Johnson & Johnson

FDA Issues Complete Response Letter for Carisbamate

TITUSVILLE, N.J., Aug 21, 2009 /PRNewswire via COMTEX News Network/ -- The U.S. Food and Drug Administration (FDA) issued a complete response letter regarding the New Drug Application (NDA) for carisbamate, an anti-epileptic drug in development, announced Ortho-McNeil-Janssen Pharmaceuticals, Inc.

The NDA, filed in October 2008 by Johnson & Johnson Pharmaceutical Research and Development, L.L.C. (J&JPRD) on behalf of Ortho-McNeil-Janssen Pharmaceuticals, Inc. seeks approval to market carisbamate (COMFYDE(TM)) for the adjunctive treatment of partial onset seizures in patients 16 years of age and older.

The company is currently evaluating the FDA's complete response letter, and will respond to the agency's questions as quickly as possible.

About Partial Onset Seizures and Epilepsy

According to the Epilepsy Foundation, epilepsy is one of the most common disorders of the nervous system. It is defined by recurrent unprovoked seizures. It is categorized as "generalized" or "partial" depending on the location of the abnormal electrical activity in the brain that characterizes the disorder. Partial-onset seizures are common and are often difficult to treat. Partial-onset seizures are most often characterized by simple or complex repetitive movements, but virtually any sensory or emotional symptom can also occur as part of a partial seizure, including complex visual or auditory hallucinations. There are two categories of partial onset seizures: simple partial seizures (in which consciousness is retained), and complex partial seizures (in which consciousness is impaired or lost). Partial seizures can generalize and lead to tonic clonic seizures, during which the patient loses consciousness and is at risk for falling or injury.

About Carisbamate (COMFYDE (TM))

Carisbamate has demonstrated anti-epileptic drug activity when given in addition to other AEDs in clinical trials. Although the precise mechanism of action remains to be elucidated, carisbamate modulates brain neuron activity and thereby reduces epileptic activity and seizures. Carisbamate has been studied in three placebo-controlled, double-blind clinical studies with most common adverse events of dizziness, headache, somnolence, nausea and fatigue.

Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Ortho-McNeil-Janssen Pharmaceuticals, Inc. (OMJPI), a subsidiary of Johnson & Johnson, provides medicines for an array of health concerns, including central nervous system disorders, such as schizophrenia and epilepsy; metabolic diseases, such as diabetes; cardiovascular diseases; women's health; urology; gastrointestinal; and infectious diseases. The company strives to provide innovative, high quality, safe and effective treatments and continually seeks new opportunities to offer solutions for unmet health care needs. Ortho-McNeil-Janssen Pharmaceuticals, Inc. is headquartered in Raritan, New Jersey.

Johnson & Johnson Pharmaceutical Research & Development

Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) is a subsidiary of Johnson & Johnson, the world's most broadly-based producer of health care products. J&JPRD is headquartered in Raritan, N.J., and has facilities throughout Europe, the United States and Asia. J&JPRD is leveraging drug discovery and drug development in a variety of therapeutic areas, including CNS, Internal Medicine and Oncology, to address unmet medical needs worldwide. More information can be found at http://www.jnjpharmarnd.com.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could vary materially from Ortho-McNeil-Janssen Pharmaceuticals, Inc. and/or Johnson & Johnson's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 28, 2008. Copies of this Form 10-K, as well as subsequent filings, are available online at http://www.sec.gov, http://www.jnj.com or on request from Johnson & Johnson. Neither OMJPI nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or

future events or developments.)

SOURCE Ortho-McNeil-Janssen Pharmaceuticals, Inc.

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