

Efficacy and Safety of Deucricitbant to Prevent HAE Attacks in People With Hereditary Angioedema:

Results From the Phase 2 Prophylaxis CHAPTER-1 Study

The purpose of this **plain language summary** is to present the key results of the CHAPTER-1 study.



Deucricitbant:
<doo-**crick**-ti-bant>

Placebo:
<pluh-**see**-bow>

Why is deucricitbant being developed for prevention of HAE attacks?

- Although approved therapies for preventing hereditary angioedema (HAE) attacks are available, there remains a need for effective and safe treatments that are easy to administer.
- Deucricitbant is being developed in two different formulations for prevention and for treatment of HAE attacks. Deucricitbant is taken by mouth, which could make it quicker and easier to take.
- The bradykinin B2 receptor plays an important role in HAE as it acts like a control valve that can prevent or allow fluid to move out of blood vessels into the surrounding tissues. Deucricitbant works by preventing the bradykinin B2 receptor from being open, so that leakage of fluids from the blood vessel into surrounding tissues is prevented.
- Currently, deucricitbant is only available in clinical studies as a potential future prophylactic treatment for HAE attacks. It is not yet approved by any health authorities as a treatment for HAE.

What did the CHAPTER-1 study look at?

- CHAPTER-1 is a clinical study looking at the potential prophylactic use of deucricitbant to prevent HAE attacks.
- The aim of the CHAPTER-1 study is to find out if taking deucricitbant prevents HAE attacks. Researchers also assess the type and frequency of any side effects that the participants may have during the study.
- Deucricitbant is taken orally.

Who took part in the CHAPTER-1 study?

- 34 adults between ages 18 and 75 years with HAE type 1 or type 2.
- The participants were from Canada, Europe, the United Kingdom, and the United States.

What happened in the CHAPTER-1 study?

- The CHAPTER-1 study is set up in 2 parts. Part 1 is complete and Part 2 is ongoing.
- This summary presents the main results of Part 1.
- At the beginning of Part 1, the participants were split into three groups at random. Participants in the three groups took either a placebo or deucricitbant (20 mg or 40 mg) daily for 12 weeks.



A placebo looks like deucricitbant but does not contain any medicine.

- During Part 1 of the study, the study doctors, researchers and participants did not know which treatment each participant was taking.
- By comparing the results of the participants who took deucricitbant (20 mg or 40 mg) and those who took the placebo, the researchers can find out if deucricitbant is able to prevent HAE attacks.
- There were 30 participants who completed Part 1 of the CHAPTER-1 study, and all of them chose to join Part 2.
- In Part 2, all participants take deucricitbant (40 mg) daily for 2.5 years or longer. Part 2 of the study is still ongoing.





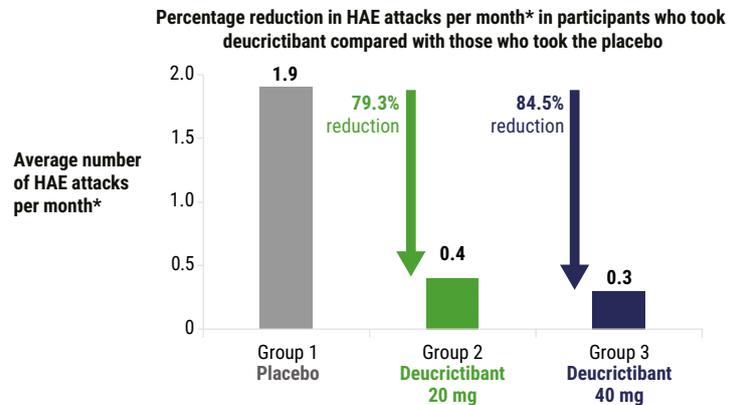
Deucricitibant:
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What were the results of the CHAPTER-1 study?

Fewer HAE attacks

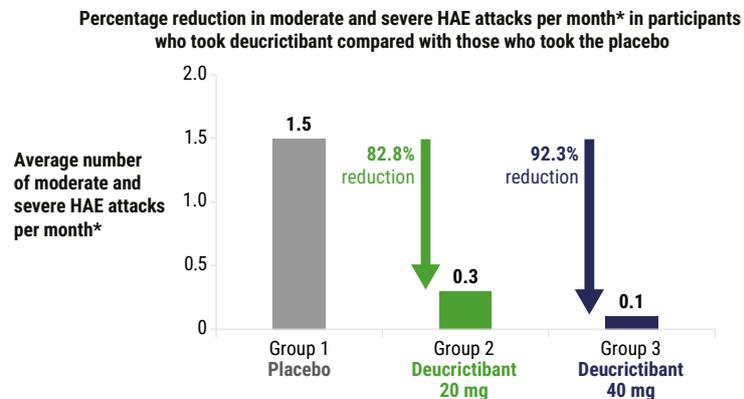
- During Part 1 of the CHAPTER-1 study, participants who took deucricitibant had fewer HAE attacks per month* than those who took the placebo.
- Deucricitibant also similarly reduced the number of HAE attacks in participants who:
 - Had fewer than 2 HAE attacks per month* before joining the study, or
 - Had 2 or more HAE attacks per month* before joining the study.



*1 month is defined as 4 weeks.

