

# ENYO Pharma strengthens its leadership team with a NASH expert and announces that its Phase Ib trial in chronic HBV infected patients is on track with its FXR agonist EYP001

. Appointment of Raphaël Darteil as VP Non-Clinical Development & Product Profiling

. EYP001 study 103 in chronic HBV patients set to deliver results in Q2 2018

. Two Phase IIa studies with EYP001 in CHBV and in NASH to start in H2 2018

Lyon, February 27, 2018 – ENYO Pharma SA, a privately held biopharmaceutical company developing innovative new drug candidates by mimicking virus strategies to modulate host cellular functions, has today announced that it is strengthening its leadership team with the appointment of a VP Non-Clinical Development & Product Profiling. ENYO Pharma also confirms that its Phase Ib trial evaluating the safety of EYP001 in chronic HBV infected patients is progressing well in Europe and in the Asia-Pacific region and is set to deliver its results in Q2 2018.

Jacky Vonderscher, Chief Executive Officer of ENYO Pharma commented: "We are delighted to welcome an expert in NASH and in Nuclear Receptors who will add important new skills and experience to our Executive Team and help us optimizing all aspects of our development plans. Now that we have demonstrated safety in Healthy Subjects and clear target engagement for our FXR agonist EYP001 in Chronic HBV infected patients, we are planning to start two Phase IIa studies, one in CHBV patients and one in NASH patients, in H2 2018. NASH is a valuable additional opportunity for our lead compound and significantly strengthens our portfolio as FXR agonism has already been validated to play an important role in NASH."

#### Dr. Raphaël Darteil, Vice-President Non-Clinical Development & Product Profiling

As a PhD with more than 20 years of R&D and portfolio management experience in pharma and biotech industries, Raphaël brings to ENYO Pharma his scientific expertise in metabolic diseases and especially in NASH as well as in the field of Nuclear Receptors. During the last 7 years, he was Executive VP, Chief Operating Officer and member of the Management Board of Genfit. Prior to this, Raphaël held various positions in the department of Gene Therapy of Aventis both in France and in the United States. He holds a PhD in Molecular and Cellular Biology from the University Claude Bernard Lyon I.

## Study 103 evaluating the Safety of EYP001 in CHBV patients set to deliver results in Q2

A phase Ib multicenter, randomized, double-blind, placebo-controlled study in chronic HBV 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 is performed in Poland, Netherlands, Thailand and Australia. The study explores the effect of various EYP001 doses given alone and compared to Entecavir (Part A) or in combination with Peg-INF $\alpha$ 2a (Part B). *"We are looking forward to the preliminary results from this important dose-ranging study as they will support and validate the design of the phase 2 study in CHBV patients planned to start in H2 2018"* commented Pietro Scalfaro, Chief Medical Officer of ENYO Pharma.

## About EYP001 and FXR

ENYO Pharma SA has licensed a family of non-bile acid 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 being developed for the oral administration in patients with Chronic Hepatitis B Viral infections and in patients having NASH. 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. 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 and it 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.

## 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 5% of the population has an 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 Contact ENYO Pharma Jacky Vonderscher contact@enyopharma.com - +33 (0)4 37 70 02 19

Press contact: NewCap Media Annie-Florence Loyer afloyer@newcap.fr - +33 (0)1 44 71 00 12/ +33 (0)6 88 20 35 59