Centanafadine in adults with attention-deficit/ hyperactivity disorder

This Plain Language Summary is for demonstrational purposes only.

Date of summary: April 2022

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The purpose of this plain language summary is to help you understand the findings from recent research

- Centanafadine is not approved to treat attention-deficit/ hyperactivity disorder (ADHD for short)
- Researchers must look at the results of many types of studies to understand whether a study drug works, how it works, and whether it is safe to prescribe to patients
- This summary reports the results from two studies. The results of these studies may be different from the results of other studies that the researchers look at

How to say medical terms used in this summary

Centanafadine
<sen-tar-NAH-fah-deen>

Dopamine
<DOW-puh-meen>

Norepinephrine
<NOR-eh-pih-NEH-frin>

Placebo
<pluh-SEE-boh>

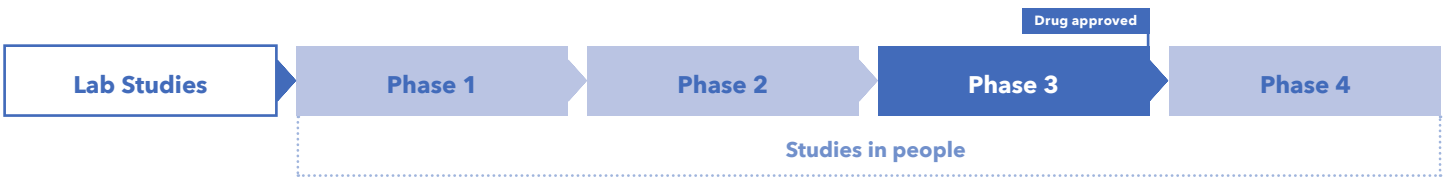
Serotonin
<SAYR-uh-TOH-nin>

1. What did these studies look at?

- ADHD is a condition that affects people's brain function and behavior
  - People with ADHD may seem restless, act on impulse, and find it hard to concentrate or remember things
- Centanafadine is being investigated to see if it could be used to treat people with ADHD
  - Centanafadine increases the levels of certain chemicals in the brain by stopping nerve cells from reabsorbing them. These chemicals are called norepinephrine, dopamine, and serotonin
  - Centanafadine is a tablet that people take twice a day by mouth
- Two studies looked at the use of centanafadine in adults with ADHD
  - In both studies, people received centanafadine or a drug with no active ingredients (called a placebo)
- The researchers wanted to look at the efficacy and safety of centanafadine. Efficacy is how well a drug works in a clinical trial
- This summary reports the main results from these two studies

2. Where are these studies in the drug development timeline?

- These were Phase 3 studies that compare potential new treatments to existing treatments or placebo in large groups of people



3. Who took part in these studies?

- Overall, 876 people took at least one dose of the study treatment during these studies
- People received study treatment for 6 weeks
  - The researchers assigned people at random to receive centanafadine or placebo
  - Neither the researchers nor the people in the study knew whether they were taking centanafadine or placebo
- The researchers measured people's ADHD symptoms using a questionnaire called the Adult ADHD Investigator Symptom Rating Scale (AISRS for short)

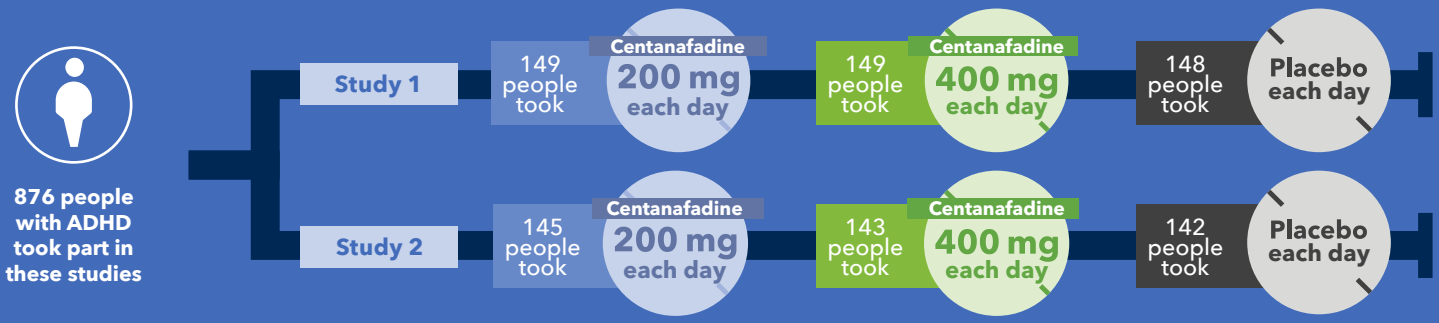
People who took part:

