

## **Transcept Pharmaceuticals Announces National Product Launch of Intermezzo® by Purdue Pharma L.P.**

### **Intermezzo is the First and Only Prescription Sleep Aid Approved for Use As Needed for the Treatment of Insomnia When a Middle-of-the-Night Awakening is Followed by Difficulty Returning to Sleep and the Patient has at Least Four Hours of Bedtime Remaining Before the Planned Time of Waking**

POINT RICHMOND, Calif., April 5, 2012 /PRNewswire/ -- Transcept Pharmaceuticals, Inc. (Nasdaq: TSPT) announced today that Intermezzo® (zolpidem tartrate) sublingual tablet CIV is now available by prescription in 1.75 mg and 3.5 mg dosage strengths in retail pharmacies nationwide. Intermezzo is the first and only prescription sleep aid approved for middle-of-the-night dosing, and should only be taken once per night in bed, as needed, when a patient wakes up in the middle of the night and has difficulty returning to sleep. Intermezzo is not indicated for use when a patient has fewer than four hours of bedtime remaining before the planned time of waking.

(Logo: <http://photos.prnewswire.com/prnh/20101102/SF93452LOGO>)

Intermezzo was developed by Transcept Pharmaceuticals and is the Company's first FDA approved product. Intermezzo is being marketed in the United States under the terms of a collaboration agreement between Transcept and Purdue Pharma L.P.

"Until today, patients with insomnia did not have an appropriate or FDA approved treatment option to take in the middle of the night because all other prescription sleep aids are approved to be used only at bedtime," said Thomas Roth, Ph.D., Director of Sleep Medicine, Henry Ford Hospital. "Intermezzo represents an important treatment option for those insomnia patients who suffer difficulty falling back to sleep after a middle of the night awakening and seek a sleep aid that they can use only when they really need it to fall back to sleep in the middle of the night."

Intermezzo, which was approved by the U.S. Food and Drug Administration in November 2011, is available in spearmint-flavored sublingual tablets that are placed under the tongue and allowed to disintegrate completely before swallowing. Intermezzo contains a bicarbonate-carbonate buffer. On average, Intermezzo is rapidly absorbed in both genders, with a mean time to maximum plasma levels across studies that ranged from about 35 minutes to about 75 minutes. The recommended and maximum dose of Intermezzo is 1.75 mg for female adults and 3.5 mg for male adults, taken only once per night as needed when a middle-of-the-night awakening is followed by difficulty returning to sleep and the patient has at least four hours of bedtime remaining. The recommended doses for women and men are different because women clear zolpidem from the body at a lower rate than men. For optimal effect, Intermezzo should not be administered with or immediately after a meal.

"When the insomnia problem is middle-of-the-night awakening followed by difficulty returning to sleep, Intermezzo offers a new treatment strategy that has the potential to make a meaningful difference for many patients," stated Glenn A. Oclassen, President and Chief Executive Officer of Transcept Pharmaceuticals. "Purdue Pharma, our Intermezzo U.S. sales and marketing partner, is firmly committed to helping patients affected by this form of insomnia, and we are confident in their ability to make Intermezzo a commercial success."

#### **Important Safety Information**

Intermezzo is contraindicated in patients with known hypersensitivity to zolpidem. Observed reactions with zolpidem include anaphylaxis and angioedema.

Co-administration with Intermezzo and other CNS depressants increases the risk of CNS depression. Intermezzo should not be taken with alcohol. The use of Intermezzo with other sedative-hypnotics (including other zolpidem products) at bedtime or the middle of the night is not recommended.

The risk of next-day driving impairment (and psychomotor impairment) is increased if Intermezzo is taken with less than four hours of bedtime remaining; if a 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 four 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.

Additional Important Safety Information is presented below.

## About Intermezzo

Intermezzo is the first and only prescription sleep aid approved 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 four hours of bedtime remaining before the planned time of waking. Intermezzo is contraindicated in patients with known hypersensitivity to zolpidem. Observed reactions with zolpidem include anaphylaxis and angioedema.

The safety and efficacy of Intermezzo was evaluated in two randomized, double-blind, placebo-controlled studies in patients with insomnia characterized by difficulty returning to sleep after a middle-of-the-night awakening. Patients met the diagnosis for primary insomnia as defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM-IV-TR) and had at least 3 prolonged middle-of-the-night awakenings per week of at least 30 minutes in duration.

In a four-week outpatient study in 295 adult patients aged 18 to 64 years (201 females, 94 males), Intermezzo 3.5 mg or placebo was taken on an as-needed basis following spontaneous awakenings when patients had difficulty returning to sleep after waking in the middle of the night, provided they had at least four hours remaining in bed. Subjective time to fall back to sleep after a middle-of-the-night awakening was significantly shorter for Intermezzo 3.5 mg (38 minutes) compared to placebo (56 minutes). The most commonly observed adverse reactions (> 1%) were headache (Intermezzo 3%, placebo 1%), nausea (1% for both patient groups), and fatigue (Intermezzo 1%, placebo 0%).

