



AUXILIUS  
PHARMA

# AUX-001

## Phase 1a key results

Exploratory Pharmacokinetics and Hemodynamics  
under Fed or Fasting Conditions



ESC




European Society  
of Cardiology

September 2024




# CSAP

## Chronic Stable Angina Pectoris

### Profile

-  Symptomatic side of coronary artery disease (CAD)
-  Manifest as chest pain and shortness of breath
-  Uncontrolled angina elevates the risk of future cardiovascular events in CAD patients

### Challenge

-  Heart Disease remains the **number one cause of death** among Americans<sup>1</sup>
-  Coronary Artery Disease (CAD) causes **~60%** of HD-related deaths<sup>1</sup>
-  Angina is present in **>50%** of CAD patients and is often the first symptom<sup>1 3</sup>

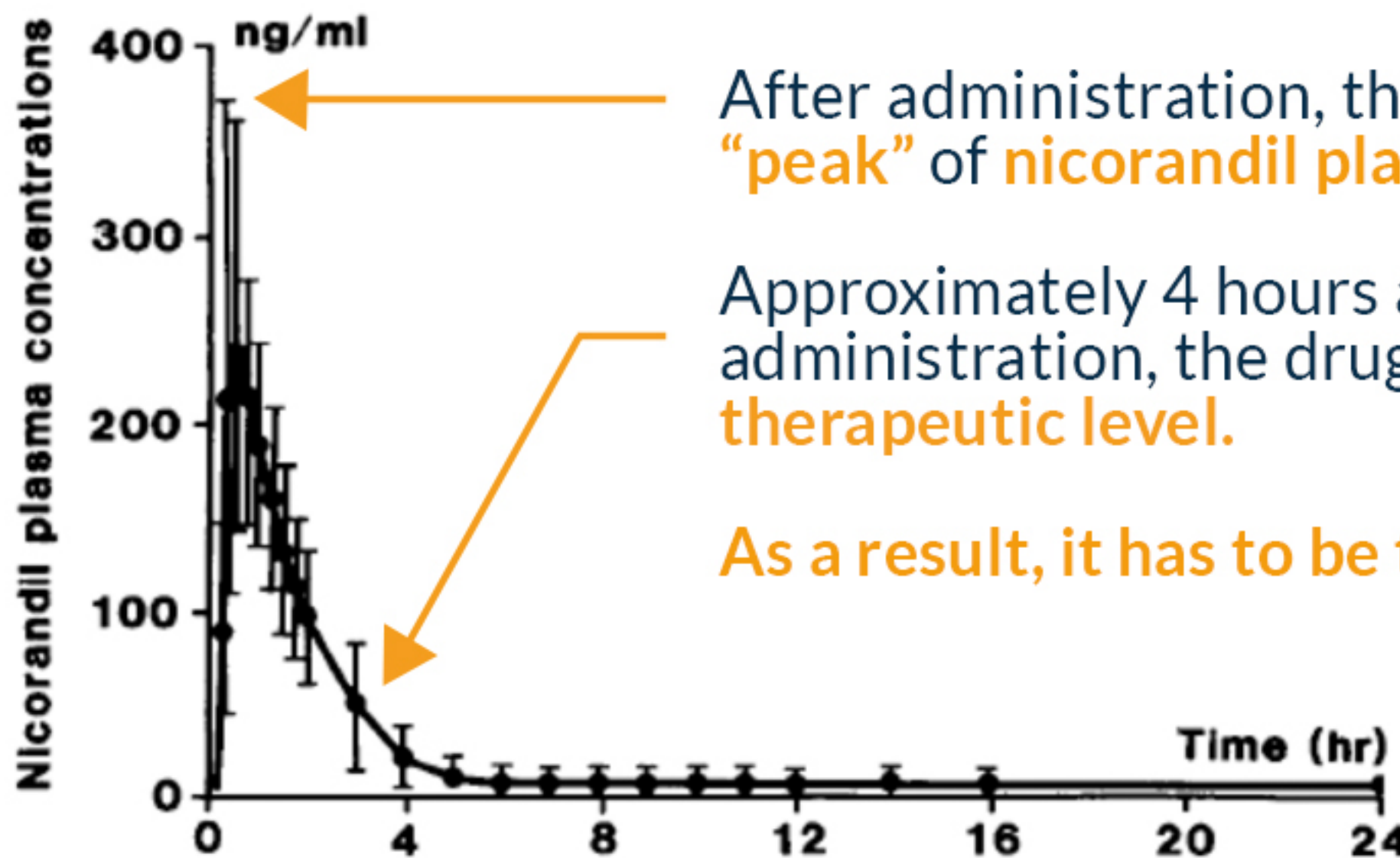


CSAP affects **11 M** Americans over the age of 20<sup>1</sup>

Stable angina symptomatic treatment annual sales in the US amount to **over \$2.5 bn**

Only **57%** of US patients with stable angina receive chronic drug treatment<sup>1 2</sup>

# Why develop an Extended-Release Nicorandil?



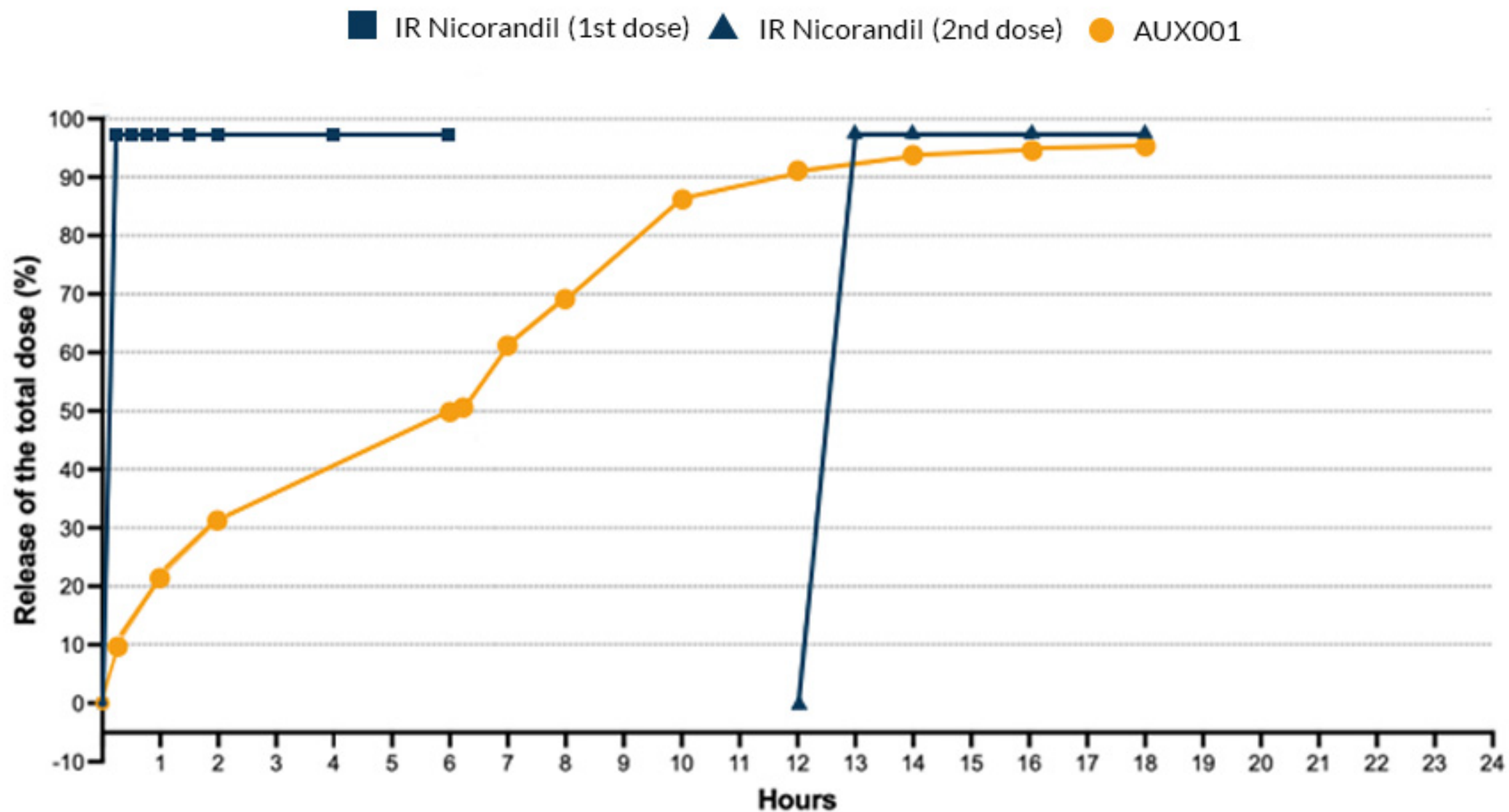
After administration, there is only a short “**peak**” of **nicorandil plasma levels**.

