



## District Court Decision Received in CONCERTA® Patent Case

Titusville, N.J. (March 31, 2009)- The U.S. District Court for the District of Delaware has rendered a decision in the patent litigation between Alza Corporation, McNeil-PPC, Inc. and Andrx Pharmaceuticals LLC. McNeil Pediatrics, Division of Ortho-McNeil-Janssen Pharmaceuticals, Inc., which markets CONCERTA® (methylphenidate HCl) Extended-Release Tablets CII, said the court held that the patent in suit is not valid or infringed by the filing of Andrx's Abbreviated New Drug Application. Alza and McNeil-PPC are analyzing the court's lengthy opinion and assessing their next steps in this litigation, which may include a request for reconsideration, or an appeal to the Court of Appeals for the Federal Circuit.

### About CONCERTA®

CONCERTA® is approved for the treatment of attention deficit hyperactivity disorder (ADHD) as part of a total treatment program that may include counseling or other therapies. McNeil previously filed a Citizen's Petition with the FDA requesting the Agency to apply additional bioequivalence metrics to ensure that the approval of any generic versions of CONCERTA® extended-release methylphenidate tablets are both bioequivalent and clinically equivalent to the innovator product.

### IMPORTANT SAFETY INFORMATION

Talk to your healthcare professional for a proper diagnosis and treatment of ADHD. Only a healthcare professional can decide whether medication is right for you or your child.

CONCERTA should not be taken by patients who have: allergies to methylphenidate or other ingredients in CONCERTA; significant anxiety, tension, or agitation; glaucoma; tics, Tourette's syndrome, or family history of Tourette's syndrome; current or past use of monoamine oxidase inhibitor (MAOI); esophagus, stomach, or intestinal narrowing. Children under 6 years of age should not take CONCERTA.

Abuse of methylphenidate may lead to dependence. Tell your healthcare professional if you or your child has had problems with alcohol or drugs; has had any heart problems, heart defects, high blood pressure, or a family history of these problems; has had depression, abnormal thoughts or visions, bipolar disorder, or seizure. Contact your healthcare professional immediately if you or your child: develops abnormal thinking or hallucinations, abnormal or extreme moods and/or excessive activity; or if aggressive behavior or hostility develops or worsens while taking CONCERTA. Your child's healthcare professional should check height and weight often and may interrupt CONCERTA treatment if your child is not growing or gaining weight as expected.

Stimulants may impair the ability of the patient to operate potentially hazardous machinery or vehicles. Caution should be used accordingly until you are reasonably certain that CONCERTA does not adversely affect your ability to engage in such activities.

The most common adverse reaction (>5%) reported in children and adolescents was upper abdominal pain. The most common adverse reactions (>10%) reported in adults were dry mouth, nausea, decreased appetite, headache, and insomnia.

For full prescribing information, go to [www.concerta.net](http://www.concerta.net).

### About ADHD

Attention Deficit Hyperactivity Disorder (ADHD) is a common and treatable medical condition, which includes a variable attention span and/or hyperactivity or impulsivity. According to the National Institutes of Health (NIH), ADHD is one of the most common psychiatric disorders in childhood. It affects an estimated four million children and an estimated eight million adults in the United States. Studies suggest that between 30 and 70 percent of children with ADHD continue to have symptoms as adults.

### About McNeil Pediatrics

McNeil Pediatrics, a division of Ortho -McNeil-Janssen Pharmaceuticals, Inc (OMJPI), markets CONCERTA® for the treatment of children, adolescents and adults with ADHD in the United States. For more information, visit [www.mcneilpediatrics.net](http://www.mcneilpediatrics.net).

CONCERTA® and OROS® are a registered trademark of ALZA Corporation.

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