Oteseconazole: Adis Evaluation

Clinical Considerations

- First drug approved in the USA for RVVC
- Approval restricted to patients who are not of reproductive potential due to risk of embryo-fetal toxicity
- Reduces the recurrence of VVC compared with placebo
- Inhibits the growth of fluconazole-resistant strains of *Candida*
- Well tolerated, with the most common adverse reactions being headache and nausea

Plain Language Summary

Background and rationale

- Recurrent vulvovaginal candidiasis (RVVC), commonly known as chronic vaginal yeast infection, causes physical discomfort and psychological distress
- Current recommended treatments, including azole antifungals (e.g., fluconazole), for RVVC fail to prevent recurrence in about half of patients

Clinical findings

- Oteseconazole (Vivjoa®) is the first drug to gain approval for the treatment of RVVC in the USA after it significantly reduced the incidence of vulvovaginal candidiasis (VVC) recurrence in patients compared with placebo in pivotal phase 3 trials
- Oteseconazole reduces recurrence for over 36 weeks after the final dose of the drug, has activity against *Candida* strains that are resistant to azole antifungals, and is generally well tolerated

Conclusion

Oteseconazole is a valuable addition to the drugs available to treat RVVC