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Pfizer Receives U.S. FDA Approval of New QuilliChew ER™ (methylphenidate hydrochloride) extended-release chewable tablets CII

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Extended-Release Is Now Chewable: First and Only Long-Acting Chewable Methylphenidate Treatment for Attention Deficit Hyperactivity Disorder (ADHD) in patients ages 6 years old and above

Pfizer today announced that the U.S. Food and Drug Administration (FDA) has approved QuilliChew ER chewable tablets. Pfizer now offers two different products for the treatment of ADHD in patients ages 6 years old and above – liquid Quillivant XR® (methylphenidate HCl) CII and new QuilliChew ER chewable tablets.

CNS stimulants, including Quillivant XR, QuilliChew ER, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy.

QuilliChew ER is available in multiple dosage strengths with scored tablet options, which enable healthcare professionals to individualize the dose* to meet the specific treatment needs of patients with ADHD. QuilliChew ER is available in 20 mg scored, 30 mg scored and 40 mg unscored tablet options that are chewable and can be taken with or without food. QuilliChew ER is expected to be available in pharmacies in the first quarter of 2016.

The recommended starting dose is 20 mg given orally once daily in the morning. Dosage may be increased or decreased weekly in increments of 10 mg, 15 mg, or 20 mg per day. Daily dosage above 60 mg is not recommended. Prior to treating pediatric patients and adults with CNS stimulants, including QuilliChew ER, assess for the presence of cardiac disease (i.e. perform a careful history, family history of sudden death or ventricular arrhythmia, and physical exam). QuilliChew ER is contraindicated in patients known to be hypersensitive to methylphenidate or other components of QuilliChew ER and hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported. QuilliChew ER is also contraindicated during treatment with monoamine oxidase inhibitors (MAOIs), and also within 14 days following discontinuation of treatment with an MAOI because of the risk of hypertensive crisis.

“As a physician, it is important to have treatment choices for patients with ADHD and their caregivers. QuilliChew ER extended-release chewable tablets give healthcare providers an additional treatment option to meet their patients’ needs,” said Ann C. Childress, M.D. Dr. Childress is an internationally-recognized expert in the treatment of adolescent psychiatry. She is Board Certified in psychiatry with a sub-specialty in child and adolescent psychiatry, is the president of the Center for Psychiatry and Behavioral Medicine, Inc., Las Vegas, and is an adjunct faculty member at the University of Nevada School of Medicine.

QuilliChew ER significantly improved attention and behavior compared to placebo in a clinical trial. The efficacy of QuilliChew ER was evaluated in a double-blind, randomized, placebo-controlled, parallel group laboratory classroom study in 90 children ages 6 to 12 years old with a diagnosis of ADHD based upon criteria in the DSM-IV. The primary and key secondary efficacy parameters were assessed pre- and post-dose, using the SKAMP† -Combined score, measured during the laboratory classroom day at 0.75, 2, 4, 8, 10, 12 and 13 hours. The average of treatment effects across all time points was statistically significantly superior to placebo. The key secondary endpoint demonstrated improvement versus placebo in attention and behavior with an onset at 45 minutes through eight-hour duration (measured at 0.75, 2, 4 and 8 hours post-dosing).

“Pfizer is pleased to announce that with new QuilliChew ER, and in partnership with Tris Pharma, the developer of ER chewable tablets, we are expanding our offering of ADHD treatments to include extended-release, chewable tablet options,” said Sam Azoulay, Senior Vice President, Chief Medical Officer, Global Established Pharma, Pfizer.

*Reduce dosage or discontinue therapy if patients exhibit paradoxical aggravation of symptoms or other side effects, or if improvement is not observed after an appropriate dose adjustment over a one-month period.

† SKAMP is the Swanson, Kotkin, Agler, M-Flynn, and Pelham (SKAMP) Rating Scale, a validated 13-item teacher-rated scale that assesses manifestations of ADHD in a classroom setting.

About ADHD

ADHD is one of the most common neurobehavioral disorders in the U.S. According to the Centers for Disease Control and Prevention’s 2011 data, approximately 11% of children ages 4 to 17 years in the U.S. have received a diagnosis of ADHD at any time in their lives, based on parent-reported outcomes. Patients with ADHD suffer from symptoms such as difficulty paying attention, impulsivity and being overly active. The condition can persist into adulthood.

The full prescribing information including BOXED WARNING and Medication Guide for QuilliChew ER can be found at www.QuilliChewER.com and for Quillivant XR can be found at http://labeling.pfizer.com/ShowLabeling.aspx?id=965.

INDICATION

Quillivant XR and QuilliChew ER are central nervous system (CNS) stimulants indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD).

IMPORTANT SAFETY INFORMATION

WARNING: ABUSE AND DEPENDENCE

CNS stimulants, including Quillivant XR, QuilliChew ER, other methylphenidate-containing products, and amphetamines, have a high potential for abuse and dependence. Assess the risk of abuse prior to prescribing, and monitor for signs of abuse and dependence while on therapy.

