ENYO Pharma SA announces successful initiation of the Phase 1 clinical programme with EYP001, its lead candidate for the treatment of Chronic Hepatitis B Virus infection.

- **The first study is rapidly advancing in line with the initial plan and all results are expected in Q2 2017**
- **Preliminary data of the Single Ascending Dose trial show excellent safety and tolerance**

Lyon, December 16, 2016 **- ENYO Pharma SA, a privately held biopharmaceutical company currently focused on developing treatments for viral infections, today announced that the Phase 1 single and multiple ascending dose trial evaluating EYP001 in healthy subjects has been initiated, and that single dose escalation has been completed. The results have shown that EYP001 is safe and well-tolerated at all doses studied in 46 healthy subjects. The safety and pharmacokinetics (PK) analysis of these first Phase 1 data will be complete by Q2 2017.**

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. ENYO Pharma also announced that next Phase 1 clinical studies of EYP001 are already planned during 2017 to test the safety, PK and initial antiviral activity of EYP001 in subjects with chronic HBV infection.

Jacky Vonderscher, Ph.D., Chief Executive Officer of ENYO Pharma SA commented: “We are very pleased with the pharmacokinetics and safety profile emerging in our Phase 1 development with EYP001. We look forward to bringing EYP001, our first candidate, into further clinical development and believe we have the potential to become a key player in the field of novel CHBV therapies.”

“Several publications with non-clinical models have now pointed strongly to FXR as an important target for HBV infection with the potential to impact disease progression. This represents an attractive approach in developing new treatments for this difficult to cure condition” added Pietro Scalfaro, M.D., Chief Medical Officer of ENYO Pharma SA.

About EYP001

ENYO Pharma SA has licensed a family of FXR agonists from Poxel SA and holds worldwide exclusive rights on these patented compounds. EYP001 is a 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). FXR is a novel and promising drug target with multiple activities required for viral replication and persistence. 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 more efficient suppression of the virus leading to improved, durable viral suppression and cure rates.

About FXR

The farnesoid X receptor (FXR) is a nuclear hormone receptor, also known as the bile acid receptor, regulating several metabolic pathways and in particular controlling the fate of bile acids in the liver and intestine. It also influences the insulin sensitivity of tissues where it is highly expressed. 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 already been shown to prevent and resolve liver fibrosis in rodents and humans.

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 ENYO Pharma's approach to pharmaceutical discovery research

ENYO Pharma's strategy for discovering therapeutic molecules is based on the work initiated by a team at Inserm in Lyon led by ENYO Pharma's co-founders, Prof. Patrice André, Dr. Benoît de Chassey, Dr. Vincent Lotteau and Laurène Meyniel-Schicklin**.** This strategy involves targeting not the constituents of a virus like most current anti-virals do, but host cellular functions necessary for the virus to replicate. To complete a productive infectious cycle, viral proteins must interact with host intracellular proteins and exploit the human cellular machinery. ENYO Pharma’s novel approach blocks the viral:host interactions that are vital for the virus. ENYO’s therapeutics will combat the emergence of new resistant strains and diversify the therapeutic tools available to treat them. As the approach is inspired by viral strategies but modulates host pathways, the molecules discovered by ENYO Pharma have demonstrated remarkable effects on molecular processes such as autophagy and apoptosis. Therapeutics with such modes of action will also have significant impact in non-viral therapeutic areas such as oncology.

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About ENYO Pharma SA - www.enyopharma.com

Based in Lyon (France), ENYO Pharma was co-founded in January 2014 by Inserm research scientists and seed funds including Inserm Transfert Initiative, ADV Life Sciences and Vonderscher & Co. to develop treatments for acute and chronic viral infections. These co-founders were joined in early 2015 by Sofinnova Partners, a venture capital firm based in Paris and, in 2016 by Morningside and Innobio during a Series A driven by Sofinnova. ENYO Pharma's strategy is to prevent virus replication by disrupting the nexus of interactions between viral proteins and human cellular proteins. ENYO Pharma has licensed several Inserm patents originating from discoveries made by the research scientists who co-founded the company and has developed a unique technology platform to identify new intracellular therapeutic targets and molecules acting against these targets, thus expanding the scope of application well beyond virology alone.

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