

Long-Term Safety and Efficacy of Oral Deucricitibant to Prevent HAE Attacks in People With Hereditary Angioedema: Results From the Open-Label Extension of the Prophylaxis CHAPTER-1 Study

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



Deucricitibant:
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Placebo:
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Why is deucricitibant 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.
- Deucricitibant is being developed in two different formulations for prevention and for treatment of HAE attacks. Deucricitibant 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. Deucricitibant 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, deucricitibant 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 deucricitibant to prevent HAE attacks.
- The ongoing CHAPTER-1 study extension is designed to monitor participants who, after completing Part 1 of CHAPTER-1, continue in the study to take deucricitibant over longer periods of time.
- This study extension aims to find out if the risks of side effects remain stable while taking deucricitibant over longer periods of time and deucricitibant continues to prevent HAE attacks.
- Deucricitibant is taken orally.

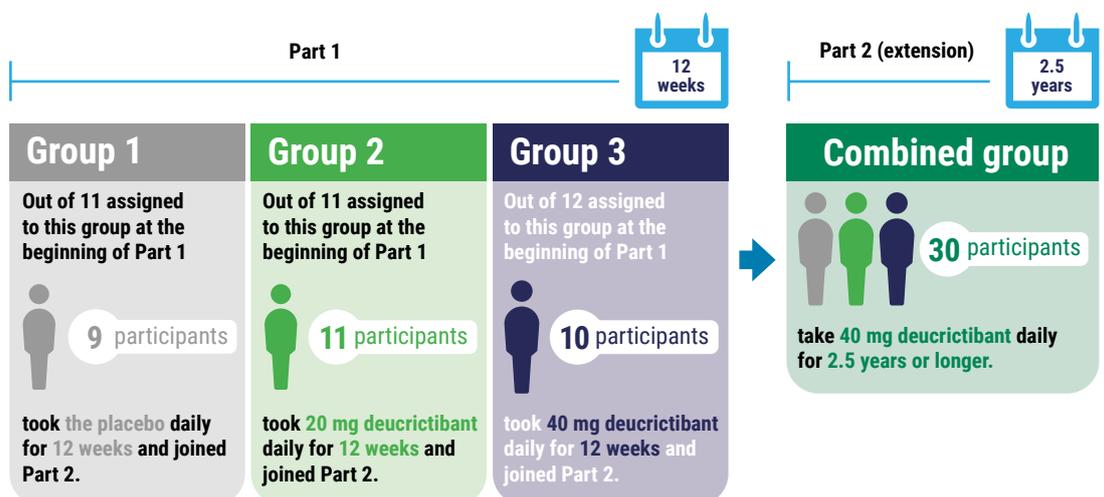
What happened in the CHAPTER-1 study?

The CHAPTER-1 study is set up in 2 parts. Part 1 is complete and Part 2 is ongoing.

- Part 1 included 34 adults between the ages of 18 and 75 years with HAE type 1 or type 2. These participants were from Canada, Europe, the United Kingdom, and the United States.
- 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 deucricitibant (20 mg or 40 mg) daily for 12 weeks.
- During Part 1, the study doctors, researchers, and participants did not know which treatment each participant was taking.
- There were 30 participants who completed Part 1 of the CHAPTER-1 study and all of them chose to join Part 2.

In the ongoing Part 2, all participants take deucricitibant 40 mg daily for 2.5 years or longer.

- The study doctors, researchers, and participants all know that the participants are taking deucricitibant.
- This summary presents the latest results from Part 2 where the participants had been taking deucricitibant for 12.8 months on average. Part 2 of the study is still ongoing.



