

FDA Accepted For Review Pfizer NDA for ADHD Treatment

NEW YORK, N.Y., July 17, 2015 - Pfizer announced that the U.S. Food and Drug Administration (FDA) accepted for review a New Drug Application (NDA) for methylphenidate hydrochloride extendedrelease chewable tablet (methylphenidate HCI ERCT). The product is being reviewed as a potential new treatment option for Attention Deficit/Hyperactivity Disorder (ADHD) in patients 6 years of age and older. The product was developed in conjunction with Tris Pharma, a manufacturing partner. The FDA Prescription Drug User Fee Act (PDUFA) date is December 4, 2015.

The NDA demonstrates Pfizer's continued commitment to patient needs, with the hope of providing another treatment option to help manage the symptoms of ADHD.

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DISCLOSURE NOTICE: The information contained in this release is as of July XX, 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 a product candidate, methylphenidate hydrochloride extended-release chewable tablet (methylphenidate HCI ERCT), including its potential benefits, that involves 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 inherent in research and development, including, without limitation, the possibility of unfavorable clinical trial results, including unfavorable new clinical data and additional analyses of existing clinical data; whether and when any applications may be filed with regulatory authorities in other jurisdictions for methylphenidate HCI ERCT; whether and when the FDA may approve the new drug application and whether and when regulatory authorities in other jurisdictions may approve any such other applications, which will depend on the assessment by such regulatory authorities of the benefit-risk profile suggested by the totality of the efficacy and safety information submitted; decisions by regulatory authorities regarding labeling and other matters that could affect the availability or commercial potential of methylphenidate HCI ERCT; 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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