Fewer moderate and severe HAE attacks

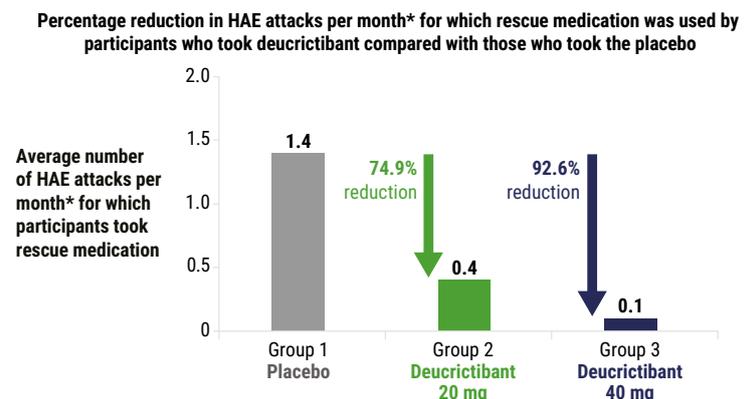
- The number of HAE attacks that were considered of moderate or severe intensity was lower for the participants who took deucricitibant than those who took the placebo.
- None of the participants who took deucricitibant had a severe attack. Some of the participants who took the placebo had severe attacks.
 - HAE attacks were defined as moderate or severe based on how much they impacted the participants' ability to perform their daily activities.



*1 month is defined as 4 weeks.

Fewer HAE attacks treated with on-demand rescue medication

- Participants who took deucricitibant had fewer attacks per month* for which they used rescue medication.
 - In this study, if an HAE attack occurred while participants were taking deucricitibant or the placebo as a preventative treatment, they could take their usual on-demand rescue medication to treat the symptoms of the attack.



*1 month is defined as 4 weeks.

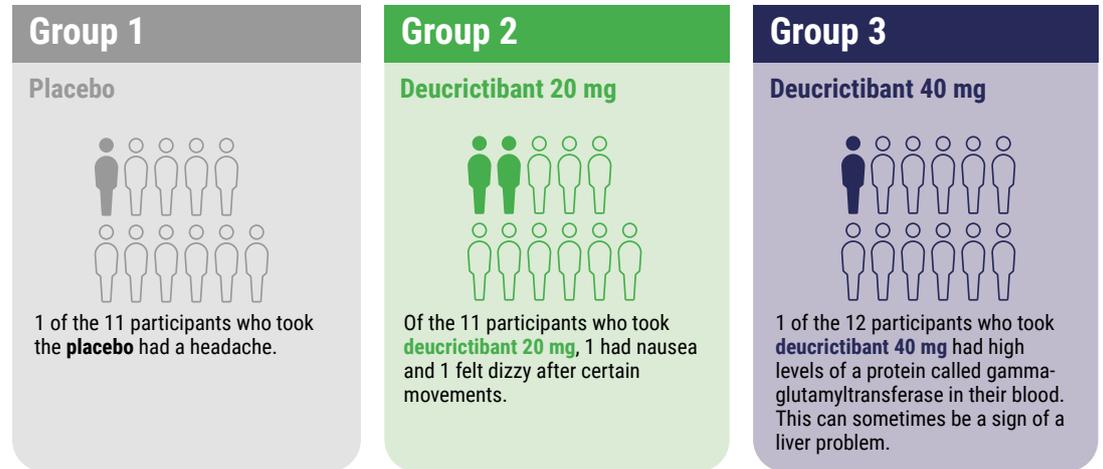


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The incidence of side effects related to treatment was similar for participants taking deucricitibant or placebo

- All of the side effects considered related to treatment that the participants reported during Part 1 of the study resulted in no or mild symptoms and did not limit activities of daily living.
- None of the participants had a serious side effect or needed to stop taking the study drug because of side effects related to treatment.
 - A serious side effect is an important medical event that may require hospitalization, be life-threatening or fatal.



What are the main findings from the CHAPTER-1 study?

- The results of the CHAPTER-1 study showed that:
 - Deucricitibant reduced the chance of having HAE attacks.
 - Participants who took deucricitibant did not appear to have higher risks of experiencing side effects compared to participants who took the placebo.

Are there any plans for future studies?

- Part 2 of this study is still ongoing and the latest results are presented in a separate summary entitled “Long-Term Safety and Efficacy of Oral Deucricitibant for HAE Prophylaxis: Results From the Open-Label Extension of the Prophylaxis CHAPTER-1 Study”. The full results will be shared when they are ready.
- A larger Phase 3 study is currently ongoing.
- Deucricitibant is being tested in a larger group of patients and over a longer periods of time to find out more information on how well deucricitibant prevents HAE attacks and what side effects it may cause. This additional testing is needed before deucricitibant can be approved for use as a treatment outside of clinical studies.

Who sponsored the CHAPTER-1 study?

- This study is sponsored by Pharvaris. Pharvaris would like to thank everyone who has taken part in the CHAPTER-1 study.

Where can I find further information?

- For more information on this study please visit: <https://clinicaltrials.gov/study/NCT05047185>.
- For more information about HAE, please visit: HAE International (www.haei.org)
 - HAE Association (www.haea.org)
- You can also speak with your doctor about new research in HAE.

Please note that this summary only contains information from the scientific poster.

Date of first presentation of CHAPTER-1 data: **February 2024**

Date of summary: **January 2025**

Medical writing support was provided by Holly Richendrfer, PhD, Natalie Hastrup, PhD, Jacqui Oliver, PhD, and Elizabeth Perdeaux, PhD, of Two Labs Pharma Services and was funded by Pharvaris.

