



## **Transcept Pharmaceuticals Announces Expected FDA Extension of Regulatory Review Period for Intermezzo(R)**

RICHMOND, Calif., June 11, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Transcept Pharmaceuticals, Inc. (Nasdaq: TSPT) announced today that the U.S. Food and Drug Administration (FDA) has informed the company that it should expect to receive formal notice of a three month extension of the review period for the new drug application (NDA) for Intermezzo(R) (zolpidem tartrate sublingual tablet). The Intermezzo(R) NDA had been assigned a Prescription Drug User Fee Act (PDUFA) date of July 30, 2009. Under this revised timeline, Transcept now anticipates action from the FDA on the NDA on or before October 31, 2009.

In the normal course of the Intermezzo(R) NDA review, the FDA previously requested additional information regarding middle of the night dosing instructions. As both the request and the Transcept response occurred late in the review cycle, the FDA has informed the company that it will extend the NDA review cycle by three months to consider the new information.

Glenn A. Oclassen, President and Chief Executive Officer, commented, "Although we have not yet received a formal written notification from the FDA, our conversations with them indicate that additional review time for the Intermezzo(R) NDA will be necessary. We felt it our responsibility to inform shareholders in advance of a formal FDA notification and will update our shareholders as appropriate after such notice is received."

Mr. Oclassen added, "We appreciate the willingness of the FDA to take the time necessary to fully consider our recent amendment to the Intermezzo(R) NDA. We remain confident in the strength of our regulatory submissions and look forward to working with the FDA as it completes its review. Our goal remains to provide a new and important therapeutic for those patients who suffer from middle of the night awakenings with difficulty returning to sleep."

### About Intermezzo(R)

Intermezzo(R) Phase 3 clinical trials have been completed and, on September 30, 2008, Transcept submitted an NDA to the FDA, which was accepted for filing and assigned a PDUFA date of July 30, 2009. On June 10, 2009 Transcept received notice that the FDA would require up to an additional three months to complete its review of the Intermezzo(R) NDA. Under the revised timeline, Transcept now anticipates action from the FDA on the NDA on or before October 31, 2009.

If approved within the anticipated time frame, Intermezzo(R) will be the first commercially available sleep aid designed specifically for use in the middle of the night when patients awaken and have difficulty returning to sleep. As part of the NDA submission, Transcept requested that the FDA grant three years of Hatch-Waxman marketing exclusivity to Intermezzo(R). Transcept is also actively pursuing patents to cover Intermezzo(R) in the United States and key non-U.S. markets.

### 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 neuroscience. On January 30, 2009, Transcept completed a merger with Novacea, Inc. As part of the transaction, Novacea changed its name to "Transcept Pharmaceuticals, Inc." and its NASDAQ ticker symbol to "TSPT." For further information, please visit the company's website at: <http://www.transcept.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, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to the timing of potential FDA approval of the Intermezzo(R) NDA and Intermezzo(R) being the first commercially available sleep aid in the United States in its target indication. Transcept may not actually achieve the plans, intentions or expectations 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 and expectations disclosed in the forward-looking statements we make. Various important factors could cause actual results or events to differ materially from the forward-looking statements that Transcept makes, including risks related to: the opinion of the FDA on the sufficiency of the NDA to support marketing approval of Intermezzo(R); FDA review of the additional information recently provided by Transcept; the grant by the FDA and maintenance of exclusivity to

Intermezzo(R) under Hatch-Waxman; commercial acceptance of Intermezzo(R), if approved; unforeseen expenses related to FDA approval, commercialization or the business of Transcept generally; Transcept dependence on third parties to manufacture Intermezzo(R); obtaining, maintaining and protecting the intellectual property incorporated into Intermezzo(R); and, if sought, the ability of Transcept to obtain additional funding to support its business activities. 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, except as required by law.

Contact:

The Ruth Group  
Investors / Media  
Jason Rando  
(646) 536-7025  
jrando@theruthgroup.com

SOURCE Transcept Pharmaceuticals, Inc.

<http://www.transcept.com>

Copyright (C) 2009 PR Newswire. All rights reserved