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Catalyst Pharmaceuticals Announces Intent to Develop a Generic Equivalent of Sabril

One Time Opportunity to Leverage Catalyst's Experience With vigabatrin

CORAL GABLES, Fla., Sept. 09, 2015 (GLOBE NEWSWIRE) -- Catalyst Pharmaceuticals, Inc. (Nasdaq:CPRX), a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, today announced the initiation of a project to develop a generic equivalent of Sabril (vigabatrin). Sabril® is marketed by Lundbeck Inc. in the United States for the treatment of infantile spasms and complex partial seizures. Catalyst has substantial previous experience with its version of vigabatrin (CPP-109), which Catalyst believes will contribute to the rapid development and filing of an ANDA for a generic version of Sabril.

Patrick J. McEnany, Catalyst's Chief Executive Officer said, "Catalyst remains extremely focused on the completion of the NDA submission for Firdapse® and on the development of other innovative drugs for the treatment of rare neurological and neuromuscular conditions." Mr. McEnany continued, "However, we view the Sabril project as a complex, high barrier, generic program, in which we can leverage our extensive experience with our version of vigabatrin, enabling us to rapidly develop a product aligned with our neurological and neuromuscular rare disease focus. Furthermore, this product provides us with an opportunity to add additional shareholder value as we build a product portfolio for commercialization."

To date, Catalyst has taken the following steps to develop this program:

- Catalyst has obtained the reference listed drug and the active pharmaceutical ingredient.
- Catalyst has entered into an exclusive supply agreement for the vigabatrin active pharmaceutical ingredient with a manufacturer that has filed a DMF, has validated the manufacturing process, and has prepared a number of batches of vigabatrin at commercial scale for Catalyst in the past. Catalyst believes that this manufacturer has an extensive and acceptable FDA inspectional history.
- The contract manufacturer of the finished dosage form has previously developed a manufacturing process for the drug product and prepared several commercial scale batches.
- Quality control and stability test methods for this product have already been developed and validated.
- Catalyst conducted a bioequivalence study in 2007 of its product formulation against the European equivalent of Sabril marketed by Sanofi Aventis, and those successful bioequivalence results were announced in a 2007 press release.
- Stability data has been collected for up to five years showing that Catalyst's formulation has acceptable shelf life in more than one container closure system.
- Catalyst has an extensive body of clinical trial vision safety data from our previous studies with vigabatrin that we believe will be useful in designing a bioequivalence study that will be acceptable to both the U.S. FDA and an institutional review board (IRB).

Dr. Steven Miller, Catalyst's Chief Operating Officer and Chief Scientific Officer said, "All of the data about vigabatrin that we collected when developing our version of vigabatrin (CPP-109) should be useful to us as we proceed quickly to perform a bioequivalence study of this product and, if successful, file an ANDA for this product." Dr. Miller continued, "In addition to all the material advantages for the rapid development of this generic product, Catalyst's management team, including our CEO, myself, and several other team members, have a long and successful history developing and commercializing generic drugs. We therefore, know how to complete this project in a timely manner, and expect to do so with minimal distraction from our primary focus of developing novel new drugs for rare diseases."

About Sabril®

Sabril (vigabatrin 500 mg tablets and 500 mg packets of powder for reconstitution) is a GABA-aminotransferase inhibitor indicated for the treatment of infantile spasms (a rare disease) and complex partial seizures. It was approved for use in various countries in the European Union throughout the late 1980's and 1990's, and is marketed in those countries by Sanofi Aventis or its licensees. Sanofi Aventis has out-licensed the North American rights to Sabril and those rights are currently held by Lundbeck, Inc. Sabril was granted approval by the FDA in the United States on August 21, 2009 for both dosage forms of the product. Lundbeck's New Chemical Entity exclusivity (NCE) for Sabril expired August 21, 2014 and orphan drug exclusivity for Sabril will expire August 21, 2016. There are a number of pediatric exclusivities (some of which are already expired) and a new patient population exclusivity that will all expire between October 26, 2016 and April 26, 2017. There are no FDA listed patents, and Catalyst does not believe that its processes infringe on any patents that may still be unexpired.

According to published reports, Lundbeck's revenues for Sabril in 2014 were about $120 million, which is a 35% increase over 2013 revenues. Catalyst believes that revenues for Sabril should continue to grow at a brisk pace for the next few years.

