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Shionogi submits NDA for INTUNIV

August 21, 2018 | News

Shire's partner, Shionogi, filed application to expand INTUNIV indication in Japan to include adults with ADHD.

Shire plc has announced that its partner in Japan, Shionogi & Co., Ltd has submitted a New Drug Application (NDA) for the manufacture and marketing in Japan of INTUNIV (guanfacine hydrochloride extended release) for the treatment of attention deficit hyperactivity disorder (ADHD) in adults. The Japanese Phase 3 clinical trial was the first ever to evaluate INTUNIV in adult patients (18 years and over) with ADHD.

“This is a key milestone, taking us a step closer to potentially providing INTUNIV to adults in Japan in addition to the approved pediatric indication,” said Brigitte Robertson, M.D., VP and Head of Global Clinical Development, Neuroscience, Shire. “There remains a significant need for new non-stimulant treatment options for adults being diagnosed with ADHD in Japan,” she said.

INTUNIV, a non-stimulant, selective alpha-2A adrenergic receptor agonist has been approved as a treatment for child and adolescent patients (6 to 17 years old) with ADHD in Japan since March 2017. INTUNIV is being co-developed and commercialized by Shire and Shionogi under a licensing contract signed in 2011.

ADHD is characterized by 3 core symptoms of inattention, hyperactivity or impulsivity, or a combination of these symptoms and can have substantial impact on major areas of life, including: schooling, work and employment, behaviour, and social functioning. Non-stimulant medications are an important alternative to stimulants for some patients with ADHD.

Topline results from the Phase 3 efficacy trial in adults in Japan showed INTUNIV (4 to 6mg), administered once daily, met its primary endpoint, demonstrating superiority over placebo in the improvement of ADHD symptoms. Results also showed statistically significant improvement over placebo in patients’ global functioning.

This Phase 3 trial was a 12- week, randomized, double-blind, multi-center, parallel-group, placebo-controlled study in 201 adult patients (18 years old and over) with ADHD. The primary efficacy analysis demonstrated that INTUNIV (4 to 6 mg), administered as a once-daily dose, was superior to placebo with respect to the change from baseline to endpoint on a clinician administered ADHD rating scale (ADHD-RS-IV with adults prompts) total score. INTUNIV also demonstrated significance over placebo at the end of treatment on the secondary efficacy analysis of the Clinical Global Impression-

Improvement scale (CGI-I), a standardized assessment tool that allows clinicians to rate changes in patients' clinical condition over time. In this study, clinicians rated more than twice as many patients taking INTUNIV as "improved" and nearly half of patients as "much improved" or "very much improved".

Treatment-emergent adverse events in the study were generally mild to moderate in severity and similar to those observed in previous INTUNIV studies with no new or unexpected safety findings. Treatment-emergent adverse events reported at more than or equal to 10% for INTUNIV were somnolence, dry mouth, blood pressure decreased, nasopharyngitis, dizziness postural and constipation.