Product Update

Dyanavel™ XR Approved to Treat Attention-Deficit/Hyperactivity Disorder in Children

Tris Pharma, Inc., announced that the U.S. Food and Drug Administration has approved Dyanavel™ XR extended-release oral suspension, CII, for the treatment of attention-deficit/hyperactivity disorder (ADHD) in children 6 and older. With this approval, Dyanavel XR becomes the only once-daily, extended-release, amphetamine-based oral liquid approved for the treatment of ADHD in children.

The approval is based on a Phase 3 randomized, placebo-controlled, laboratory classroom efficacy study conducted with 108 children (ages 6 to 12 years). The study, which included a 5-week, open-label, dose optimization followed by a 1-week, double-blind treatment period, demonstrated a positive outcome by meeting its primary endpoint of change from pre-dose in the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP)-Combined score at 4 hours post-dosing. Dyanavel XR also met key secondary endpoints by demonstrating an onset of clinical effect at 1 hour that persisted through 13 hours post-dosing compared to placebo. The most common adverse reactions reported were epistaxis (i.e., nose bleed), allergic rhinitis, and upper abdominal pain.


Phase 2 Clinical Study of NBI-98854 for Adults With Tourette Syndrome Begins

Neurocrine Biosciences, Inc., announced it has expanded clinical efforts for NBI-98854 (valbenazine), a highly selective small molecule vesicular monoamine transporter 2 inhibitor, by initiating a Phase 2 clinical trial in adults with Tourette syndrome.

The study is a randomized, double-blind, placebo-controlled, multi-dose, parallel group study of up to 90 adults. Participants with Tourette syndrome will receive once-daily dosing of NBI-98854 during an 8-week treatment period to assess its safety, tolerability, and efficacy. The primary endpoint of the study is a change from baseline of placebo versus active scores using the Yale Global Tic Severity Scale at the end of Week 8. Data readout from the study is expected later in 2016.