CleveXel Pharma Announces Initiation of a Randomized Phase 2 Clinical Trial of CVXL-0107 in Advanced Parkinson’s Disease Patients

Efficacy of CVXL-0107 at controlling motor symptoms and dyskinesia in patients will be compared to placebo, through Levodopa challenge tests

Paris - France, April 28, 2016 - CleveXel Pharma, a pharmaceutical company focused in the development of compounds for Parkinson’s disease (PD) and other neuro degenerative diseases, today announced the randomization of a first patient in a randomized, double-blinded, placebo-controlled with cross-over Phase 2a clinical trial of CVXL-0107, a glutamate release inhibitor, in patients with advanced Parkinson’s Disease with motor fluctuations and dyskinesia.

“The clinical pharmacology design of this study makes it a quite unique and good model for optimally assessing a new non-dopaminergic drug in the field of PD” said Jean-Christophe Corvol, Professor of Neurology (PUPH), Department of Neurology and Centre d’Investigations Cliniques, Pitié-Salpêtrière Hospital and principal investigator of the study. “Encouraging data in animal models and in a previous early Phase 2a trial support running this new trial to confirm that this compound can improve motor symptoms and reduce L-DOPA-induced dyskinesia in patients with PD. This is an opportunity for the French NS-Park/FCRIN network to help providing the patients with a non-dopaminergic drug using an original mechanism of action. Positive results would be a new advance in the treatment of PD and we are delighted to launch this adventure with the participation of ICM”, said Olivier Rascol, Professor of Clinical Pharmacology, Neurosciences Department and Centre d’Investigations Cliniques, Toulouse University Hospital, who is co-chairing with Pr Corvol the NS-Park/FCRIN network.

As part of this cross-over trial, 30 patients with advanced Parkinson’s disease who volunteer for this study will be randomized to receive CVXL-0107 or placebo for two weeks before performing one day of challenge test combined with supra optimal doses of levodopa, followed by 2 weeks under placebo or CVXL-0107 and another challenge test.

"We are very excited to launch our first clinical phase 2a study in Parkinson’s Disease, which is our primary area of expertise”, said Christian Bloy President and CEO of CleveXel Pharma. "We are looking forward to continuing the development program of this compound with a new formulation that we are currently developing for our next clinical study.”

Patients eligible for the trial must have a diagnosis of idiopathic Parkinson’s disease with clear daily motor fluctuations and dyskinesia under optimal levodopa-based therapy, translating into at least 2 hours in “OFF” state per day including morning OFF. The two co-primary endpoints, assessed during the challenge test days are (1) the difference in the AUC of the motor severity change and (2) the difference in the AUC for dyskinesia severity change. Secondary endpoints include during the acute levodopa challenge the evaluation of dyskinesia, the evaluation of PD axial and non-motor symptoms, the ON-time duration without dyskinesia and a number of endpoints based on patient’s diaries filled during the two weeks outpatient treatment (Total “ON-time”, “ON-time” with troublesome dyskinesia, “Good ON time”...) and safety of the compound given at the dose of 160 mg daily.
CleveXel plans to conduct the trial at 5 key sites from the French NS-Park network. For more information, please visit clinicaltrials.gov : NCT02641054.

**About CVXL-0107**
CVXL-0107 is a glutamate release inhibitor, and has shown evidence of antiparkinsonian and antidyskinetic activity in the MPTP macaque model when associated with an optimal dose of levodopa (Brotchie et al, 2007). In a small proof of concept study in 7 parkinsonian patients using a multiple cross-over, placebo controlled, n-of-one design, CVXL-0107 has shown a significant effect on the UPDRS-III while “ON”, as well as an increase of “ON-time” without dyskinesia or without troublesome dyskinesia as recorded in patient diaries (Rascol et al, 2008). Naftazone thus may increase the “good ON-time” (“ON” time without troublesome dyskinesia) when administered in combination with a supra maximal dose of levodopa to advanced patients suffering from fluctuations “ON-OFF” and dyskinesia. The present study will consolidate the clinical proof of concept of the antiparkinsonian activity of CVXL-0107.

**About CleveXel Pharma**
Created in 2013 as a spinoff from Cephalon laboratories (TEVA group), CleveXel Pharma is a pharmaceutical company specializing in innovative treatments for diseases of the central nervous system. The Company is developing a portfolio of drug candidates, including two disruptive molecules for treating Parkinson’s disease. The most advanced of these, CVXL-0107, which is currently in phase II clinical trials, aims to improve the quality of life of patients with Parkinson’s and treat motor impairments resulting from the reference treatment, L-DOPA. The other drug candidate, CVXL-0069, focuses on the early treatment of motor and non-motor symptoms of Parkinson’s, and is expected to enter its clinical phase in early 2018.

For further information, please go to our website: CleveXel Pharma.

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