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Auxilius Pharma to launch Phase Ib anti-anginal trial after IND application

Auxilius Pharma has developed AUX-001 which is a once-daily version of nicorandil for patients with chronic stable angina pectoris.

Abigail Beaney | March 27, 2024

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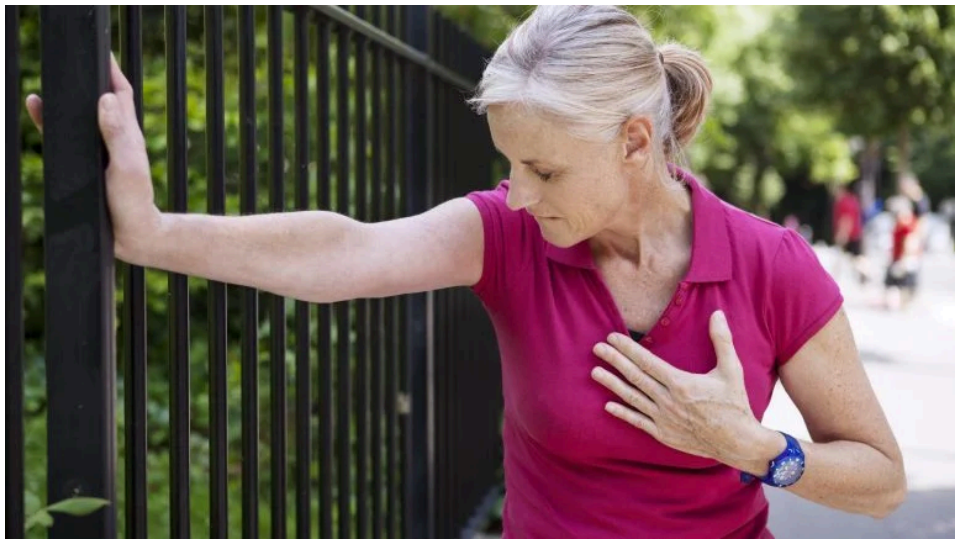

Auxilius Pharma has agreed with the FDA to submit a 505(b)(2) NDA for the candidate. Image credit: Shutterstock / Image Point Fr.

Auxilius Pharma will be submitting an investigative new drug (IND) application for AUX-001 with plans to initiate a Phase Ib trial in chronic stable angina pectoris (CSAP).

The company hopes to start the Phase Ib trial in Q4 2024 or early Q1 2025, quickly after it anticipates receiving IND approval from the US Food and Drug Administration (FDA), CEO Jed Litwiniuk told the *Clinical Trials Arena*.

AUX-001 is an oral, extended-release, once-daily version of Roche's nicorandil which was originally developed by Chugai Pharmaceutical.

"Chugai Pharmaceutical intended to introduce it to the US. The company was acquired by Roche who did not want to continue the cardiovascular portfolio so disposed of the project," Litwiniuk explains.

The Phase Ib trial will be a bioequivalence study investigating the PK of AUX-001 over one month and will enrol approximately 35 healthy volunteers. The study will need to show the once-daily AUX-001 is bioequivalent to the twice-daily product.

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Due to the candidate being a developed version of a previously investigated drug, the FDA has accepted a 505(b)(2) NDA for the candidate, meaning the company does not need to conduct a Phase II trial.

Therefore, if the candidate shows a good PK profile in Phase Ib, the company aims to initiate a Phase III trial of the candidate in H2 2025.

The Phase III trial will be a 12-week study to determine efficacy compared to a placebo. The Phase III trial will enrol approximately 250 patients in two arms.

Litwiniuk said that the move to once-daily dosing is due to changes across the industry since nicorandil was first introduced.

"20 years ago, it probably would have been okay to introduce a twice-daily candidate but that is not the case now. Once daily dosing brings about many advantages in terms of convenience for patients and better adherence," Litwiniuk adds.

On 15 March, the company announced positive results of the candidate's safety profile from its Phase Ia, first-in-human trial of the candidate.

CSAP landscape

Chronic stable angina pectoris is a type of angina that is characterised by recurring chest pain or discomfort. It occurs when there is reduced blood flow to the heart muscle due to narrowed or blocked coronary arteries.

The chest pain in chronic stable angina is usually triggered by physical exertion or emotional stress and typically lasts for a few minutes.

GlobalData estimates that sales of the angina market (stable, microvascular, variant) to be approximately $7.8bn across the seven major markets (7MM: US, France, Germany, Italy, Spain, UK, and Japan) in 2028.

GlobalData is the parent company of the *Clinical Trials Arena*.

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