



Press release

ABIONYX announces the signing of a strategic partnership with GTP Biologics (Fareva Group) and V-Nano (VBI Therapeutics group) for the bioproduction of the bio-HDL CER-001 in France

- **Bioengineering redevelopment of the production of bio-HDL, CER-001**
- **Relocation of the bioproduction to France**

Toulouse, FRANCE, March 25, 2021, 8.00am CET – ABIONYX Pharma (FR0012616852 – ABNX – PEA PME eligible), a new generation biotech company dedicated to the discovery and development of innovative therapies for patients, today announces the conclusion of a strategic partnership with GTP Biologics (Fareva Group) and V-Nano (VBI Therapeutics Group), specialized in the production and formulation of biological nanomedicines.

CER-001 showed positive results in the treatment of an ultrarare kidney disease in a French patient, delaying the need for dialysis and diminishing corneal lipid deposits resulting in improved vision, as reported in a case study recently published in a world-renowned medical journal. Clinical development of CER-001 in renal disease continues in a phase 2a study to prevent acute kidney injury in septic patients, currently underway in Italy. In view of these advances, ABIONYX Pharma has decided to relaunch and reengineer the biomanufacturing of its recombinant bio-HDL mimetic.

GTP Biologics, based in Saint-Julien-en-Genevois, and V-Nano, based in Toulouse, are French companies specializing in bioproduction and nanoformulation. They have the necessary infrastructure and expertise to bioengineer and re-launch the biomanufacture of CER-001. Indeed, CER-001, which is a cutting-edge biomedicine, requires an innovative technological approach to ensure its successful complex bioproduction with high added value in France. GTP Biologics is a major site for biomanufacturing in Saint-Julien-en-Genevois. V-Nano is also a partner of CEA Tech Occitanie in the framework of a technology transfer in nano-characterisation for the opening of a joint laboratory which works in particular on the development of nano-formulations and will have a pilot unit upstream of the production site.

Alain Sainsot, Chief Executive Officer at GTP Biologics/Group Fareva and President of V-Nano/Group VBI Therapeutics, member of CSF-Santé and contributor to the latest report in the National Bio-Production Strategy in France, declares: *“We are very pleased to make a strategic contribution to the development of ABIONYX Pharma’s CER-001 biomedical product, alongside Fareva. It is a major challenge for our industry to be able to produce the most advanced biomedicines in France, in addition to more mature products such as vaccines and monoclonal antibodies. In the case of ABIONYX, the aim is to produce this new biomedicine as quickly as possible to meet the needs of patients without existing treatment and to extend the field of medical innovations that can be carried by this bio-HDL, both in the kidney and in ophthalmology.”*

CER-001 is a complex engineered cell biology-based biomolecule with a diverse mechanism of action similar to natural HDL and therefore has considerable potential. CER-001 as a recombinant bio-HDL mimetic has considerable value in that it has proven to be safe and very well tolerated at high doses of 10-30 mg/kg/week in various indicated studies to date.

Cyrille Tupin, Managing Director of ABIONYX Pharma concludes: *"We would like to thank Alain Sainsot, his team and shareholders for their strategic interest and support for the re-launch of the bioproduction of CER-001 in this next generation biomanufacturing facility in France. We are also delighted with the support of Fareva, through its strategic partnership with VBI Therapeutics in the context of the Saint-Julien-en-Genevois activities. The availability of new batches of bio-HDL is highly anticipated in the context of new ATUs in ultra-rare renal diseases or new indications in nephrology and ophthalmology, in order to improve the prognosis of rare and orphan diseases or other diseases for which there are currently no treatments".*

About Fareva / GTP Biologics

Fareva is a family-owned company with a strategy based on financial independence and is one of the world's leading suppliers of pharmaceuticals, cosmetics, make-up and industrial household products. Fareva is located in 12 countries with 42 manufacturing plants, more than 12,500 employees and a turnover of EUR 1.8 billion. The subsidiary GTP Biologics, which came from the Pierre-Fabre group, was integrated into the Fareva group in December 2020.

About V-Nano

Founded in May 2018 by Alain Sainsot, former industrial director of the pharmaceutical group Pierre Fabre and ex-president of Amatsigroup, V-Nano specialises in the market for the development of biomedicines, in particular injectable nano-emulsions, with the construction, in Toulouse (Haute-Garonne), of a unit specialising in the production of clinical batches for third parties.

About d'ABIONYX Pharma

ABIONYX Pharma is a new generation biotech company dedicated to the discovery and development of innovative therapies for patients. The biotech assets inherited from CERENIS Therapeutics constitute a rich portfolio of valuable programs for the treatment of metabolic diseases as well as with a HDL targeted drug delivery platform.

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