions associated with Parkinson's disease in a 6-week, randomized, placebo-controlled, parallel-group, phase III trial. The study randomly assigned 199 patients with Parkinson's disease psychosis to either pimavanserin 34 mg or a placebo. An international Delphi consensus panel of 11 experts in the treatment of BPSD chose risperidone as the recommended pharmacological option for this indication, with pimavanserin given the highest priority for the future. Treatment. Given its approval for Parkinson's disease related psychosis, consensus panel selection for future treatment, and promising published results from phase II and III clinical trials showing a superior efficacy profile of pimavanserin versus placebo compared with current pharmacological options, pimavanserin is likely to be used beyond Indication for treatment of DRP pending FDA approval.

### CONCLUSION

However, there are no published data on the status of its likely off-label use in clinical practice, to our knowledge. Preliminary clinical evidence suggests that pimavanserin may have a favorable benefit-risk profile for the short-term treatment of DRP, which helped qualify it as a breakthrough therapy for this FDA indication. The results of the Phase III Harmony trial will pave the way for the FDA to prioritize review and eventually approve pimavanserin for DRP.

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### CONFLICT OF INTEREST

The author's declared that they have no conflict of interest.

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