ENYO Pharma Announces Two Vonafexor Data Presentations at AASLD The Liver Meeting

– An oral presentation on Vonafexor's positive effects after 12 weeks of treatment on liver and kidney functions of NASH patients –

– A poster on modelling efforts to optimize the study design of a combination of Vonafexor and Peg-IFN in chronic HBV patients –

Lyon, France. November 3rd, 2021 - ENYO Pharma (ENYO), a private clinical stage biotechnology company developing innovative drug candidates, today announced that two abstracts on Vonafexor were accepted one as oral presentation and one as poster during the upcoming The Liver Meeting® 2021, organized by the American Association for the Study of Liver Diseases (AASLD) on November 12-15, 2021.

This follows two press releases published late July 2021 by ENYO:

- Positive Vonafexor results for the LIVIFY Phase 2a Study in F2-F3 NASH patients over 12 weeks, where key primary and secondary endpoints were met demonstrating a robust impact on NASH. Vonafexor was safe and well tolerated and is the first FXR agonist showing also improvement of renal function measured by eGFR over 12w treatment.
- 16 weeks Vonafexor top-line interim results from two on-going Phase 2a studies in chronic hepatitis B patients: Vonafexor is the first oral treatment to reduce HBsAg an average of -1.0 log10 after 16 weeks when administered in combination with Peg-IFN in viremic, HBeAg negative, CHB patients. Vonafexor was also safe and well tolerated in these patients.

The first late-breaker abstract refers to an oral presentation by the LIVIFY Principal Investigator Pr Stephen Harrison and will emphasize the key findings with Vonafexor in NASH patients:

Abstract title: "Vonafexor, a FXR agonist, induced hepatic and renal improvement in the randomized, double-blind, placebo-controlled LIVIFY NASH trial"
Publication number: LO2
Session: Late Breaking Session 1 - Sunday, November 14, 2021, 1:00 PM - 2:30 PM

The second abstract refers to a poster presentation on modelling efforts by our collaborators from Novadiscovery to optimize the combination of Vonafexor and Peg-IFN in HBV patients:

Abstract title: "Mechanistic modeling to optimize phase 2b clinical trial design of a new combination therapy for chronic hepatitis B infection"
Publication number: 834
Session: Hepatitis B: Therapeutics: New Agents

"We are very proud that our abstract on the LIVIFY study in NASH patients has been selected for an oral presentation. Vonafexor is getting the attention it deserves as a key therapeutic drug for NASH patients suffering from multiorgan dysfunctions", stated Jacky Vonderscher, PhD, co-founder and Chief Executive Officer of ENYO.

"Last week the prospective 4-year outcome-based study from the NASH CRN cohort reported that in addition to liver related events, a kidney function decrease is a common associated problem in these patients[1]. In this context we are very pleased that the LIVIFY results will be presented at the Liver Meeting showing that Vonafexor has a real potential to improve both kidney and liver function. This is the first FXR agonist with a potential to address several key aspects of a complex disease for which a multidisciplinary approach towards a cardiometabolic liver disease has been advocated[2]", said Pietro Scalfaro, MD, ENYO's Chief Medical Officer.

About Vonafexor

Vonafexor (EYP001) is a synthetic non-steroidal, non-Bile Acid, highly selective FXR agonist orally bioavailable with preferential liver distribution and sustained target engagement that is currently in Phase II clinical development for the treatment of Chronic Hepatitis B (CHB) and of Non-Alcoholic Steato-Hepatitis (NASH).
FXR agonists have gained attention as potential therapeutic agents in hepatobiliary and metabolic diseases. FXR has multiple activities and regulates several metabolic pathways. In particular, it controls the homeostasis 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.

About ENYO Pharma

ENYO Pharma is a privately held, clinical stage biopharmaceutical company incorporated in January 2014 and headquartered in Lyon, France. The Company's most advanced compound, Vonafexor, is a small molecule (non-Bile Acid FXR agonist) therapeutic in Phase II clinical development for the treatment of Chronic Hepatitis B and NASH. Vonafexor and the Company's discovery programs are based on a proprietary technology platform that uses a virus bio-mimetic approach to enable the rapid discovery of first-in-class drug candidates with good safety profiles. For more information on ENYO and Vonafexor, please visit http://www.enyopharma.com/.

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[1] Sanyal AJ et al.; NASH Clinical Research Network (CRN). Prospective Study of Outcomes in Adults with Nonalcoholic Fatty Liver Disease. N Engl J Med. 2021 Oct 21;385(17):1559-1569.
[2] Ruissen M et al.; Management of endocrine disease: Non-alcoholic fatty liver disease: a multidisciplinary approach towards a cardiometabolic liver disease. European Journal of Endocrinology, 2020; 183(3), R57-R73.