



## **Transcept Pharmaceuticals Announces Purdue's Exercise of Option to Commercialize Intermezzo® in the United States**

POINT RICHMOND, Calif., Nov. 30, 2011 /PRNewswire/ -- Transcept Pharmaceuticals, Inc. (Nasdaq: TSPT) announced today that Purdue has exercised its option to commercialize Intermezzo® in the United States. Purdue plans to launch Intermezzo in the second quarter of 2012 and to invest approximately \$100 million to support sales and marketing during the first year of commercialization.

On November 23, 2011, the U.S. Food Drug Administration (FDA) approved Intermezzo® (zolpidem tartrate) sublingual tablet C-IV for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Intermezzo is not indicated for the treatment of middle-of-the-night insomnia when the patient has fewer than 4 hours of bedtime remaining before the planned time of waking.

Middle-of-the-night awakening with difficulty falling back to sleep is a common sleep problem, and Intermezzo is the first and only prescription sleep aid approved for dosing in the middle of the night to treat this form of insomnia.

"Intermezzo provides an important new therapeutic option for physicians and patients for the treatment of insomnia characterized by middle-of-the-night awakening," said John H. Stewart, President and Chief Executive Officer of Purdue Pharma L.P. "This decision marks our entry into a new therapeutic area, and underscores the company's commitment to therapeutic advances to address unmet medical needs."

"We are excited that Purdue will be launching and marketing Intermezzo in the United States," stated Glenn A. Oclassen, President and Chief Executive Officer of Transcept Pharmaceuticals. "Purdue has one of the most accomplished primary care sales and marketing organizations in the industry. We believe their commercial expertise provides a strong foundation to establish Intermezzo as a successful brand in the insomnia category."

### **About the Transcept—Purdue Intermezzo Commercialization Agreement**

Transcept and Purdue are parties to a collaboration agreement for the development and commercialization of Intermezzo in the United States. Purdue has the right to negotiate for the commercialization of Intermezzo in Mexico and Canada. Transcept retains all rights to Intermezzo in the rest of the world.

Under the terms of the agreement, Purdue will assume responsibility for activities and expense associated with Intermezzo sales and marketing, manufacturing, patent defense, and post-approval studies. Transcept will share in patent defense costs, capped at certain annual and aggregate amounts.

Two patents related to the formulation of Intermezzo have been issued by the United States Patent and Trademark Office. Transcept has submitted these patents for publication in the FDA Orange Book. Transcept will be entitled to receive a \$10.0 million milestone payment after either of these patents is published in the Orange Book. Transcept expects that both patents will be published in the Orange Book at the end of December 2011. Transcept is also eligible to receive up to an additional \$80 million in sales and intellectual property related milestone payments pursuant to the terms of its collaboration agreement with Purdue.

Purdue will pay Transcept a tiered base royalty on U.S. net sales of Intermezzo that ranges from the mid-teens to the mid-20% level. The base royalty is tiered depending upon the achievement of certain fixed net sales thresholds by Purdue, which net sales levels reset each year for the purpose of calculating the royalty.

Transcept has the option to co-promote Intermezzo to psychiatrists in the United States as early as the first anniversary of commercial launch of Intermezzo, and as late as approximately 4.5 years post-launch. Upon entry into the market under the co-promote option, Transcept is entitled to receive an additional co-promote royalty from Purdue on net revenue that is generated by psychiatrist prescriptions, ranging from 40%, if Transcept begins marketing to psychiatrists in the first month following the one year anniversary of commercial launch of Intermezzo in the United States, down to approximately 22%, if Transcept does not begin marketing to psychiatrists until 55 months after the commercial launch of Intermezzo. Net revenue qualifying for this additional co-promote royalty is limited by an annual cap of 15% of total Intermezzo annual net sales in the United States.

## About Intermezzo

Intermezzo® (zolpidem tartrate) sublingual tablet C-IV is indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Intermezzo is not indicated for the treatment of middle-of-the-night insomnia when the patient has fewer than 4 hours of bedtime remaining before the time of waking.

Intermezzo is formulated as a sublingual tablet that contains a bicarbonate-carbonate buffer and is intended to be placed under the tongue where it is allowed to disintegrate completely before swallowing. Intermezzo is to be taken in bed when a patient wakes in the middle of the night and has difficulty returning to sleep.

The recommended dose of Intermezzo for non-elderly patients is 1.75 mg for women and 3.5 mg for men, taken only once per night as needed if a middle-of-the-night awakening is followed by difficulty returning to sleep. The 1.75 mg dose is also recommended for patients over the age of 65.

