

# rise EPILEPSY

PHASE 2/3 CLINICAL TRIAL



## ABOUT EPILEPSY

Epilepsy is a chronic brain disorder that affects people of all ages and causes recurring, unprovoked seizures.<sup>1</sup>

APPROXIMATELY **1.5 MILLION PEOPLE IN THE US AND 50 MILLION WORLDWIDE** HAVE EPILEPSY<sup>1,2</sup>



Epilepsy is one of the most **common neurological diseases** globally.<sup>1</sup>



People with epilepsy tend to have **more physical problems and higher rates of anxiety and depression**.<sup>1</sup>



The risk of **premature death** in people with epilepsy is up to **three times higher** than for the general population.<sup>1</sup>

## ABOUT SEIZURES

Seizures are sudden surges of abnormal and excessive electrical activity in your brain and can affect how you appear or act. Where and how the seizure presents itself can have profound effects.<sup>3</sup>

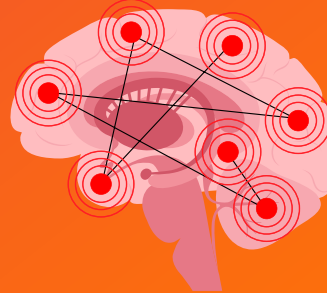
There are **two main types of seizures** that describe where a seizure starts in the brain and how it may affect a person:<sup>4</sup>

### Focal Seizures



Focal seizures affect up to approximately **61% of people with epilepsy**.<sup>5</sup> They begin on **one side of the brain** and may cause changes in awareness, behavior, sensation, or abnormal movements usually on just one side of the body.<sup>4</sup>

### Generalized Seizures



Generalized seizures begin on **both sides of the brain** at the same time and usually cause a loss of consciousness or awareness and may also cause abnormal movements on both sides of the body.<sup>4</sup>

## UNMET NEED FOR NEW EPILEPSY TREATMENT OPTIONS

There is a high unmet need for new epilepsy treatment options with **fewer adverse events**.<sup>5</sup>



Approximately **40% of people with epilepsy are drug-resistant**.<sup>5</sup>



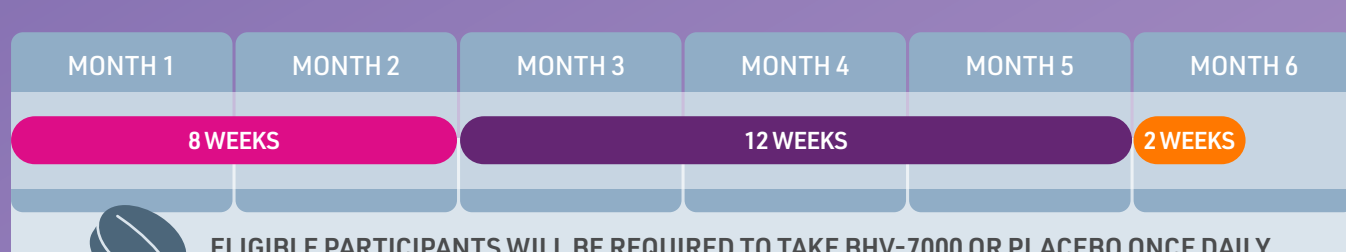
There is an urgent need for more research, better treatments, and more support for people with epilepsy.<sup>5</sup>

## RISE CLINICAL TRIAL OVERVIEW

The Rise Clinical Trial is a national multi-site, randomized, double-blind placebo-controlled Phase 2/3 study to evaluate the efficacy, safety and tolerability of BHV-7000 in patients with focal onset epilepsy.