Approximately 4 hours after administration, the drug is **below therapeutic level**.

**As a result, it has to be taken twice daily.**

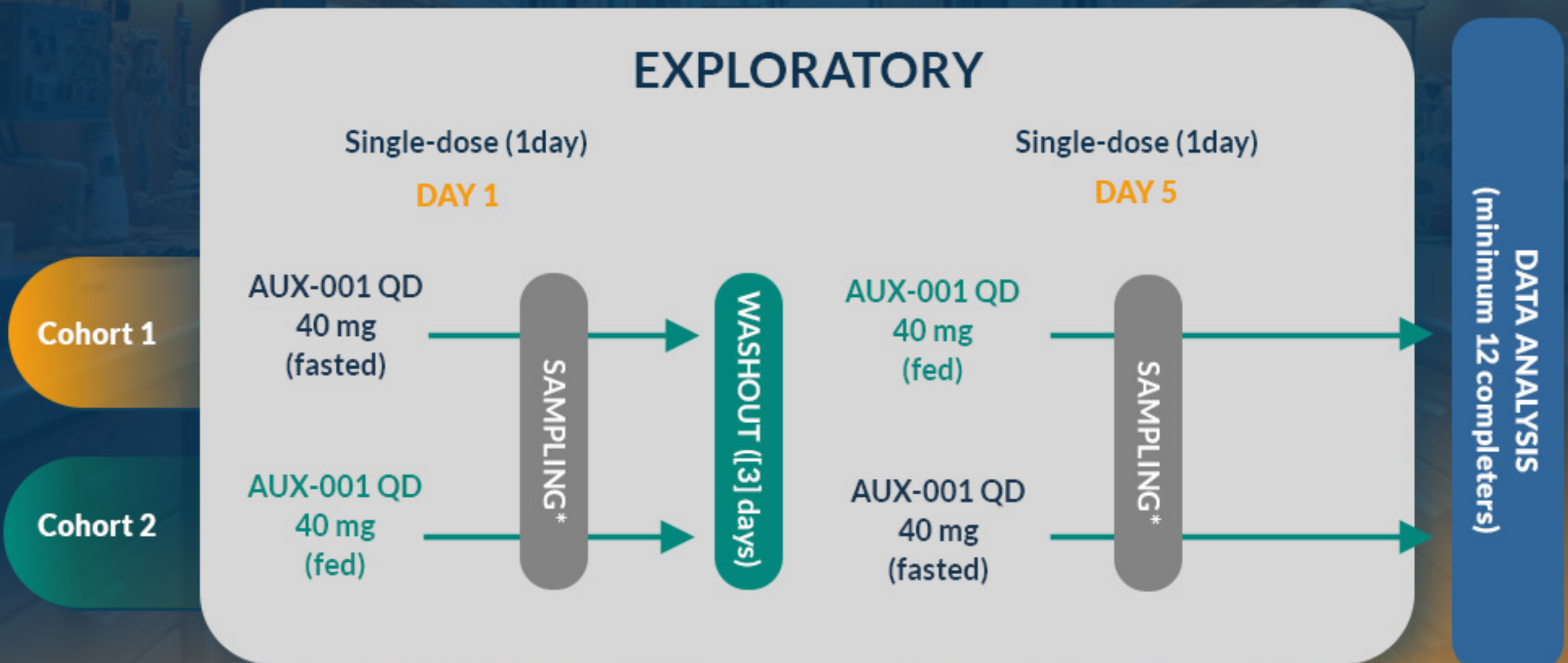
# Proof-of-concept

AUX-001 demonstrates  $\geq 18$ h of extended release vs. IR nicorandil twice -daily in an in-vivo dissolution profile



