



ENYO PHARMA ANNOUNCES A €39 MILLION SERIES C FINANCING AND FDA CLEARANCE TO ADVANCE VONAFEXOR IN A PHASE 2 CLINICAL TRIAL FOR PATIENTS WITH ALPORT SYNDROME

- *The Company will initiate a Phase 2 clinical study of Vonafexor in Alport Syndrome - called "ALPESTRIA-1" - in the first half of 2024.*
- *Series C proceeds will fund the Phase 2 study, as well as operations and further R&D through the first half of 2026.*

Lyon, France – January 3, 2024 - ENYO Pharma ("ENYO") announced that it has received clearance of its Investigational New Drug (IND) application from the U.S. Food and Drug Administration (FDA) to initiate a Phase 2 clinical study of Vonafexor, a highly selective FXR agonist, for the treatment of Alport Syndrome.

Furthermore, ENYO announced the first closing of a 39 million € Series C equity financing, positioning ENYO as an emerging biotechnology company in the field of renal diseases. The financing will support the Phase 2 Alpestria-1 study and further profiling of Vonafexor in other kidney diseases, such as Autosomal Dominant Polycystic Kidney Disease (ADPKD). The financing was co-led by OrbiMed and Morningside Ventures with participation from other existing investors including AndEra Partners, Bpifrance InnoBio and Bpifrance Large Ventures.

The clearance of ENYO's IND represents a significant milestone for the company as it embarks on its first clinical trial focusing on renal disease. ENYO's lead candidate Vonafexor, as well as fast follower EYP651, are highly specific FXR agonists given as once-daily oral treatments. Both compounds have strong fibrolytic and anti-inflammatory properties that are broadly applicable across several renal diseases. Vonafexor effect on renal function (eGFR) was already shown in the Phase 2 LIVIFY study of patients with both kidney impairment and fibrotic liver disease. Preclinical studies in both Alport syndrome and Chronic Kidney Disease mouse models showed beneficial effects of Vonafexor on kidney remodeling and function in a curative mode. In 2023, Vonafexor was granted as Orphan Drug Designation (ODD) by both the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) for Alport syndrome.

"We are delighted with this support from our existing investors" said Dr. Jacky Vonderscher, CEO at ENYO Pharma. "There are huge unmet needs in many kidney diseases with fibrosis or inflammatory components. These patients almost invariably progress to end-stage kidney

disease despite current therapies. The results already obtained with Vonafexor, our highly differentiated anti-inflammatory and fibrolytic lead compound, in patients with moderate kidney impairment and in several preclinical protocols, make us confident that it will greatly benefit to those patients with rare kidney diseases like Alport syndrome. “

” Kidney diseases were somewhat neglected for decades, and it is refreshing to see a team like ENYO pursuing with persistence the development of Vonafexor for the benefit of these patients. “ said **Iain Dukes of OrbiMed,**

About ENYO Pharma:

ENYO is a clinical-stage biopharmaceutical company headquartered in Lyon (France) and developing proprietary drug candidates to improve quality of life and avoid end stage renal disease and dialysis for patients with rare and common kidney diseases.

Since its inception ENYO collected extensive phase I/II clinical data through 9 completed clinical studies with 300+ subjects. For more information : [ENYO Pharma – Developing therapeutics for diseases with impaired kidney function](#)

About OrbiMed:

OrbiMed is a leading healthcare investment firm with \$17 billion in assets under management. OrbiMed invests globally across the healthcare industry, from start-ups to large multinational corporations, through a range of private equity funds, public equity funds and royalty/credit funds. OrbiMed seeks to be a capital provider of choice, providing tailored financing solutions and extensive global team resources to help build world-class healthcare companies. OrbiMed’s team of more than 130 professionals is based in New York City; London; San Francisco; Shanghai; Hong Kong; Mumbai, India; Herzliya, Israel; and other key global markets. For more information : [OrbiMed](#)

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