

Arctic Therapeutics Announces Enrollment of First Patients in Phase IIa Trial of AT-004 for Acne Vulgaris

- *Acne vulgaris affects an estimated 650 million people worldwide with a significant impact on quality of life, mental well-being, and self-esteem.*
- *AT-004 targets a novel, TNF- α -modulating anti-inflammatory pathway in the skin, with relevance across multiple inflammatory dermatologic conditions.*

REYKJAVIK, ICELAND – February 11, 2026 – Arctic Therapeutics (ATx) today announced that the first patients have been enrolled in a Phase IIa randomized, double-blind, placebo-controlled clinical trial evaluating the safety and efficacy of topical AT-004 in patients with acne vulgaris (AV).

The study follows regulatory approval from the European Medicines Agency (EMA) in December 2025 and is conducted across three clinical sites in Denmark

AV is one of the most common inflammatory skin diseases worldwide, affecting an estimated 650 million people globally and ranking among the most prevalent diseases across all age groups, research shows. While often associated with adolescence, acne frequently persists into adulthood and can have a significant impact on quality of life, contributing to anxiety, reduced self-esteem, and depression.

“AV affects hundreds of millions of people worldwide and is far more than a cosmetic condition,” said Ivar Hakonarson, chief executive officer and co-founder of ATx. “The initiation of patient enrollment marks an important milestone for AT-004 as we work to advance a novel approach that has the potential to meaningfully improve outcomes for people living with this disease,” he added.

AT-004 is an acetylcholinesterase inhibitor representing a novel and innovative approach to treating inflammatory skin diseases. By targeting the non-neuronal cholinergic anti-inflammatory pathway, a biological system present in human skin involved in regulating inflammation and pro-inflammatory cytokines such as TNF- α , AT-004 has the potential to introduce a first-in-class mechanism in dermatologic therapy. Preclinical and early clinical findings further suggest that AT-004 could deliver robust local anti-inflammatory effects without systemic exposure, positioning it as a promising investigational treatment option beyond AV.

“As AT-004 targets a novel anti-inflammatory pathway in the skin, it represents a new approach to the treatment of inflammatory dermatologic conditions,” said ATx founder Dr. Hakon Hakonarson. “While our current clinical focus is acne vulgaris, these findings suggest the mechanism underlying AT-004 could be relevant across a range of inflammatory skin diseases, including atopic dermatitis, psoriasis and rosacea, warranting further clinical investigation,” Dr. Hakonarson added.

About the Phase IIa Study

The Phase IIa clinical trial is a randomized, double-blind, placebo-controlled study designed to evaluate the safety, tolerability, and preliminary efficacy of AT-004 in adults with AV. The study will enroll 60 participants aged 18 to 45, randomized 1:1 to receive either AT-004 or placebo for a 12-week treatment period, with 30 participants in each arm. All enrolled participants will be included in the final analysis.

Safety assessments will include monitoring of adverse events, local skin reactions, physical examinations, vital signs, and clinical laboratory testing, including serum chemistry and hematology, as well as pregnancy testing for women of child-bearing potential. Clinical efficacy will be assessed using the Investigator’s Global Assessment (IGA) scale in combination with lesion counts at baseline and at Weeks 4, 8, and 12.

The study will be conducted across three clinical sites in Denmark and is being carried out by Blueskin, a leading European contract research organization (CRO) specializing in dermatology. Blueskin is part of the Sanos Group of companies, a multi-niche CRO with a strong track record in the design and execution of dermatology clinical trials.

About Arctic Therapeutics

ATx is a clinical-stage biopharmaceutical company, established in 2015 as a spin-off from the US-based Center for Applied Genomics (CAG), a research centre at the Children’s Hospital of Philadelphia. Our diversified pipeline reflects our deep commitment to address diseases with a high unmet need, where we have identified a pathway from a genetic discovery to

safe and effective treatment. The company has operations in Iceland, the US and multiple collaborations across Europe. For more information, please visit: www.arctictherapeutics.com and follow us on [LinkedIn](#).

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