



PRESS RELEASE

## **ENYO Pharma SA announces successful completion of EYP001 first in man Phase 1 study**

- Study results confirm that FXR agonist EYP001 is safe and well tolerated in healthy subjects and demonstrates engagement of nuclear receptor FXR related biology.
- EYP001 is advancing according to the initial plan for chronic hepatitis B and is also exploring expansion for use in other liver indications, such as NASH.

***Lyon, June 14, 2017*** - ENYO Pharma SA, a privately held biopharmaceutical company currently focused on developing treatments for viral infections, today announced that the Phase 1a single and multiple ascending dose trial evaluating EYP001 in healthy subjects has been completed. The results show that EYP001 was safe and well-tolerated at all doses studied in 80 subjects. The safety, pharmacokinetics (PK) and pharmacodynamic (PD) analysis are in line with established FXR biology and reported results from other early stage compounds that are in development for NASH. In particular, the levels and pattern of plasma concentrations changes of C4 (7 $\alpha$ hydroxy4cholesten3one) and fibroblast growth factor 19 (FGF19) are consistent with FXR agonism over the dose range of 60mg up to 500mg of multiple single doses administered over 15 days. These clinical results were presented at the international liver conference in Amsterdam earlier this year. In addition, *in vitro* data were presented confirming that EYP001 inhibits HBV particle release similarly to Tenofovir (TFV) or Entecavir (ETV), with an additive effect when combined. Moreover, EYP001 alone inhibited viral protein (HBsAg and HBeAg) production, reduced cccDNA and pgRNA, while TFV or ETV mono-treatment had negligible effect on these HBV markers *in vitro*.

EYP001 is a synthetic farnesoid X receptor (FXR) agonist with a favorable profile for oral therapy. The first Phase 1 study was designed to determine the safety, tolerability and pharmacokinetics of EYP001 in healthy subjects. Another ongoing Phase 1 study evaluates the safety, food effect and PK of EYP001 in subjects with chronic HBV infection.

Jacky Vonderscher, Ph.D., Chief Executive Officer of ENYO Pharma SA commented: "We are pleased with the profile emerging in our Phase 1 development with EYP001. We look forward to bringing the compound into further clinical development and believe EYP001 has the potential to be explored in additional indications such as NASH."

"Throughout the clinical program completed thus far, EYP001 has demonstrated an excellent tolerability and safety profile. By using the novel approach of enriched digitized ECG analysis we also showed that EYP001 does not impact QT. This supports our focus to progress swiftly with efficacy trials,

while advancing the required regulatory clinical package.” added Pietro Scalfaro, M.D., Chief Medical Officer of ENYO Pharma SA.

### **About EYP001 and FXR**

ENYO Pharma SA has licensed a family of farnesoid X nuclear hormone receptor (FXR) agonists from Poxel SA and holds worldwide exclusive rights on these patented compounds for any indication. EYP001 is a synthetic small non-bile acid molecule, acting on the host target nuclear receptor FXR, and is developed for the oral administration in patients with Chronic Hepatitis B (CHB). EYP001 interferes with HBV replication in the liver at post-entry steps likely impacting transcriptional activity of cccDNA. Activation of FXR function by EYP001 offers the potential for durable suppression of the virus with higher cure rates. The class of FXR agonists is gaining 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 in rodents and humans. FXR has multiple activities required for viral replication / persistence and FXR 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 lipid metabolism. Several FXR agonists are currently in development for the treatment of non-alcoholic steatohepatitis (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 (PEG-Interferon and nucleot(s)ides like Tenofovir or Entecavir) effectively suppress the virus presence in blood but are seldom curing patients as the virus continues its destructive course in the liver cells of these patients through its embedded cccDNA.

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

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