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





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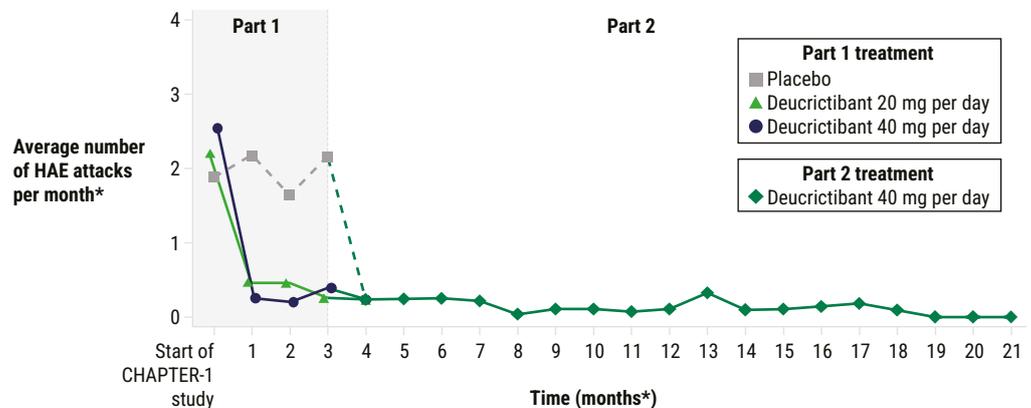
What are the results of the CHAPTER-1 study extension so far?

The incidence of side effects related to deucricitibant remained low

- To monitor the safety of potential future treatments in development, clinical studies report any side effects that happen during the study.
- In Part 1, the incidence of side effects considered related to treatment was similar for participants taking deucricitibant or placebo.
- All of the side effects related to treatment were reported as mild in severity 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.
- In Part 2, the incidence of side effects considered related to treatment remained low for participants taking deucricitibant 40 mg over longer periods of time. There was one reported side effect related to treatment of tooth discoloration.

Reduced number of HAE attacks in Part 1 stayed low in Part 2

- In Part 1, the number of HAE attacks per month* was reduced by deucricitibant treatment compared with the placebo.
- In Part 2, participants taking deucricitibant continued to have a low number of HAE attacks.

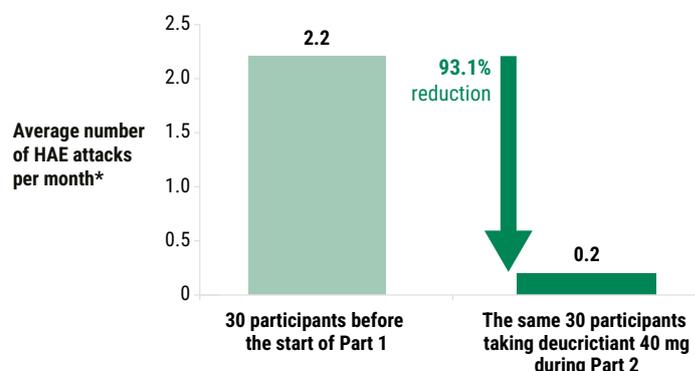


*1 month is defined as 4 weeks.

Fewer HAE attacks

- During Part 2 of the CHAPTER-1 study, participants taking deucricitibant had fewer HAE attacks per month* than they were having before starting the study.
- Before the study, participants had around 2 HAE attacks per month* on average. During long-term deucricitibant treatment in Part 2 of the study, this number had reduced by 93% to a frequency of approximately 1 HAE attack every 5 months on average.

Percentage reduction in HAE attacks per month* in participants who took deucricitibant during Part 2 compared with before they started Part 1



*1 month is defined as 4 weeks.

