



## **Transcept Pharmaceuticals Receives Notice of Allowance for Second U.S. Patent Application Covering *Intermezzo*(R)**

POINT RICHMOND, Calif., Dec 14, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Transcept Pharmaceuticals, Inc. (Nasdaq: TSPT) today announced that it has received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for claims under U.S. patent application no. 11/060,641, which covers the composition and use of *Intermezzo* (R) (zolpidem tartrate sublingual tablet), the lead Transcept product candidate. Once issued, this patent will expire no earlier than February 2025.

"This is the second USPTO Notice of Allowance issued to Transcept to cover our proprietary low-dose sublingual *Intermezzo* (R) formulation. We are pleased with the continued progress of our patent prosecution efforts," commented Glenn A. Oclassen, President and Chief Executive Officer.

"Other key elements in our program to protect *Intermezzo*(R) include a request to the U.S. Food and Drug Administration (FDA) to grant three years of Hatch-Waxman regulatory exclusivity to *Intermezzo*(R), and multiple applications on file with the USPTO related to an additional family of patents to cover methods of treating middle of the night awakenings."

Under the terms of the exclusive license and collaboration agreement between Transcept and Purdue Pharmaceutical Products, L.P. to commercialize *Intermezzo*(R) in the United States, Transcept is eligible to receive one \$10 million milestone payment from Purdue after either of the two formulation patents, once issued, is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book. The obligation of Purdue to make this milestone payment is subject to an FDA approval of *Intermezzo*(R) and to Purdue electing to continue with the alliance after its review of the terms of such FDA approval. This single \$10 million milestone payment is part of the previously announced \$90 million of potential milestones which Transcept is eligible to receive upon the achievement of certain intellectual property and U.S. net sales targets.

### *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. The most advanced Transcept product candidate is *Intermezzo*(R) (zolpidem tartrate sublingual tablet), for which a New Drug Application (NDA) was submitted to the U.S. Food and Drug Administration (FDA) in September 2008 seeking approval as a prescription sleep aid for use in the middle of the night at the time a patient awakens and has difficulty returning to sleep. In October 2009, Transcept received a Complete Response Letter from the FDA on the *Intermezzo*(R) NDA and is working to respond to issues raised in the letter. Transcept and Purdue Pharmaceutical Products, L.P. have entered into a collaboration agreement for the development and commercialization of *Intermezzo*(R) in the United States. For further information, please visit the company's website at: [www.transcept.com](http://www.transcept.com).

### *Forward Looking Statements*

This press release contains forward looking statements for purposes of the Private Securities Litigation Reform Act of 1995 (the Act). Transcept disclaims any intent or obligation to update these forward-looking statements, and claims the protection of the safe harbor for forward-looking statements contained in the Act. Examples of such statements include, but are not limited to, the ability of patents to provide important intellectual property protection for *Intermezzo*(R); expectations with regard to Hatch-Waxman regulatory exclusivity; expectation of patent issuance and Orange Book listing after a Notice of Allowance is published by the USPTO; the potential favorable outcome of additional patent prosecution and issuance efforts in favor of *Intermezzo*(R); expectations with respect to the activities of Transcept and Purdue and the satisfaction of conditions and obligations under the parties' United States License and Collaboration Agreement (the Collaboration Agreement); expectations regarding potential milestone payments under the Collaboration Agreement; the ability of Transcept to satisfy the issues raised by the FDA in the Complete Response Letter; and the timing of regulatory submissions and decisions with respect to the NDA for *Intermezzo*(R) with the FDA. Such statements are based on management's current expectations, but actual results may differ materially due to various risks and uncertainties, including, but not limited to, whether Transcept is able to satisfy concerns expressed by FDA in its October 28, 2009 Complete Response Letter and otherwise satisfy FDA that the *Intermezzo* (R) NDA is sufficient to approve *Intermezzo*(R) for its intended indication and any further delays in, and the final form of, any FDA approval of *Intermezzo*(R); possible claims of patent invalidity; obtaining patent issuance, maintaining adequate patent protection and successfully enforcing such patent claims against third parties; commercializing *Intermezzo*(R) without violating the intellectual property rights of others; a decision by Purdue to terminate the Collaboration Agreement, even if the *Intermezzo*

(R) NDA is approved; obtaining and maintaining Hatch-Waxman exclusivity for *Intermezzo*(R) and other difficulties or delays in, clinical development, market acceptance and commercialization of *Intermezzo*(R).

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