# Exploratory Pharmacokinetic Phase 1a Study:

Single-dose, 2-sequence crossover study  
in healthy adult volunteers

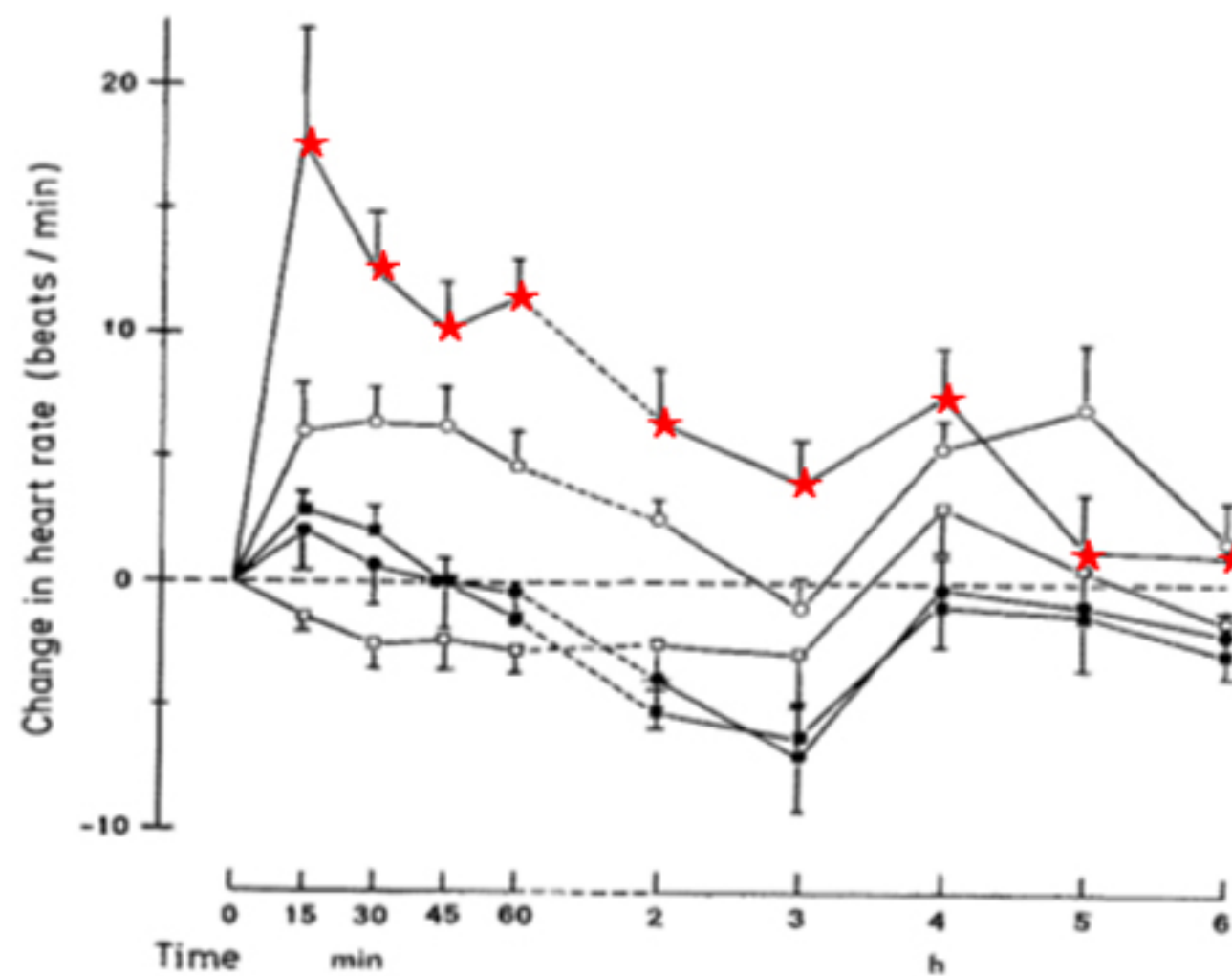


N=16 - Health Volunteers (3 females, 13males);  
Age  $\geq 18$  and  $\leq 55$  years, BMI  $\geq 18.0$   
and  $\leq 31.0$  kg/m<sup>2</sup>

