**U.S. Food and Drug Administration Approval of Fanapt® for Treatment of Schizophrenia**

Vanda Pharmaceuticals, Inc., announced that the U.S. Food and Drug Administration (FDA) has approved their supplemental New Drug Application for Fanapt®, modifying and expanding the prescribing information to describe the effectiveness of Fanapt as a maintenance treatment for schizophrenia in adults. FDA approval was based on the results of the REPRIEVE placebo-controlled clinical study that evaluated the long-term maintenance of efficacy and safety of Fanapt, in which 79.6% of patients treated with Fanapt remained relapse-free compared to 36.6% for placebo-treated patients.

The REPRIEVE study was a randomized, double-blind, placebo-controlled study to evaluate prevention of relapse in adult patients with schizophrenia receiving either flexible dose Fanapt or placebo. Participants were adults with schizophrenia titrated up to 12 mg/day given as 6 mg twice daily with open-label Fanapt and then stabilized for a further 14 to 24 weeks with a flexible dose Fanapt regimen (between 8 mg/day and 24 mg/day given twice daily). Participants who remained clinically stable for at least 12 weeks entered the relapse prevention phase and were randomized 1:1 to either continue on the same flexible dose regimen or withdraw from Fanapt to matched placebo in a double-blinded fashion. Participants were followed for up to 26 weeks and were withdrawn upon showing signs of relapse or impending relapse. A predefined unblinded interim analysis was conducted after 68 relapse or impending relapse events were observed. The primary outcome was time-to-relapse or impending relapse using the interim analysis population. Of 587 patients entering the stabilization phase, 195 (33%) met the criteria for the double-blind relapse prevention phase, with 99 randomized to continue with Fanapt and 96 to switch to placebo. The study was stopped early after 68 events were observed and confirmed the hypothesis that Fanapt was more effective than placebo in relapse preventions.

**Shire Announces Positive Topline Results of SHP465 Efficacy and Safety Study in Adults With ADHD**

Shire announced positive topline results from a 4-week randomized, double-blind, multicenter, parallel-group, placebo-controlled, forced-dose titration, efficacy, and safety study in 275 adults ages 18 to 55 with attention-deficit/hyperactivity disorder (ADHD). SHP465 is an investigational oral stimulant medication being evaluated in the United States as a potential treatment for ADHD.

The primary efficacy analysis showed that SHP465 12.5 mg and 37.5 mg, both administered as a daily morning dose, were superior to placebo with respect to the change from baseline on a clinically administered ADHD rating scale total score, with least squares mean differences from placebo at Week 4 of –8.1 for 12.5 mg and –13.3 for 37.5 mg. SHP465 12.5 mg and 37.5 mg doses were also significantly better than placebo on the key secondary efficacy analysis of the Clinical Global Impression Improvement scale at Week 4 (–0.8 for 12.5 mg and –1.2 for 37.5 mg), suggesting a marked clinical improvement in patients’ global functioning.