



Axalbion Presented Promising Phase 2 Clinical Data in Chronic Cough with AX-8, a Novel TRPM8 Agonist, in an Oral Presentation at the American Thoracic Society (ATS) 2023 International Conference

Proof-of-Concept Study Signals AX-8's Potential in Chronic Cough Treatment, Especially in Patients with Moderate-to-Severe Throat Discomfort

Washington, DC, May 22, 2023 – Axalbion, a clinical-stage biopharmaceutical company focused on developing novel medicines to treat cough, presented positive results from a Phase 2 proof-of-concept study with its transient receptor potential melastatin 8 (TRPM8) agonist, AX-8, in patients with refractory or unexplained chronic cough, in an oral session at the American Thoracic Society (ATS) 2023 International Conference, being held in Washington, DC, from May 19 - 24, 2023. ([ClinicalTrials.gov NCT04866563](https://clinicaltrials.gov/NCT04866563); EudraCT Number 2021-000844-23).

“Refractory chronic cough is a burdensome condition that significantly impacts a patient’s quality of life, leading to urinary incontinence, social stigma, sleep disturbances, anxiety, depression and social isolation. There are currently no approved treatments. AX-8 shows promising results in this proof-of-concept study with a robust reduction in cough frequency in patients experiencing the greatest throat discomfort. This distressing symptom, often described as irritation or tickle, is observed in most patients and is indicative of the sensory hypersensitivity associated with the condition,” said Jaclyn Smith, MD, principal investigator and professor of respiratory medicine at University of Manchester, UK. “We believe that AX-8 acts as a counterirritant that activates TRPM8 channels in throat sensory fibers. With its distinct mechanism of action and favorable safety profile, it possesses the potential to be a groundbreaking first-in-class treatment for refractory chronic cough.”

Presentation Details

Abstract: #7315

Title: Randomized Proof-of-Concept Study of AX-8, a TRPM8 Agonist, in Refractory or Unexplained Chronic Cough

Presenter: Dr. Jaclyn Smith, Professor of Respiratory Medicine, University of Manchester, UK, and Principal Investigator

Session: A99 – Clinical Trials in Chronic Lung Disease – Mini Symposium

Date and Time: Sunday, May 21, 2023, 3 pm- 3:15 pm ET

The abstract is available [here](#), in the online abstract issue of the American Journal of Respiratory and Critical Care Medicine, Volume 207, 2023.

Additional Phase 2 Study Planned in Patients with Chronic Cough

Based on these positive findings, the company plans to initiate a Phase 2 study of AX-8 in patients with chronic cough with moderate-to-severe throat discomfort, who are the most likely to benefit from treatment with AX-8.

About TRPM8 and AX-8

TRPM8 is expressed in many of the sensory fibers innervating the upper airways. Axalbion believes that activating TRPM8-expressing fibers with AX-8, a potent TRPM8 agonist, will normalize the upper airway sensitivity in chronic cough patients, decreasing coughing (antitussive effect) and irritation of the throat (counterirritant effect). David Julius and Ardem Patapoutian were awarded the 2021 Nobel Prize in Physiology or Medicine for their discoveries of thermal and mechanical transducers, including the discovery of TRPM8. Since its cloning in 2002, extensive research has identified TRPM8 as a potential target to relieve symptoms or cure several diseases. Animal models have shown that activation of TRPM8-expressing fibers in the skin inhibits sensory hypersensitivity in peripheral neuropathy and inflammation, as well as itching.

About Chronic Cough

Chronic cough is defined as a cough lasting for more than eight weeks, often occurring in bouts. More than 80% of patients in tertiary cough clinics have throat irritation which triggers cough bouts, defining a population with oropharyngeal hypersensitivity potentially responding to a topical locally acting drug such as AX-8. After potential triggers such as gastro-intestinal reflux disease (GERD) and asthma have been excluded or treated, cough still remains a significant and common problem for many patients. Chronic cough has a substantial impact on quality of life with, for example, around half of female patients having urinary stress incontinence. There are no approved drugs for the treatment of chronic cough, making it a significant unmet need affecting approximately 26 million people in the U.S. alone, with approximately three million having refractory or unexplained chronic cough lasting for more than a year and approximately six million having refractory or unexplained chronic cough lasting more than eight weeks and less than one year.

About Axalbion

Axalbion is a privately held, clinical-stage biotechnology company developing novel medicines for the treatment of chronic cough. The company, founded in December 2016, is based in Manchester, United Kingdom, a region known for its centers of excellence in respiratory research, with offices in Lausanne, Switzerland and Mountain View, CA. For further information, please visit www.axalbion.com.

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