In a sleep laboratory study, 82 adult patients aged 19 to 64 years (58 females, 24 males) were evaluated in a 3-period, 2-consecutive-night treatment period cross-over design. Patients were awakened four hours after bedtime, administered Intermezzo 3.5 mg, 1.75 mg, or placebo, and were kept awake for 30 minutes before lights-out. As compared to placebo, Intermezzo significantly decreased objective mean time to fall back asleep after a middle-of-the-night awakening (women taking 1.75 mg: 16 min vs. placebo: 28 min; men taking 3.5 mg: 13 min vs. placebo: 29 min).

## How to Take Intermezzo

The recommended and maximum dose of Intermezzo for male adults is 3.5 mg and for female adults is 1.75 mg, administered as a sublingual tablet only once per night as needed if a middle-of-the-night awakening is followed by difficulty returning to sleep. The recommended doses for men and women are different because women clear zolpidem from the body at a lower rate than men.

The recommended dose for elderly men and women over 65 years old or patients with hepatic impairment is 1.75 mg. The recommended dose for men and women who are taking concomitant CNS depressants is 1.75 mg. Dose adjustment of concomitant CNS depressants may be necessary when co-administered with Intermezzo because of potentially additive effects. The use of Intermezzo with other sedative-hypnotics (including other zolpidem products) at bedtime or the middle of the night is not recommended.

Intermezzo is to be taken in bed when a patient wakes in the middle of the night and has difficulty returning to sleep. Intermezzo should only be taken if the patient has at least four hours of bedtime remaining before the planned time of waking.

Intermezzo should be placed under the tongue and allowed to disintegrate completely before swallowing. The tablet should not be swallowed whole. For optimal effect, Intermezzo should not be administered with or immediately after a meal. The blister should be removed from the pouch just prior to dosing.

Each sublingual tablet is individually packaged in a foil blister inside a unit-dose pouch. Before going to bed, a single pouch should be placed by the bedside with a clock or watch nearby. All other unopened Intermezzo pouches should be stored with other medicines away from the bedside. Patients should open the Intermezzo pouch only when they are ready to use it.

Patients can either use the Dosing Time Chart or the Dosing Time Tool that comes with Intermezzo to find the latest time during the night they can take Intermezzo.

**Dosing Time Tool:** Patients turn a wheel to find the earliest time they must be awake, which corresponds with instructions to take Intermezzo before a specified time.

**Dosing Time Chart:** The chart helps patients locate the earliest time they need to be awake and match it to the latest time they can take Intermezzo.

When patients wake in the morning, they should make sure that at least four hours have passed since they took Intermezzo

and they feel fully awake before driving or engaging in other activities requiring full mental alertness. Patients should not do dangerous activities until they know how Intermezzo affects them.

### **Additional Important Safety Information**

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.

Cases of angioedema involving the 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. Angioedema and additional symptoms suggesting anaphylaxis may be fatal. Patients who develop angioedema or anaphylaxis should not be re-challenged.

Abnormal thinking and behavior changes have been reported in patients treated with a sedative-hypnotic, including zolpidem. Complex behaviors, including driving or eating while not fully awake, with amnesia for the event, as well as visual and auditory hallucinations and abnormal behaviors such as decreased inhibition, bizarre behavior, agitation, and depersonalization may occur. 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 Intermezzo should be strongly considered for patients reporting a "sleep-driving" episode.

In primarily depressed patients, worsening of depression, including suicidal thoughts and actions (including completed suicides) have been reported with the use of sedative-hypnotics. Intentional overdose is more common in this group of patients; therefore, protective measures may be required. Prescribe the least amount of Intermezzo that is feasible in these patients.

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 a Schedule IV controlled substance. Post-marketing reports of abuse, dependence, and withdrawal resulting from use of oral zolpidem tartrate have been received. Zolpidem has produced withdrawal signs and symptoms following a rapid dose decrease or abrupt discontinuation.

For additional information, please read the Intermezzo Full Prescribing Information available at <http://app.purduepharma.com/xmlpublishing/pi.aspx?id=i>.

### **About Transcept**

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. Purdue holds commercialization and development rights for Intermezzo in the United States. Transcept is currently conducting a Phase 2 study of an investigational product, TO-2061, in patients with obsessive-compulsive disorder. For further information about Transcept, please visit [www.transcept.com](http://www.transcept.com).

### **About Purdue Pharma L.P.**

Purdue Pharma L.P. and its independent associated companies are privately-held pharmaceutical companies known for pioneering research on persistent pain. Headquartered in Stamford, Conn., Purdue Pharma L.P. is engaged in the research, development, production, and distribution of both prescription and over-the-counter medicines and hospital products. Additional information about Purdue Pharma L.P. can be found at [www.purduepharma.com](http://www.purduepharma.com).

### **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, prospects, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to the potential for Intermezzo to make a meaningful difference for many patients and to be a commercial success. Transcept and/or Intermezzo may not actually 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's Annual Report on Form 10-K filed on March 30, 2012 and other 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.

**Contact Information**

Greg Mann

Transcept Pharmaceuticals, Inc.

510-215-3567

[gmann@transcept.com](mailto:gmann@transcept.com)

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