A Phase 2 Study to Investigate Ampreloxetine in the Treatment of Symptomatic Neurogenic Orthostatic Hypotension (nOH)

[Ampreloxetine is being investigated for the treatment of symptomatic nOH and is not yet approved]

THANK YOU to the participants who took part in this clinical study and their caregivers

What is symptomatic nOH?

- In symptomatic nOH, the nerves that control blood pressure do not work adequately
- When people with symptomatic nOH sit up or stand up, blood pressure falls, with symptoms of dizziness, lightheadedness, and feeling faint
- Symptomatic nOH occurs in people with multiple system atrophy, Parkinson's disease, and pure autonomic failure

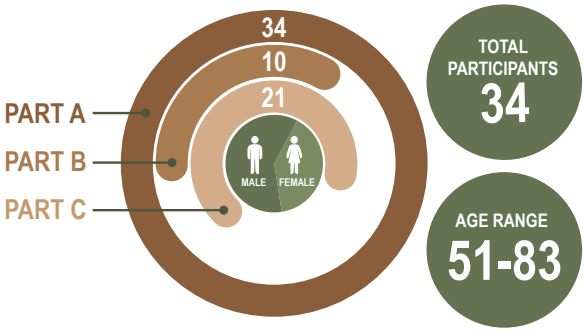
What did we want to learn during the study?

PART A Which dose of ampreloxetine works?

PART B Does ampreloxetine work better than placebo?

PART C Does the effect of ampreloxetine last?

Who took part in the study?



What study drug did each participant take?

P Placebo A Ampreloxetine

PART A — 5 days

P → A

Day 1: single dose

Days 2-5: single dose 2.5-20 mg

Participants did not know whether placebo or ampreloxetine was being taken

PART B — 1 day

P → A

Day 1: single dose

Day 1: single dose (most common dose 15 mg)

Participants nor study investigators knew whether placebo or ampreloxetine was being taken

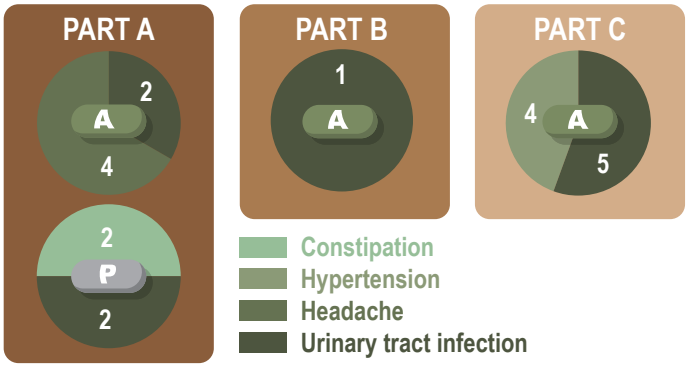
PART C — 20 weeks

A

Once a Day (most common dose 10 mg)

Participants and study investigators knew ampreloxetine was being taken

What were the most common adverse events?



What were the clinical effects of ampreloxetine?

PART A 5- and 10-mg doses of ampreloxetine were most effective at increasing sitting and standing blood pressure

PART B Ampreloxetine increased sitting and standing blood pressure more than placebo

PART C Ampreloxetine increased standing blood pressure and improved symptoms of lightheadedness, dizziness, and feeling faint for up to 20 weeks

How did this study help?

- Ampreloxetine was well tolerated
- For most participants, once-daily ampreloxetine improved symptomatic nOH for up to 20 weeks, with worsening of symptoms after ampreloxetine was stopped
- These encouraging results led to the initiation of Phase 3 studies in larger numbers of participants, which are currently ongoing

Theravance Biopharma