Sabril's launch in the United States was difficult initially due to an onerous FDA mandated REMS (Risk Evaluation and Mitigation Strategy) program. In recent years, however, the adoption and use of Sabril has been accelerating due to the medical community's acceptance of the REMS program and the obvious therapeutic benefit of Sabril to infantile spasms patients and treatment refractory complex partial seizure patients.

About Infantile Spasms

An infantile spasm is a specific type of seizure seen in an epilepsy syndrome of infancy and childhood. The onset of infantile spasms is usually in the first year of life, typically between 4-8 months. The seizures primarily consist of a sudden bending forward of the body with stiffening of the arms and legs; some children arch their backs as they extend their arms and legs. Spasms tend to occur upon awakening or after feeding, and often occur in clusters of up to 100 spasms at a time. Infants may have dozens of clusters and several hundred spasms per day. Infantile spasms usually stop by age five, but may be replaced by other seizure types.

About Complex Partial Seizures

In complex partial seizures, consciousness is altered. Patients may exhibit automatisms (automatic repetitive behavior) such as walking in a circle, sitting and standing, or smacking their lips together. Often accompanying these symptoms are the presence of unusual thoughts, such as the feeling of déjà vu, uncontrollable laughing, fear, visual hallucinations, and experiencing unusual unpleasant odors. These symptoms are thought to be caused by abnormal discharges in the temporal lobe.

About Catalyst Pharmaceuticals

Catalyst Pharmaceuticals is a biopharmaceutical company focused on developing and commercializing innovative therapies for people with rare debilitating diseases, including Lambert-Eaton myasthenic syndrome (LEMS), congenital myasthenic syndromes (CMS), infantile spasms, and Tourette's Disorder. Catalyst's lead candidate, Firdapse for the treatment of LEMS, recently completed testing in a global, multi-center, pivotal Phase 3 trial resulting in positive top-line data. Firdapse for the treatment of LEMS has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and orphan drug designations for LEMS and CMS. Firdapse is the first and only European approved drug for symptomatic treatment in adults with LEMS.

Catalyst is also developing CPP-115 to treat infantile spasms, epilepsy and other neurological conditions associated with reduced GABAergic signaling, like post-traumatic stress disorder and Tourette's Disorder. CPP-115 has been granted U.S. orphan drug designation for the treatment of infantile spasms by the FDA and has been granted E.U. orphan medicinal product designation for the treatment of West Syndrome by the European Commission.

Forward-Looking Statements

This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties, which may cause Catalyst's actual results in future periods to differ materially from forecasted results. A number of factors, including whether the receipt of breakthrough therapy designation for Firdapse will expedite the development and review of Firdapse by the FDA or the likelihood that the product will be found to be safe and effective, what clinical trials and studies will be required before Catalyst can submit an NDA for Firdapse for the treatment of CMS and whether any such required clinical trials and studies will be successful, whether an NDA for Firdapse will ever be accepted for filing by the FDA, the timing of any such NDA filing or acceptance, whether, if an NDA for Firdapse is accepted for filing, such NDA will be given a priority review by the FDA, whether Catalyst will be the first company to receive approval for amifampridine (3,4-DAP), giving it 7-year marketing exclusivity for its product, whether CPP-115 will be determined to be safe for humans, whether CPP-115 will be determined to be effective for the treatment of infantile spasm, post-traumatic stress disorder, Tourette's Disorder or any other indications, whether Catalyst can successfully design and complete a bioequivalence study of its version of vigabatrin compared to Sabril that is acceptable to the FDA, whether any such bioequivalence study the design of which is acceptable to the FDA will be successful, whether any ANDA that Catalyst files for a generic version of Sabril will be accepted for filing, whether any ANDA for Sabril accepted for filing by the FDA will be approved (and the timing of any such approval), whether any of Catalyst's product candidates will ever be approved for commercialization or successfully commercialized, and those other factors described in Catalyst's Annual Report on Form 10-K for the fiscal year 2014 and its other filings with the U.S. Securities and Exchange Commission (SEC), could adversely affect Catalyst. Copies of Catalyst's filings with the SEC are available from the SEC, may be found on Catalyst's website or may be obtained upon request from Catalyst. Catalyst does not undertake any obligation to update the information contained herein, which speaks only as of this date.

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