Alentis Therapeutics starts First-in-Human Clinical Trial for the Treatment of Liver and Kidney Fibrosis

- *FDA greenlights Alentis Phase 1 protocol study design*
- *Alentis to begin transition from pre-clinical to clinical*

Basel, Switzerland., 04 January 2022 -- Alentis Therapeutics, AG today announced it has dosed the first cohort of healthy participants in a first-in-human Phase 1 clinical trial of ALE.F02, a monoclonal antibody highly selective for Claudin-1, currently being developed for the treatment of advanced unmet liver and kidney fibrosis. Alentis is a clinical stage biopharma focused on discovering and developing novel therapies for the treatment of unmet fibrotic diseases.

"ALE.F02 has demonstrated compelling safety and efficacy in preclinical patient-derived models of liver and kidney fibrosis. We look forward to further investigating this compound, in this dose-escalating Phase 1 study," said Markus Meyer Ph.D, Vice President R&D. Roberto Iacone, CEO of Alentis Therapeutics added, "We believe our differentiated approach of inhibiting pathological overexpressed and conformation-dependent Claudin-1 epitopes in liver and kidney fibrosis holds the potential to reverse clinically advanced fibrosis."

In the US and Europe alone, about 45% of deaths can be attributed to fibrotic disorders. Fibrosis affects nearly all tissues and organ systems such as the liver, kidneys, and lungs. Advanced liver fibrosis and associated cirrhosis is the fastest-growing indication for liver transplantation in the United States. While multiple investigational agents target mechanisms that impact the earlier metabolic stages of the fibrosis development, Alentis is targeting clinically advanced liver fibrosis associated with different etiologies through inhibition of Claudin-1, a recently discovered therapeutic target for organ fibrosis.

About ALE.F02

ALE.F02 is a highly selective anti-Claudin-1 mAb that recognizes pathological overexpressed and conformation-dependent Claudin-1 epitopes in fibrotic disease. In preclinical studies, the lead molecule ALE.F02 modulates the function of non-junctional Claudin-1, preventing, and possibly reversing, the growth of fibrotic tissue within the liver and kidney by changing the plasticity of key cell types mediating fibrosis. Safety studies in non-human primates have supported translatability of the approach into patients.

About Alentis Therapeutics

Alentis Therapeutics is a clinical stage biopharmaceutical company focused on discovering and developing novel targeted therapies to slow or halt the progression of life-threatening fibrotic diseases. The company was founded in 2019 based on ground-breaking research in the laboratory of Prof. Thomas Baumert MD at the University of Strasbourg and the French National Institute of Health (Inserm).

The Company's lead candidates are monoclonal antibodies that are highly selective for Claudin-1, a novel, previously unexploited target with a unique mechanism of action that plays a key role in the pathology of liver fibrosis and fibrosis-driven hepatobiliary cancers. It also has early discovery programs exploring the potential of Claudin-1 inhibition in the treatment of fibrosis of other tissues including the kidney and lung. These represent very large and expanding markets with high unmet need. Furthermore, the company uses a patient-derived drug and target discovery platform to develop medicines for advanced fibrosis.

Unlike current therapies in fibrosis, which mostly address the disease indirectly, Alentis' pioneering approach has the potential to directly modify and reverse the course of disease progression.

Alentis is headquartered in Basel's pharma-biotech hub in Switzerland with a subsidiary for R&D in Strasbourg, France.

For more information, visit www.alentis.ch

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