Phase III Data Show Vanda Pharmaceuticals' Tasimelteon (VEC-162) Significantly Improves Sleep in Patients with Chronic Insomnia

June 26, 2008

Study Meets Primary Endpoint, with Positive Effect Sustained Through Duration of 4-Week Study

ROCKVILLE, Md., June 26 /PRNewswire-FirstCall/ -- Vanda Pharmaceuticals Inc. (Nasdaq: VNDA) (Vanda) today announced positive top-line results from a Phase III trial showing that its investigational drug candidate, tasimelteon (VEC-162), a novel melatonin agonist, met the primary endpoint of the trial and significantly improved sleep in adult patients with chronic insomnia.

We are excited that the results of this Phase III chronic insomnia study demonstrate the clinical utility of tasimelteon and the ability of the compound to treat sleep disorders over a period of four weeks. The mechanism of action of tasimelteon as a circadian regulator gives Vanda the opportunity to explore its use for the treatment of circadian rhythm sleep disorders as well as chronic primary insomnia, stated Paolo Baroldi, MD, PhD, Vanda's Chief Medical Officer.

This Phase III, multi-center, placebo-controlled, 4-week trial evaluated 322 patients with chronic primary insomnia. Patients were randomized to receive either 20 mg or 50 mg of tasimelteon or placebo over the course of four weeks. The primary endpoint consisted of the evaluation of the immediate and short-term (average of Nights 1 and 8) ability of tasimelteon to improve sleep onset as measured by Latency to Persistent Sleep (LPS) through polysomnography (PSG). Secondary endpoints evaluated tasimelteon's ability to maintain improvements on sleep onset after long-term (average of Nights 22 and 29) use of the compound as well as measures of sleep duration (Total Sleep Time, TST) and sleep maintenance (Wake After Sleep Onset, WASO). Patients were eligible for the study if symptoms of insomnia were chronic and LPS was greater than 30 minutes.

Significant Improvement in Sleep Onset Sustained through Study Duration

These results demonstrate that tasimelteon was able to improve LPS significantly, and that this effect persisted for the 4 week duration of the study. The results on LPS at night 1 (N1)/night 8 (N8), and night 22 (N22)/night 29 (N29) are as follows.

-- Mean LPS at baseline (before drug treatment) was 78.8 minutes in the 20mg group, 76.4 minutes in the 50mg group, and 78.2 minutes in the placebo group. On Nights 1 and 8 of treatment, mean LPS improved by 45.0 minutes in the 20mg group (p