FDA Approves Clonidine Hydrochloride For Treatment of ADHD in Pediatric Patients

The treatment is the first liquid non-stimulant for attention deficit hyperactivity disorder to be approved in the United States.

The FDA has approved clonidine hydrochloride (Onyda XR; Tris Pharma), a once-daily oral treatment for attention deficit hyperactivity disorder (ADHD) as a monotherapy or adjunctive therapy to approved central nervous system (CNS) stimulant medications in pediatric patients 6 years of age and older. It is the first and only liquid non-stimulant ADHD medication to be approved in the US, and the only approved non-stimulant ADHD medication with nighttime dosing. According to the FDA, the approval follows adequate results from studies that evaluated extended-release tablets of clonidine hydrochloride in patients with ADHD.[1]

Clonidine hydrochloride, which is the hydrochloride salt form of clonidine, is an extended-release, oral suspension, liquid non-stimulant treatment for ADHD that is expected to be in pharmacies during the second half of 2024. It is a centrally acting alpha-2 adrenergic agonist and has become significant for patients who do not respond to or have an inadequate response to stimulant medications, or those who experience adverse effects (AEs) from them. Non-stimulants such as clonidine hydrochloride are increasingly used as an effective alternative to stimulant treatments.[1,2]

“People with ADHD require a range of therapeutic options that are designed for their individual needs because not every medication or type of therapy works for every patient,” said Ann Childress, MD, in a news release. “The approval of [clonidine hydrochloride], the only liquid non-stimulant ADHD medication, with nighttime dosing that shifts the release profile, is a convenient option for patients needing better ADHD control.”[1]

In a 2018 study published in *Psychiatry Investigation*, study authors assessed the efficacy and safety of extended-release clonidine treatment in patients with ADHD with or without Tourette syndrome. For this study, the medical records of 29 children and adolescents (age range: 5.2-17.8 years) who received extended-release clonidine were reviewed, with the effectiveness of the treatment being retrospectively measured at baseline, and then again after the 4-week and 12-week period based on Clinical Global Impression-Severity (CGI-S) and Clinical Global Impression-Improvement (CGI-I) scores.[3]

The study findings demonstrated that the patients’ ADHD symptoms were significantly decreased during the 12-week clonidine extended-release treatment ($F = 23.478$, $p < .001$, partial $\eta 2 = 0.540$), with 7 of 22 patients (31.8%) showing a treatment response. Additionally, of the 22 patients with ADHD, 17 had reported a prior history of insufficient response to psychostimulants and/or atomoxetine. The CGI-S scores for patients experiencing ADHD symptoms were decreased significantly during the 12-week period, and of the 20 patients experiencing Tourette symptoms, 16 had an inadequate response to antipsychotics prior to

clonidine treatment. The CGI-S scores for tic symptoms were also improved during the treatment period ($F = 15.137$, $p < .001$, partial $\eta 2 = 0.443$), with 5 patients (25.0%) demonstrating a treatment response.[3]

In this particular study, 19 patients (65.5%) of patients reported AEs, with the most common including somnolence (n = 9; 31%), dizziness (n = 5; 17.2%), fatigue (n = 1; 3.4%), insomnia (n = 1; 3.4%), night terrors (n = 1; 3.4%), hypotension (n = 1; 3.4%), nausea (n = 1; 3.4%), chest discomfort (n = 1; 3.4%), headache (n = 1; 3.4%), and an increase in both motor and vocal tics (n = 1, 3.4%). Additionally, 2 patients had to discontinue clonidine treatment due to their somnolence, and 6 patients discontinued within 12 weeks due to other AEs. An additional 2 patients stopped treatment due to lack of efficacy.[3]

“Securing FDA approval for [clonidine hydrochloride] is not just an important milestone, but a testament to our unwavering commitment to innovating and improving outcomes for this patient population,” said Ketan Mehta, founder and CEO at Tris Pharma, in the news release. “Our relentless pursuit to offer a range of ADHD medicines to patients of all ages does not stop here, and we look forward to continuing to expand our portfolio in other ADHD indications.”[1]

References

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