Cath Lab Digest

ANGINA

Auxilius Pharma Announces Successful Conclusion of First-in-Human Clinical Trial of AUX-001 for Treatment of Chronic Stable Angina Pectoris

Auxilius Pharma News

03/15/2024

BOSTON – Auxilius Pharma announces the successful conclusion of the first-in-human clinical trial of its product-in-development, AUX-001, for the treatment of chronic stable angina pectoris (NCT06249581). The trial, an exploratory Phase 1a pharmacokinetics study enlisting 16 healthy adult volunteers, was conducted in Portugal, with the clinical phase concluding just before the end of 2023.

The study investigated the pharmacokinetics of AUX-001, an oral, extended-release, once-daily version of nicorandil under fasting and fed nutritional states. The secondary objective was to assess the safety and tolerability of Auxilius' investigational anti-anginal medication.

The study's topline results showed that AUX-001 effectively extended the half-life of nicorandil from the standard 49±8 min, as seen with the current immediate-release form administered twice daily, to over 9 hours. Other pharmacokinetic parameters fall within the

proactively managed by using over the counter NSAID headache remedies, predominantly acetaminophen (paracetamol). Other AEs included asymptomatic hypotension, nasal congestion, and palpitations; however, most were mild, and none were serious, aligning with the known side effects of the active compound. Said Auxilius CMO Uwe Tigör, MD: "Headaches upon treatment initiation with nicorandil can lead 15 to 30% of patients to leave any trial. Ours is probably one of very few angina studies using oral nicorandil with no headache related patient dropouts, thanks to our preemptive management and proactive patient communication". Nicorandil usually causes lower rates of initial headaches compared to the other vasodilator class of anti-angina medication, long-acting nitrates (LANs), which are very frequently used in the US and Europe in chronic angina patients.

Auxilius Pharma considers the collective results of this clinical trial with its lead R&D product a very encouraging first step in the clinical development process. The company is actively looking toward the future and the opportunities for growth that lie ahead. Said Auxilius Pharma CEO Jed Litwiniuk: "*We are reassured by the outcomes of the trial. With our IND filing for AUX-001 planned for later this year, we are now actively opening our partnering window to seek a mid- to large-size pharmaceutical partner company to finalize the clinical development of our lead asset AUX-001.*"

The company is set to introduce AUX-001, an innovative, proprietary, once-daily formulation of Nicorandil, to the US market. This initiative follows a collaborative agreement with the FDA on the 505(b)2 regulatory pathway, capitalizing on the extensive historical data from the immediate-release version long used in Europe and Asia. As AUX-001 is anticipated to enter the US as a new chemical entity (NCE), it stands to gain up to five years of market exclusivity upon approval, further supported by Auxilius's comprehensive intellectual property rights being secured in the US and globally. This strategic move not only underscores Auxilius Pharma's commitment to enhancing cardiac care but also positions AUX-001 to significantly impact the treatment landscape for chronic angina in the United States.

About Chronic Stable Angina

Chronic Stable Angina Pectoris (CSAP) is one of the most common cardiovascular conditions affecting over 11 million patients in the US. It is a common manifestation of atherosclerotic coronary artery disease (CAD), marked by chest pain or discomfort due to reduced myocardial blood flow, usually triggered by physical exertion, emotional stress, or other factors. CSAP prevalence is significant and growing, with around 650.000 new cases annually in the US. Standard of care for most patients with stable coronary artery disease underlying their chronic angina optimized medical therapy with anti-anginal medications. In the US, CSAP patients suffering either daily or weekly angina symptoms are treated with at least 2 antianginal medications to control their symptoms. Despite the availability of various anti-anginal medications, there has been a considerable paucity of developing new, innovative anti-angina medications since the last anti-anginal drug launched in the US in 2006.

About AUX-001

AUX-001 is an innovative, once-daily, extended-release formulation of Nicorandil. For decades, immediate-release, twice daily Nicorandil has been a cornerstone treatment for chronic angina symptoms outside the US, distinguished by its dual mechanism of action that targets both the micro- and macrovascular coronary artery flow bed, and providing sustained angina symptom relief without the common issue of tachyphylaxis seen with other anti-anginal vasodilators like long-acting nitrates. AUX-001 offers efficacy comparable to conventional anti-anginal medications such as beta-blockers, calcium channel blockers, and long-acting nitrates while also potentially enhancing control of the underlying coronary disease and reducing angina-related hospitalizations.

About Auxilius Pharma

Auxilius Pharma is a privately held pharmaceutical company that commenced operations in 2019. Auxilius operates in the space of value-added medicines and brings innovation to areas of high unmet need for patients with diseases such as chronic stable angina pectoris that aim to impact public health positively. Auxilius Pharma’s R&D Strategy is driven by patients' need for affordable medications to manage their chronic conditions in the US and on other major markets.

Find More:

[The Latest Clinical & Industry News]

[Grand Rounds With Morton Kern, MD]

[Watch: Cath Lab Live Videos]

[Podcasts: Cath Lab Conversations]