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Catalyst Pharmaceuticals Announces Agreement with FDA on Confirmatory Phase 3 Study Protocol for Firdapse in Lambert-Eaton Myasthenic Syndrome

Reorganized operations plan projects that current capital resources are adequate to reach NDA acceptance

CORAL GABLES, Fla., June 13, 2016 (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 that it has reached agreement with the U.S. Food and Drug Administration (FDA) on a confirmatory Phase 3 study protocol for Firdapse® (amifampridine phosphate) for the symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS). As part of the clinical protocol for the confirmatory study, Catalyst expects to initiate a small, single-center study with Firdapse during the second half of 2016. Catalyst also expects to announce additional information about the study design and timelines for the study once they are finalized.

"We are pleased to have the FDA's agreement on the design of the protocol for our second Phase 3 trial evaluating Firdapse for the treatment of LEMS. This is an important milestone in our effort to provide all LEMS patients with access to an FDA approved therapy," said Patrick J. McEnany, Catalyst's Chief Executive Officer. "Additionally, we have recently completed an analysis of our cash forecasts and budgets under our reorganized operational plan and believe, based on currently available information, that our existing capital resources are adequate to get us to an accepted NDA submission without the need for additional financing."

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. Firdapse for the treatment of LEMS has received Breakthrough Therapy Designation from the U.S. Food and Drug Administration (FDA) and orphan drug designation for LEMS and CMS. Firdapse is the first and only approved drug in Europe 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. In addition, Catalyst is developing a generic version of Sabril® (vigabatrin).

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, whether the study design for a second trial evaluating Firdapse for the treatment of LEMS will be acceptable to the FDA to approve an NDA for Firdapse, the timing of such trial, and whether such trial will be successful, whether Catalyst's assumptions as to its reorganized business plan will be accurate and the impact of unanticipated events or delays in projected activities on Catalyst's cash requirements and on Catalyst's ability to obtain an NDA approval for Firdapse without the need for additional financing, what clinical trials and studies will be required before Catalyst can resubmit an NDA for Firdapse for the treatment of CMS and whether any such required clinical trials and studies will be successful, whether any NDA for Firdapse resubmitted to the FDA will ever be accepted for filing, 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 Firdapse will be approved for commercialization, 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, what additional testing will be required before CPP-115 is "Phase 2 ready", 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 2015 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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