Pfizer Logo

Pfizer Announces Availability Of Quillivant XR™ (methylphenidate hydrochloride) CII For Extended-Release Oral Suspension In The United States

Sunday, January 13, 2013 - 09:30pm

The First Once-Daily, Extended-Release Liquid Medication for the Treatment of ADHD is Now Available in Pharmacies

"In order to effectively treat patients with chronic conditions such as ADHD, it is important to consider individual patient needs, including options for medication administration,"

(BUSINESS WIRE)--Pfizer Inc. (NYSE: PFE) today announced that Quillivant XR™ (methylphenidate hydrochloride) CII for extended-release oral suspension is now available in the U.S. for the treatment of attention deficit hyperactivity disorder (ADHD). Quillivant XR is the first once-daily, extended-release liquid methylphenidate for ADHD and is now available by prescription.

"In order to effectively treat patients with chronic conditions such as ADHD, it is important to consider individual patient needs, including options for medication administration,"said Ann Childress, M.D., president of the Center for Psychiatry and Behavioral Medicine, Las Vegas, who was an investigator in the Quillivant XR laboratory classroom study. "As the first once-daily, extended-release liquid medication for patients with ADHD, Quillivant XR represents a new alternative to other ADHD treatments."

Quillivant XR was approved by the U.S. Food and Drug Administration (FDA) on September 27, 2012 for the treatment of ADHD in patients aged 6 years and above. The efficacy of Quillivant XR was evaluated in a randomized, double-blind, placebo-controlled, crossover, multicenter, laboratory classroom study of 45 children with ADHD. Quillivant XR significantly improved ADHD symptoms compared to placebo at the primary endpoint of four hours post-dose, and in a secondary analysis, showed significant improvement at every time point measured, from 45 minutes to 12 hours after dosing.

ADHD is one of the most common neurobehavioral disorders in the U.S.[1] According to the Centers for Disease Control and Prevention's 2007 data, about one in ten children aged 4 -- 17 in the U.S. had at any time in their life received a diagnosis of ADHD.[1] Patients with ADHD may suffer from symptoms such as difficulty paying attention, impulsivity and being overly active in some cases.[2] The condition can last into adulthood.[3] Although there are many treatment options for ADHD, until Quillivant XR there was no once-daily, extended-release liquid option for the treatment of this condition.

"Pfizer is pleased to provide patients and their caregivers with a new option to help manage this challenging condition,"said Sam Azoulay, M.D., senior vice president of medical and development for Pfizer's Emerging Markets and Established Products Business Units. "We also recognize that caring for and treating a child with

ADHD goes beyond medication. We look forward to working with mothers and other caregivers of children with ADHD to provide meaningful resources to the ADHD community."

Pfizer acquired NextWave Pharmaceuticals on November 27, 2012. Quillivant XR was developed in conjunction with NextWave's manufacturing partner, Tris Pharma, using Tris Pharma's patent-protected drug delivery platform. For more information, please visit www.quillivantxr.com.

Pfizer plans to offer Quillivant XR to patients in need through our *Pfizer Helpful Answers*® program. *Pfizer Helpful Answers* is Pfizer's family of patient-assistance programs that helps eligible patients in the U.S. in need get access to their Pfizer medicines. In 2011, *Pfizer Helpful Answers* helped more than 1 million patients receive over 7.8 million Pfizer prescriptions through our programs. For more information, call *Pfizer Helpful Answers* toll-free at 1-866-706-2400 or visit www.PHAHelps.com.

About Quillivant XR

IMPORTANT SAFETY INFORMATION

Quillivant XR is a federally controlled substance (CII) because it can be abused or lead to dependence. Keep Quillivant XR in a safe place to prevent misuse and abuse. Selling or giving away Quillivant XR may harm others and is against the law. Tell your doctor if you or your child have (or have a family history of) ever abused or been dependent on alcohol, prescription medicines, or street drugs.

Quillivant XR should not be taken if you or your child are allergic to methylphenidate hydrochloride, or any of the ingredients in Quillivant XR, or are taking or have taken within the past 14 days an antidepression medicine called a monoamine oxidase inhibitor or MAOI.

Heart-related problems have been reported with methylphenidate hydrochloride and other stimulant medications:

Sudden death in patients who have heart problems or heart defects

Stroke and heart attack in adults

Increased blood pressure and heart rate

Your doctor should check you or your child's blood pressure and heart rate regularly during treatment with QUILLIVANT XR.

Mental (psychiatric) problems can be caused or worsened by methylphenidate hydrochloride and other stimulant medications:

New or worse behavior or thought problems

New or worsening bipolar symptoms

New or worsening psychotic symptoms (such as hearing voices, believing things that are not true, are suspicious)

Call your doctor right away if you or your child have any heart-related symptoms such as chest pain, shortness of breath or fainting or new or worsening mental (psychiatric) symptoms or new manic symptoms while taking Quillivant XR.

Quillivant XR may not be right for you. Tell your doctor if:

You or your child have heart problems, heart defects, or high blood pressure

You or your child have mental problems including psychosis (hearing voices, believing things that are not true, suspicious), mania, bipolar illness, or depression or about a family history of suicide, bipolar illness or depression

You are pregnant or plan to become pregnant. It is not known if Quillivant XR will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant

You are breastfeeding or plan to breast feed. Quillivant XR passes into your breast milk. You and your doctor should decide if you will take Quillivant XR or breast feed

Possible **serious side effects** of Quillivant XR are heart-related problems and mental problems, as well as slowing of growth (height and weight) in children. Children should have their height and weight checked often while taking QUILLIVANT XR. QUILLIVANT XR treatment may be stopped if a problem is found during these check-ups.

Common side effects include:

Decreased appetite	Vomiting	Mood swings	Blurred vision
Weight loss	Trouble sleeping	Agitation	Increased blood pressure
Nausea	Anxiety	Irritability	Fast heart beat
Stomach pain	Nervousness	Dizziness	Increased sweating
Dry mouth	Restlessness	Shaking (tremor)	Fever

Talk to your doctor if you or your child have side effects that are bothersome or do not go away.

This is not a complete list of possible side effects. Ask your doctor or pharmacist for more information.

INDICATION

Quillivant XR is a central nervous system (CNS) stimulant prescription medicine. **Quillivant XR is used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).** Quillivant XR may help increase attention and decrease impulsiveness and hyperactivity in patients with ADHD.

Please see full Prescribing Information and Medication Guide, including BOXED WARNING regarding Abuse and Dependence, at www.quillivantxr.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit or call 1-800-FDA-1088.

Pfizer Inc.: Working together for a healthier world®

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

References:

1. Centers for Disease Control and Prevention. Increasing prevalence of parent-reported attention deficit/hyperactivity disorder among children -- United States, 2003 and 2007. *MMWR*. 2010;59(44):1439 --1443.

2. American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders: DSM-IV-TR*. Washington: American Psychiatric Association; 2000.

3. Kessler R, Adler L, Barkley R, et al. The prevalence and correlates of adult ADHD in the United States: Results from the National Comorbidity Survey replication. *Am. J. Psychiatry*. 2006;163(4):716--23.

Pfizer Inc. Media Contact: Lauren Starr, 212-733-2798 or Investor Contact: Suzanne Harnett, 212-733-8009