EudraCT number: 2008-005532-32  
US NLM ClinicalTrials.gov: NCT06249581

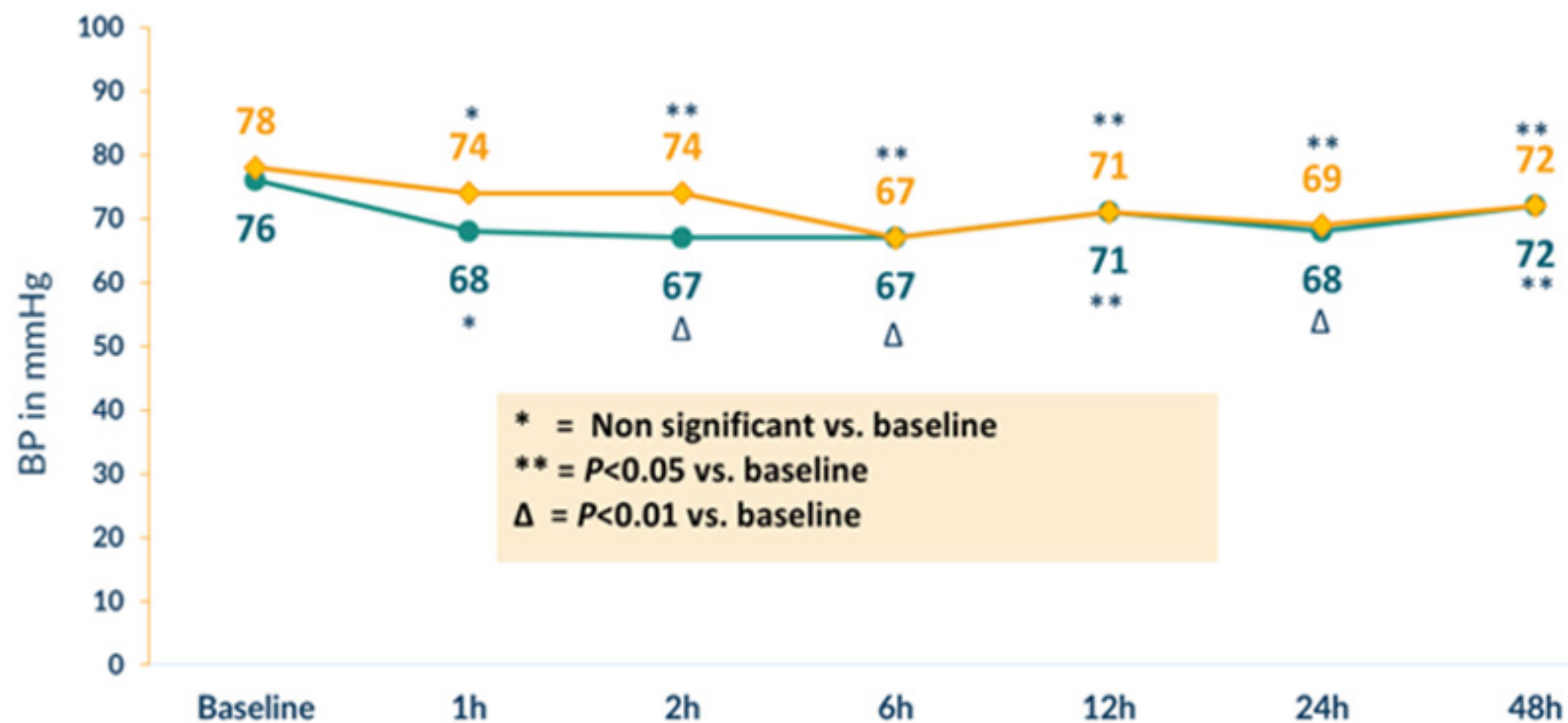
## Heart Rate response to Oral Immediate-release Nicorandil

Change in heart rate ( $\Delta$ HR; mean  $\pm$  SEM) from baseline)



