

- **Frontier Biotechnologies obtains exclusive rights to develop and commercialize AFFITOPE® AT04 in Greater China**
- **Collaboration accelerates the global development of AFFiRiS' potential first-in-class active immunotherapy with plans to bring production and clinical trials of AT04 to Greater China**

Vienna, Austria, December 22, 2021 – AFFiRiS AG, a clinical-stage biotechnology company developing novel disease-modifying Specific Active Immunotherapies (SAITs), today announced an exclusive collaboration and license agreement with Frontier Biotechnologies Inc. (688221.SH), a commercial-stage biopharmaceutical company, for the development and commercialization of AFFITOPE® AT04 for the treatment of patients with hypercholesterolemia in the Greater China region, including mainland China, Hong Kong, Macau and Taiwan. AFFITOPE® AT04 is a potential first-in-class investigational active immunotherapy targeting PCSK9, with results of a large phase 1 clinical study having recently been published. Shanghai-based Lynx Financial served as the sole financial advisor in this transaction.

Subject to the terms of the agreement, AFFiRiS will receive an upfront cash payment and will be eligible to receive development and regulatory milestone payments, as well as tiered royalties in the upper single-digit range on annual net sales of AT04 in Greater China. Frontier Biotechnologies will be responsible for all development costs for AT04 occurring in Greater China and will receive the rights to develop, manufacture and exclusively commercialize AT04 in the licensed territory. AFFiRiS will retain all rights to AT04 in the rest of the world.

Noel Barrett, PhD, CEO of AFFiRiS AG commented: “This collaboration further validates our AFFITOME® technology platform. In our clinical phase 1 study, AT04 has demonstrated that it could lead to a substantial reduction in low-density lipoprotein cholesterol (LDLc), and we are very excited about the opportunity to collaborate with Frontier Biotechnologies to bring AT04 as a patient-friendly and affordable treatment alternative to China. This collaboration fuels our ongoing efforts to license AT04 globally as we see a growing need for efficacious treatments in hypercholesterolemia.”

Dr. Changjin Wang, CEO of Frontier added: “AT04, with its novel mechanism of action, can be uniquely positioned in the treatment of hypercholesterolemia which is associated with an elevated risk of cardiovascular disease, the leading cause of death worldwide and in China. We are excited about working with Affiris' team and committed to accelerating the development of AT04 in China.”

The agreement is subject to customary regulatory approval in Austria and is expected to complete early in 2022.

About AFFITOPE® AT04:

Using its AFFITOME technology, AFFiRiS develops amino acid sequences that mimic the epitopes of self-proteins, which are modified by mutating the original amino acid sequence. These amino acid sequences, termed AFFITOPEs®, are coupled to a carrier protein and are formulated with an adjuvant to further enhance the immune response. The AFFITOPE® formulation, the basis of SAIT, is administered to patients via a subcutaneous injection, which stimulates the generation of antibodies against the target proteins. AFFITOPE® AT04 is AFFiRiS' novel immunotherapy candidate for the treatment of hypercholesterolemia. AFFiRiS published positive Phase 1 clinical results with AT04 targeting PCSK9 to treat the cardiovascular condition hypercholesterolemia in the peer-reviewed journal *European Journal of Clinical Pharmacology* ([Zeitlinger et al. 2021](#)). In this study, AT04 was demonstrated to be well-tolerated, safe and elicited a humoral immune response against the PCSK9 target epitope. The data also showed that immunization with AT04 resulted in a significant reduction of low-density lipoprotein cholesterol (LDLc), with a reduction of up to 39% in the highest antibody responders.

About AFFiRiS AG:

AFFiRiS is a clinical-stage biotechnology company located in Vienna, Austria, with a vision of using the immune system to identify and target human proteins central to the development and progression of chronic diseases, based on its proprietary patented AFFITOME® technology. The Company's ultimate goal is to improve the lives of patients suffering from these diseases by providing specific immunotherapies. In addition to its active immunotherapy AT04, AFFiRiS' pipeline also includes the monoclonal antibody mAB C6-17 targeting mutated huntingtin (mtHTT) protein, which causes Huntington's disease.

For further information, please visit www.affiris.com and follow us on [LinkedIn](#) and [Twitter](#).

For further information on AFFiRiS' SAIT programme, please also visit <https://affiris.com/approach/#overview-of-sait>

About Frontier Biotechnologies Inc.:

Frontier is an innovation-driven biopharmaceutical company. Through more than a decade of committed effort, Frontier Biotech has built an extraordinary team with international vision and deep expertise in new drug development and established a fully integrated state-of-the-art long-acting peptide new drug innovation platform with global intellectual properties. In addition to the launch of Aikening®, a Category 1 product and the first long-acting HIV fusion inhibitor in the world, Frontier Biotech is advancing an array of clinical assets through our R&D pipeline. This includes multiple programs reaching Phase 1 and 2 clinical trials in China and the United States.

For more information:

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