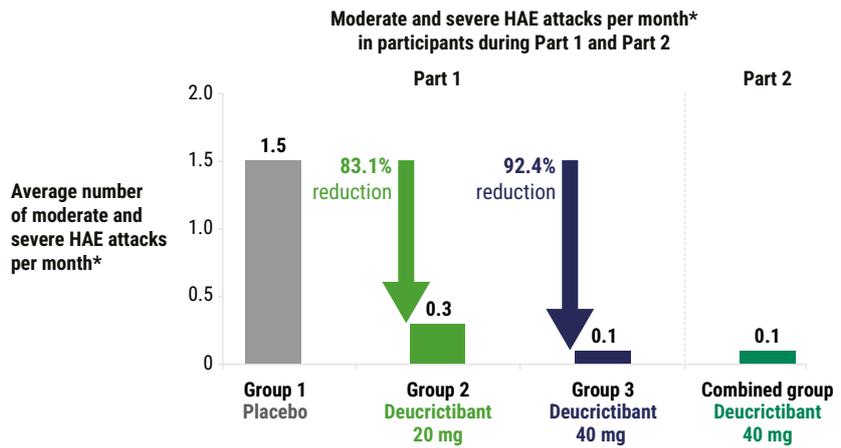
Fewer moderate and severe HAE attacks

- HAE attacks were defined as moderate or severe based on how much they impacted the participants' ability to perform their daily activities.
- In Part 1, the number of attacks that were considered of moderate or severe intensity was lower in the participants who took deucricitibant than in those who took the placebo for 12 weeks.
- In Part 2, participants continued to have a low number of moderate and severe HAE attacks when treated with deucricitibant over longer periods of time.



Deucrictribant:
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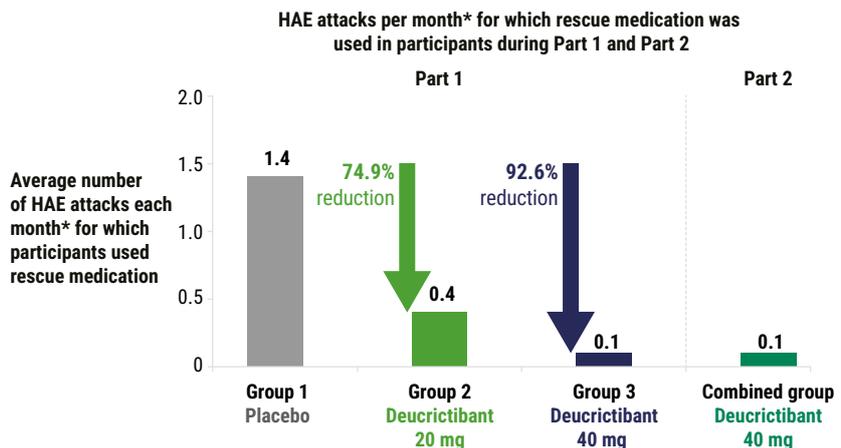
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*1 month is defined as 4 weeks.

Fewer HAE attacks treated with rescue medication

- If an HAE attack occurred while participants were taking deucrictribant or the placebo in Part 1 or deucrictribant in Part 2 as preventative treatment, they could take their usual on-demand rescue medication to treat the symptoms of the attacks.
- In Part 1, participants who took deucrictribant for 12 weeks had fewer HAE attacks for which they used rescue medication compared with participants who took placebo.
- In Part 2, participants continued to have a low number of HAE attacks for which they used rescue medication while taking deucrictribant over longer periods of time.



*1 month is defined as 4 weeks.

What were the main findings in Part 2 of the CHAPTER-1 study so far?

The results of Part 2 of the CHAPTER-1 study showed:

- Deucrictribant continued to be well tolerated by participants treated over longer periods of time in Part 2 of the CHAPTER 1 study.
- Deucrictribant reduced the frequency of HAE attacks in Part 1 and participants continued to experience a low number of HAE attacks in Part 2 for over 1 year in the ongoing extension part of the study.

Are there any plans for future studies?

- Part 2 of the CHAPTER-1 study is still ongoing. The full results will be shared when they are ready.
- Researchers will test deucrictribant in larger groups of people and over longer periods of time to find out more information on how well deucrictribant prevents HAE attacks and what side effects it may cause. This additional testing is needed before deucrictribant 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 Part 2 data:
September 2024

Date of summary: **January 2025**

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