

PRESS RELEASE

Paris, June 11th, 2015

[AP-HP – Ethypharm: signature of an agreement regarding baclofen for the treatment of alcohol dependence.](#)

AP-HP (Assistance Publique - Hôpitaux de Paris) and Ethypharm announce the signing of an agreement which will allow Ethypharm to use the data of the Bacloville study to apply for a marketing authorization (AMM) for baclofen in the treatment of alcohol dependence.

Since March 2014, the use of baclofen to treat alcohol dependence has been regulated in France by an RTU (temporary recommendation for use) drawn up by the French Medicines Agency (ANSM). This provision, which is temporary by definition, was introduced based on a presumably favourable risk/benefit balance in the light of available data¹. The said RTU gives physicians a framework for prescribing baclofen pending the results of two ongoing clinical studies: Bacloville² sponsored by AP-HP, with public financing coming from the 2011 national hospital clinical research program, and Alpadir³ sponsored by Ethypharm.

These two studies, which include 320 patients each, are complementary: the main criterion for Alpadir is the maintenance of abstinence, while the Bacloville study is targeting primarily a reduction in the intake of alcohol. Together, these two studies have been designed to confirm the efficacy of baclofen for the treatment of alcohol dependence and to confirm the drug's safety profile.

A conclusion to the discussions held between AP-HP and Ethypharm, the signed agreement governs how Ethypharm can access and use the data from the Bacloville study.

Professor P. Jaury, the Bacloville study's principal investigator, said: *"I am delighted with this agreement which results from the joint determination of AP-HP and Ethypharm to consolidate together all available data on baclofen in the treatment of alcohol dependence."*

The signing of this agreement marks a new stage in the development of baclofen led by Ethypharm since the end of 2010.

¹ ANSM update dated March 14, 2014: "A temporary recommendation for use (RTU) is granted for baclofen"

² Pragmatic randomized double-blind therapeutic trial of baclofen versus placebo for a year in ambulatory care

³ Randomized, multicentric, double-blind study to assess the efficacy of Xylka® (Baclofen) at the target dosage of 180mg/day compared to placebo, for maintenance of abstinence in alcohol dependent patients.

About AP-HP

AP-HP, Greater Paris University Hospital, is a care provider known worldwide with its 38 hospitals and the largest university medical center in France and in Europe. Each year, AP-HP welcomes 7 million patients, takes care of more than 1, 1 million emergencies and makes more than 5 million outpatient visits. It provides a public healthcare service for all, 24/7. AP-HP is the largest employer in Paris Region with 95,000 people - doctors, researchers, paramedical, administrative staff and workers.

www.aphp.fr

About Ethypharm

Ethypharm is an independent pharmaceutical company with global reach. It is dedicated to developing innovative drugs to treat pain and addiction, two major therapeutic areas with large unmet medical needs. Ethypharm also develops complex generics that contribute to the optimisation of healthcare costs. 800 people work at Ethypharm, mostly in France where its innovation and development centre is based as well as two manufacturing sites that comply with the best quality standards. Ethypharm drugs are marketed in 30 different countries around the world. Ethypharm's ALPADE project aims to bring to market a range of tablets containing a dose of up to 60 mg of baclofen for the treatment of alcohol dependence. The project is supported in the Centre Region by the European Fund for Regional Development (FEDER).

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