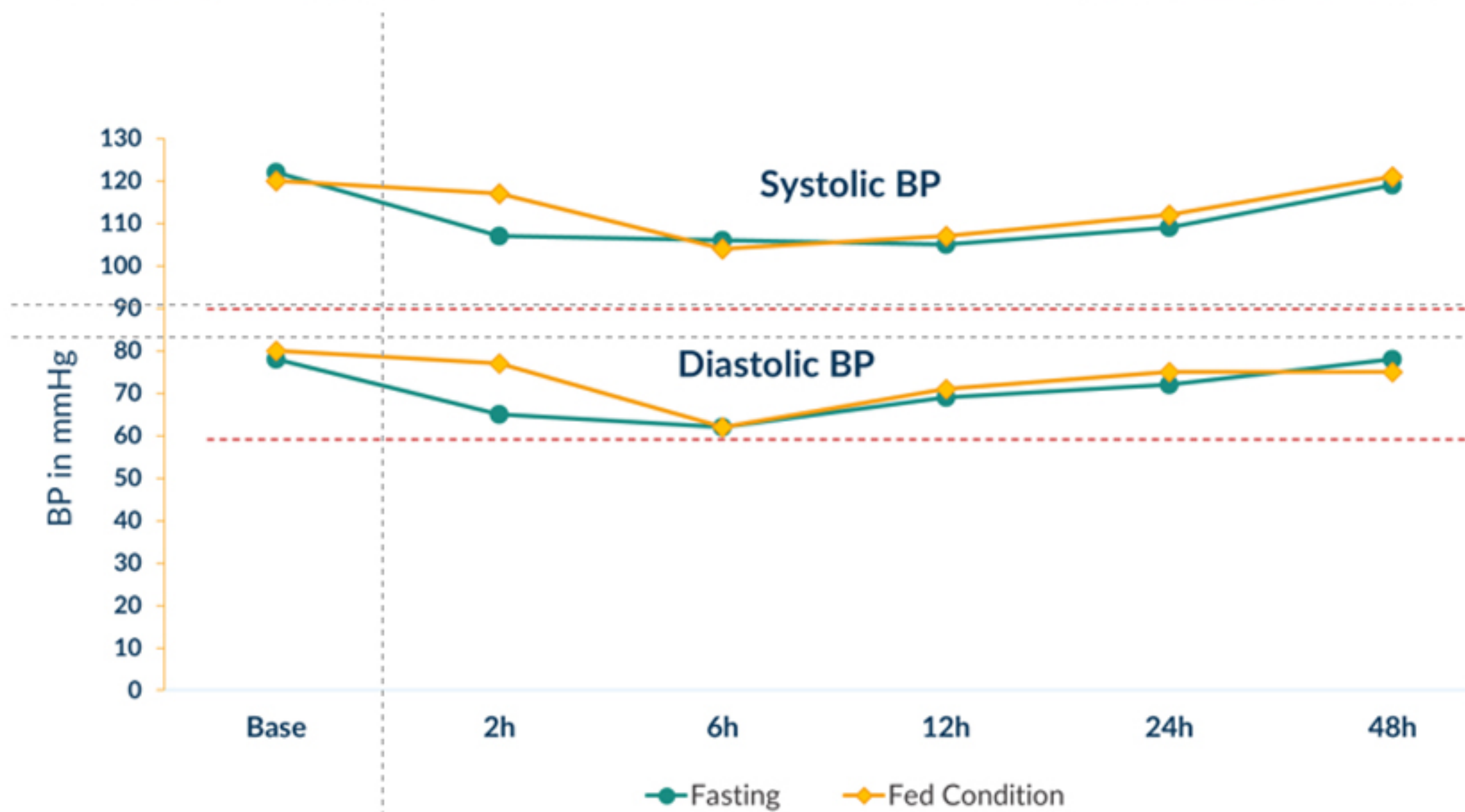
- - Placebo
- - sublingual ISDN 5 mg
- - sublingual nicorandil 15mg
- - sublingual nicorandil 30mg
- ★ - sublingual nicorandil 60mg

## Heart Rate Response to a single-dose of AUX-001 under Fasting vs. Fed Conditions



Source: Auxilius Pharma. AUX-PN19-PK01 Study. Data on File. April 2024

## Systolic and Diastolic Blood Pressure Response to a single-dose of AUX-001 under Fasting vs. Fed Conditions



Source: Auxilius Pharma. AUX-PN19-PK01 Study. Data on File. April 2024





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**Contact us for more details:**

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