lived in the United States

were between 18 and 55 years old

had moderate or severe ADHD

Study design



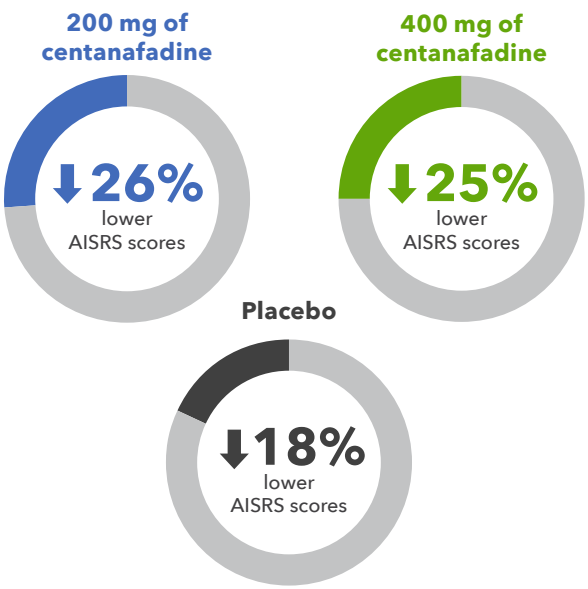
4. What were the results of these studies?

Efficacy of centanafadine

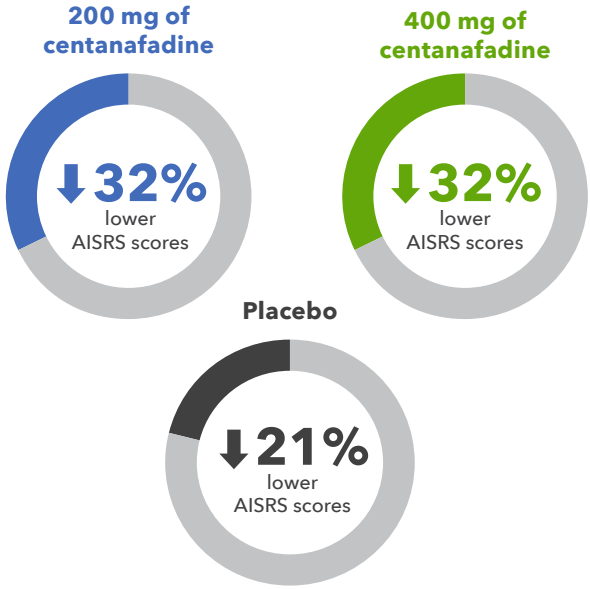
- After 6 weeks of treatment, the AISRS scores of people who took centanafadine were reduced by more than the AISRS scores of people who took placebo. This means that their ADHD symptoms were reduced more than the symptoms of people who took placebo
- Everyone who took centanafadine had a similar level of improvement, regardless of whether they took 200 mg or 400 mg of centanafadine

Changes in AISRS scores after 6 weeks of treatment

Study 1



Study 2

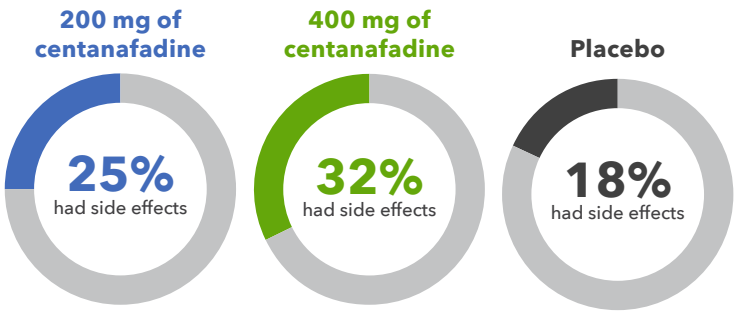


4. What were the results of these studies?

Safety of centanafadine

- Overall, around one in four people (25%) had side effects that were considered related to the study treatment
- The proportion of people with side effects considered related to the study treatment was slightly higher for people who took the higher dose of centanafadine
- Three people in the study had serious side effects

Proportion of people who had side effects considered related to the study treatment



5. What were the main conclusions reported by the researchers?

- These studies are the first to test centanafadine in relatively large groups of adults with ADHD
- Centanafadine may help reduce symptoms for some adults with ADHD. Centanafadine was well tolerated by most people in the studies

6. Are there any plans for further studies?

- These studies are completed
- People who completed these studies could enroll in another study (NCT03605849) looking at the long-term safety of centanafadine. This study is now also completed

7. Who sponsored these studies?

- These studies were sponsored by Otsuka <insert contact details>
- Otsuka would like to thank everyone who took part in these studies

8. Where can I find more information?

You can visit the websites below to find more information on these studies:

- Study 1: https://clinicaltrials.gov/ct2/show/NCT03605680
- Study 2: https://clinicaltrials.gov/ct2/show/NCT03605836

For more information on clinical studies in general, please visit:

- https://www.clinicaltrials.gov/ct2/about-studies/learn
- http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/what-clinical-trials-are

The full title of this abstract is: Efficacy, safety, and tolerability of centanafadine sustained-release tablets in adults with ADHD: Results of two phase 3, randomized, double-blind, multicenter, placebo-controlled trials

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