The safety and efficacy of Intermezzo were evaluated in a sleep laboratory study and an outpatient study. In both studies, treatment with Intermezzo after a middle-of-the-night awakening helped patients return to sleep significantly faster than placebo.

In the sleep laboratory study, 82 adult patients aged 19 to 64 years (58 women, 24 men) with a history of difficulty returning to sleep after middle-of-the-night awakenings were evaluated in a double-blind, placebo-controlled, 3-period cross-over trial. The primary outcome measure was latency to persistent sleep. Doses of 3.5 mg and 1.75 mg of Intermezzo significantly decreased both objective and subjective sleep latency after a scheduled middle-of-the-night awakening as compared to placebo. The effect on sleep latency was similar for females receiving 1.75 mg of Intermezzo and males receiving 3.5 mg of Intermezzo.

In the outpatient study, 295 adult patients aged 18 to 64 years (201 women, 94 men) with difficulty returning to sleep after middle-of-the-night awakenings were evaluated in a double-blind, placebo-controlled 4-week trial. Patients took study drug (3.5 mg of Intermezzo or placebo) on an as needed (prn) basis, when they had difficulty returning to sleep after waking in the middle of the night, provided they had at least 4 hours time remaining in bed. Subjective time to fall back to sleep after middle-of-the-night awakening was significantly shorter for Intermezzo 3.5 mg compared to placebo.

The most commonly reported adverse reactions in these studies were headache, nausea and fatigue. In the outpatient study, the incidence of these adverse reactions was: headache, 3% for Intermezzo and 1% for placebo; nausea, 1% for Intermezzo and 1% for placebo, and fatigue, 1% for Intermezzo and 0% for placebo.

## Important Safety Information About Intermezzo

Intermezzo, like other sedative-hypnotic drugs, has central nervous system (CNS) depressant effects. Co-administration with other CNS depressants (e.g., benzodiazepines, opioids, tricyclic antidepressants, alcohol) increases the risk of CNS depression. The use of Intermezzo with other sedative-hypnotics (including other zolpidem products) at bedtime or in the middle of the night is not recommended. The failure of insomnia to remit after 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated.

Intermezzo is contraindicated in patients with known hypersensitivity to zolpidem. Cases of angioedema involving tongue, glottis or larynx have been reported in patients after taking the first or subsequent doses of zolpidem. Some patients have had additional symptoms such as dyspnea, throat closing, or nausea and vomiting that suggest anaphylaxis. Some patients have required medical therapy in the emergency department. These symptoms may be fatal. Patients who develop angioedema or anaphylaxis after treatment with zolpidem should not be re-challenged with Intermezzo.

In a driving study, healthy subjects who received Intermezzo with fewer than four hours of bedtime remaining had evidence of impaired driving compared to subjects who received placebo. The risk of next-day driving impairment (and psychomotor impairment) is increased if Intermezzo is taken with less than 4 hours of bedtime remaining; if higher than recommended dose is taken; if co-administered with other CNS depressants; or co-administered with other drugs that increase the blood levels of zolpidem. A small negative effect on SDLP (standard deviation of lateral position, a measure of driving impairment) may remain in some patients 4 hours after the 1.75 mg dose in women, and after the 3.5 mg dose in men, such that a potential negative effect on driving cannot be completely excluded.

Abnormal thinking and behavior changes have been reported to occur in association with the use of sedative-hypnotics, including decreased inhibition, bizarre behavior, agitation, and depersonalization, as well as visual and auditory hallucinations. Complex behaviors such as "sleep-driving" (i.e., driving while not fully awake after ingestion of a sedative hypnotic with amnesia for the event) have been reported in sedative-hypnotic-naïve as well as in sedative-hypnotic-experienced persons. Although behaviors such as "sleep-driving" have occurred with zolpidem alone at therapeutic doses, the co-administration of zolpidem with alcohol and other CNS depressants increases the risk of such behaviors, as does the use of zolpidem at doses exceeding the maximum recommended dose. Discontinuation of zolpidem should be strongly considered for patients who report a "sleep-

driving" episode. The emergence of any new behavioral sign or symptom of concern requires careful and immediate evaluation. Other complex behaviors (e.g., preparing and eating food, making phone calls or having sex) have been reported in patients who are not fully awake after taking a sedative-hypnotic. As with "sleep-driving," patients usually do not remember these events. Amnesia, anxiety and other neuro-psychiatric symptoms may also occur.

