



PRESS RELEASE

## **ENYO Pharma announces the successful completion of phase Ib with its FXR agonist EYP001 and the start of phase II studies in two indications, NASH and HBV**

- ENYO Pharma's Phase Ib clinical study confirmed the safety and tolerability of its drug candidate EYP001 in chronic hepatitis B patients.
- Phase II clinical studies with EYP001 are planned to start in Q4 2018 for NASH and in Q1 2019 for chronic Hepatitis B.

**Lyon, November 6, 2018 – ENYO Pharma, a clinical stage biotech company developing innovative drug candidates, today announced completion of its phase Ib clinical trial evaluating the safety, pharmacokinetics and pharmacodynamics of its FXR agonist compound EYP001 in patients with chronic hepatitis B virus infection (CHBV). The company highlights that EYP001 was well-tolerated by patients and induced a prolonged FXR target engagement after QD dosing over 4 weeks. ENYO Pharma will now initiate two Phase II clinical trials of EYP001 in NASH and CHBV.**

A phase Ib multicenter, randomized, double-blind, placebo-controlled study in chronic HBV infected patients was initiated at the end of 2017 to determine the safety and tolerability of daily oral administration of EYP001 over 4 weeks. The study was performed in Poland, the Netherlands, Thailand and Australia with men and women 30 to 40 years of age with different ethnic origins (Asia, Australia and Europe). The study explored the effect of various EYP001 doses given alone (Part A) or in combination with Peg-IFN $\alpha$ 2a (Part B).

In this CHBV study population, the most common treatment-emergent adverse events (TEAEs) were gastrointestinal (GI) disorders. These TEAEs were transient and of mild to moderate intensity. Mild self-limited pruritus was reported in only 10% of subjects with all EYP001 QD doses and no LDL-cholesterol increase was observed. No off-target effects were seen, and no serious adverse event or serious unexpected serious adverse reaction were reported. This contrasts with what was observed with other FXR agonists currently in clinical development (e.g. Obeticholic Acid) and also supports the use of EYP001 for NASH.

EYP001 alone or in combination, across the different study arms, showed consistent anti-viral effects on several HBV parameters: HBV viral load, HBV RNA, HBcrAg and HBsAg levels in both HBeAg negative and HBeAg positive subjects.

*“We are really pleased with the results from this important dose-ranging study as they support the progression of this interesting therapeutic to our planned phase II study in CHBV patients, due to start early 2019”* commented Pietro Scalfaro, Chief Medical Officer of ENYO Pharma.

*“These results confirm our starting hypothesis that FXR is an important host factor in maintaining the chronicity of HBV infection, and that our compound EYP001 may help cure this disease in many patients”* said Jacky Vonderscher, CEO of ENYO Pharma. *“The strong target engagement concomitant with a lack of LDL-cholesterol increase and lack of pruritus, also positions our compound very well in the race to cure NASH which we are actively pursuing”* he also added.

ENYO Pharma intends to publish all results of the EYP001-103 study at the EASL meeting in Vienna (Austria) on April 10-14, 2019.

### **About EYP001 and FXR**

The molecule developed by ENYO Pharma, EYP001 is an orally bioavailable 2nd generation non-bile acid FXR agonist. The pioneering ENYO founding team discovered that FXR agonists interfere with the interaction between FXR and HBx, a hepatitis B viral protein essential for the replication of the virus. Current treatments are life-long and control viral replication without allowing a complete cure of the disease. ENYO Pharma's molecule targets the cccDNA virus reservoir and has the potential to offer a complete cure for the disease compared to the current standards of care. ENYO Pharma has licensed the use of FXR agonists against HBV from Inserm and obtained a worldwide exclusive license to a chemical class of FXR agonists from Poxel for all indications.

The class of FXR agonists has also gained attention as potential therapeutic agents in hepatobiliary and metabolic diseases. FXR activation has a favorable effect on liver growth and regeneration and has been shown to prevent and resolve liver fibrosis and steatosis in rodents and humans. FXR has multiple activities and regulates several metabolic pathways. In particular it controls the fate of bile acids in the liver and intestine, it influences the insulin sensitivity of tissues where it is highly expressed and impacts upon lipid metabolism. Several FXR agonists are currently in development for the treatment of NASH.

### **About HBV**

According to the WHO, over 350 million people chronically infected with the hepatitis B virus are awaiting treatment, half of them in Asia. Despite progress with vaccine coverage, close to 300 million people will remain chronically infected in the 2030s, putting them at major risk of developing cirrhosis and liver cancer. Current standard of care drugs approved for the treatment of CHB infections (PEGInterferon and nucleot(s)ides like Tenofovir or Entecavir) effectively suppress the virus presence in blood but seldom cure patients as the virus continues its destructive course in the liver cells of these patients through its embedded cccDNA.

## **About NASH**

NASH is the most common liver disorder in Western countries and results in liver fat accumulation leading to inflammation and hepatocyte injury. It is estimated that more than 4% of the population has advanced NASH. Its main consequence is liver fibrosis, cirrhosis and hepatocellular carcinoma. Currently no treatment exists for this disease which represents an important challenge.

**ENYO Pharma's technology and pipeline** -<http://www.enyopharma.com/science/principle/>

**ENYO Pharma SA** - [www.enyopharma.com](http://www.enyopharma.com)

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