- Quillivant XR and QuilliChew ER are contraindicated:
  - In patients known to be hypersensitive to methylphenidate or other components of Quillivant XR and QuilliChew ER. Hypersensitivity reactions such as angioedema and anaphylactic reactions have been reported.
  - During treatment with monoamine oxidase inhibitors (MAOIs), and also within 14 days following discontinuation of treatment with an MAOI because of the risk of hypertensive crisis.
- Sudden death, stroke and myocardial infarction have occurred in adults treated with CNS stimulants at recommended doses. Sudden death has occurred in pediatric patients with structural cardiac abnormalities and other serious cardiac problems, and in adults taking CNS stimulants at recommended doses for ADHD. Avoid use in patients with known structural cardiac abnormalities, cardiomyopathy, serious cardiac arrhythmias, coronary artery disease, or other serious cardiac problems. Further evaluate patients who develop exertional chest pain, unexplained syncope, or arrhythmias during treatment with Quillivant XR or QuilliChew ER.
- CNS stimulants cause an increase in blood pressure (mean increase approximately 2-4 mm Hg) and heart rate (mean increase approximately 3-6 bpm). Some individuals may have larger increases. Monitor all patients for hypertension and tachycardia.
- Use of stimulants may cause psychotic or manic symptoms in patients with no prior history, or exacerbation of symptoms in patients with pre-existing psychiatric illness. Evaluate for bipolar disorder prior to Quillivant XR or QuilliChew ER use.
- Cases of painful and prolonged penile erections and priapism have been reported with methylphenidate products. Immediate medical attention should be sought if signs or symptoms of prolonged penile erections or priapism are observed.
- Stimulants used to treat ADHD are associated with peripheral vasculopathy, including Raynaud’s phenomenon. Signs and symptoms are usually intermittent and mild; however, very rare sequelae include digital ulceration and/or soft tissue breakdown. Careful observation for digital changes is necessary during treatment with ADHD stimulants.
- CNS stimulants have been associated with weight loss and slowing of growth rate in pediatric patients. Growth should be monitored during treatment with stimulants, including Quillivant XR and QuilliChew ER. Patients who are not growing or gaining weight as expected may need to have their treatment interrupted.
- QuilliChew ER contains phenylalanine, a component of aspartame, and can be harmful to patients with phenylketonuria (PKU).
- Based on accumulated data from other methylphenidate products, the most common (?5% and twice the rate of placebo) adverse reactions are

appetite decreaseddyspepsia dizziness

insomnia	abdominal pain	irritability
nausea	weight decreased	affect lability
vomiting	anxiety	tachycardia
		blood pressure increased

There is limited experience with Quillivant XR and QuilliChew ER in controlled trials.

- Quillivant XR: The most common (?2% in the Quillivant XR group and greater than placebo) adverse reactions reported in the Phase 3 controlled study conducted in 45 ADHD patients (ages 6-12 years) in Quillivant XR compared to placebo were affect lability (9% Quillivant XR, 2% placebo), excoriation (4%, 0%), initial insomnia (2%, 0%), tic (2%, 0%), decreased appetite (2%, 0%), vomiting (2%, 0%), motion sickness (2%, 0%), eye pain (2%, 0%), and rash (2%, 0%).
- QuilliChew ER: The most common (?2% in the QuilliChew ER group and greater than placebo) adverse reactions reported in the Phase 3 controlled study conducted in 90 pediatric subjects (ages 6-12 years) in QuilliChew ER compared to placebo were decreased appetite (2.4% QuilliChew ER, 0% placebo), aggression (2.4%, 0%), emotional poverty (2.4%, 0%), nausea (2.4%, 0%), headache (2.4%, 0%), and weight decreased (2.4%, 0%).
- Based on animal data, use of Quillivant XR or QuilliChew ER during pregnancy may cause fetal harm. Quillivant XR or QuilliChew ER should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Nursing mothers should be advised to discontinue drug or discontinue nursing, taking into consideration the importance of the drug to the mother because methylphenidate is present in human milk.

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At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products. Our global portfolio includes medicines and vaccines as well as many of the world's best-known consumer health care 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 one of the world's premier innovative biopharmaceutical companies, we 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, please visit us at www.pfizer.com.

DISCLOSURE NOTICE: *The information contained in this release is as of December 7, 2015. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

This release contains forward-looking information about QuilliChew ER™ (methylphenidate hydrochloride) extended-release chewable tablets CII and about an indication for the treatment for attention deficient hyperactivity disorder in patients ages 6 years old and above (the "Indication"), including their potential benefits, that involve substantial risks and uncertainties that could cause actual results to differ materially from those expressed or implied by such statements. Risks and uncertainties include, among other things, the uncertainties regarding the commercial success of QuilliChew ER and the Indication; whether and when drug applications may be filed in any other jurisdictions for the Indication; and competitive developments.

A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2014 and in its subsequent reports on Form 10-Q, including in the sections thereof captioned "Risk Factors" and "Forward-Looking Information and Factors That May Affect Future Results," as well as in its subsequent reports on Form 8-K, all of which are filed with the SEC and available at www.sec.gov and www.pfizer.com.

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