In primarily depressed patients, worsening of depression, including suicidal thoughts and actions (including completed suicides), has been reported in association with the use of sedative-hypnotics. Suicidal tendencies may be present in such patients and protective measures may be required. Intentional over-dosage is more common in this group of patients; therefore, the lowest number of tablets that is feasible should be prescribed for the patient at any one time.

Because persons with a history of addiction to or abuse of drugs or alcohol are at increased risk for misuse, abuse and addiction of zolpidem, they should be monitored carefully when receiving Intermezzo. Zolpidem tartrate is classified as a Schedule IV controlled substance by federal regulation. Post-marketing reports of abuse, dependence, and withdrawal resulting from the use of oral zolpidem tartrate have been received. There have been reports of withdrawal signs and symptoms following the rapid dose decrease or abrupt discontinuation of zolpidem.

Intermezzo is to be taken in bed when a patient wakes in the middle of the night and has difficulty returning to sleep. For optimal effect, Intermezzo should not be administered with or immediately after a meal. Intermezzo is not indicated for the treatment of middle-of-the-night insomnia when the patient has fewer than 4 hours of bedtime remaining before the planned time of waking. Patients should not drive or undertake other dangerous activities after taking Intermezzo until they are fully awake. Patients should be cautioned about possible combined effects with CNS-depressant drugs. Intermezzo should not be taken with alcohol.

To view the full prescribing information please visit:  
[http://www.transcept.com/images/stories/docs/intermezzo\\_pi\\_23nov\\_2011.pdf](http://www.transcept.com/images/stories/docs/intermezzo_pi_23nov_2011.pdf).

## **About Transcept Pharmaceuticals**

Transcept Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on the development and commercialization of proprietary products that address important therapeutic needs in the field of neuroscience. Intermezzo® (zolpidem tartrate) sublingual tablet C-IV is the first FDA approved Transcept product and is indicated for use as needed for the treatment of insomnia when a middle-of-the-night awakening is followed by difficulty returning to sleep. Transcept and Purdue have entered into a collaboration agreement for the development and commercialization of Intermezzo in the United States .

Transcept is currently conducting a Phase 2 study of an investigational product, TO-2061, to determine its effectiveness and safety when used as augmentation treatment in patients with obsessive-compulsive disorder who have not adequately responded to first-line pharmacotherapy. For further information, please visit the Transcept website at [www.transcept.com](http://www.transcept.com).

## **Conference Call and Webcast Information**

Transcept will host a conference call and webcast on Thursday, December 01, 2011, at 8:30 a.m. ET to discuss the exercise of the Purdue option to commercialize Intermezzo in the United States. Telephone numbers for the live conference call are 877-638-4558 (U.S.) or 914-495-8537 (International). The webcast can be accessed on the Investors page of the Transcept website at [www.transcept.com](http://www.transcept.com) and will be available for replay until close of business on December 31, 2011. A playback of the call will be available through December 9, 2011, by dialing 855-859-2056 (U.S.) or 404-537-3406 (International), replay ID: 32092646.

## **Forward Looking Statements**

This press release contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this press release regarding our strategy, future operations, future financial position, future revenues, projected expenses, prospects, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to the following: the expected timing for and the success of the commercial launch of Intermezzo by Purdue in the United States; Purdue plans to invest approximately \$100 million to support sales and marketing during the first year of commercialization; expectation that Transcept patents will be published in the FDA Orange Book, and the timing for such publication; expectations regarding the receipt of royalties and milestone payments from Purdue under the Intermezzo collaboration agreement. Transcept may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in our forward-looking statements, and you should not place undue reliance on these forward-looking statements. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Transcept makes, include, but are not limited to, the following: achieving acceptance of Intermezzo by physicians, patients and third party payors; supplying sufficient quantities of Intermezzo from third party manufacturers and suppliers to meet anticipated market demand; the impact of competitive products and the market for Intermezzo generally; our dependence on our collaboration with Purdue; and

obtaining, maintaining and protecting regulatory exclusivity and intellectual property protection for Intermezzo. These and other risks are described in greater detail in the "Risk Factors" section of Transcept periodic reports filed with the SEC. Forward-looking statements do not reflect the potential impact of any future in-licensing, collaborations, acquisitions, mergers, dispositions, joint ventures, or investments Transcept may enter into or make. Transcept does not assume any obligation to update any forward-looking statements.

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