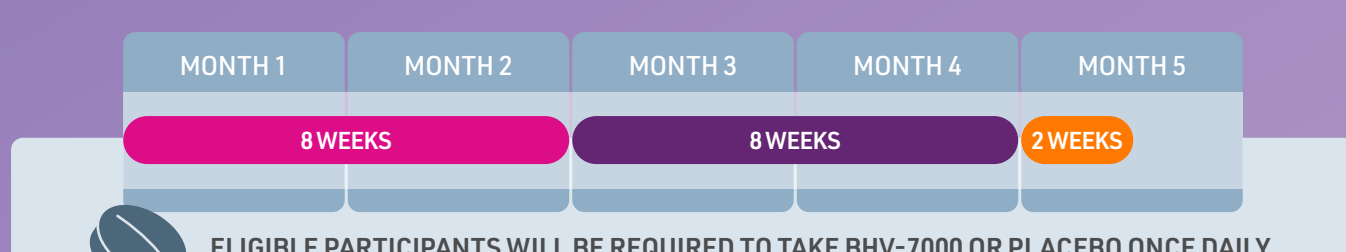
### RISE 2 STUDY

Participants are enrolled in the study for at least 5.5 months with six visits including an 8-week observation phase, 12-week double-blind treatment phase and 2-week follow-up phase.



### RISE 3 STUDY

Participants are enrolled in the study for at least 4.5 months with five visits including an 8-week observation phase, 8-week double-blind treatment phase and 2-week follow-up phase.



The primary objective of the study is to determine the change from baseline in 28-day average seizure frequency.

## KEY ELIGIBILITY CRITERIA

Between the ages of 18 to 75

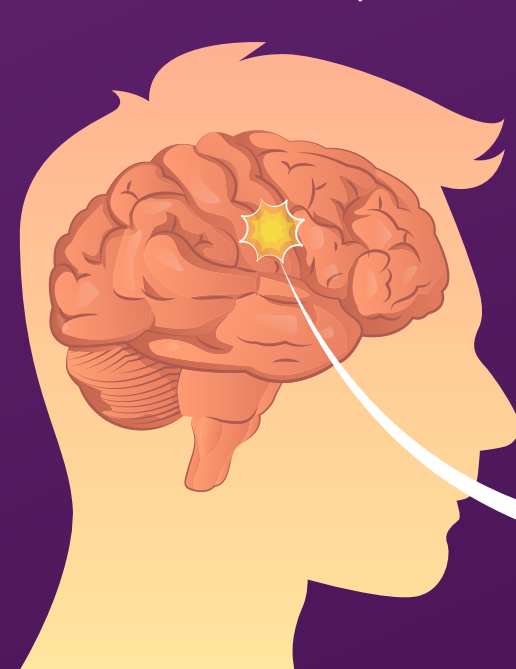
Have been diagnosed with focal onset epilepsy for at least one year

Have been unsuccessful with at least two anti-seizure medications (ASMs) and currently on a stable dose of one to three ASMs

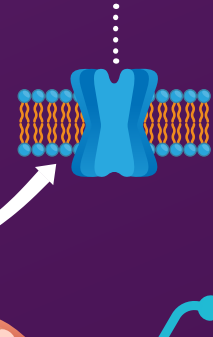
Have at least four or more observable focal seizures every 28 days

## BHV-7000

BHV-7000 works on a part of the nerve cells in the brain called potassium channels, which help balance the electrical activity in the brain.



Activating potassium channels can stabilize overactive brain activity responsible for seizures.



FOR MORE INFORMATION ABOUT THE TRIAL AND TO FIND A SITE, VISIT **EPILEPSYRESEARCHSTUDY.COM**

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1. World Health Organization. Epilepsy. Available at <https://www.who.int/news-room/fact-sheets/detail/epilepsy>. Accessed June 6, 2024.  
2. Kobau R, Luncheon C, Greenlund KJ. About 1.5 million community-dwelling US adults with active epilepsy reported uncontrolled seizures in the past 12 months, and seizure control varied by annual family income-National Health Interview Survey, United States 2021 and 2022. Epilepsy Behav. Published online May 30, 2024. doi:10.1016/j.yebeh.2024.109852.  
3. Epilepsy Foundation. Understanding Seizures. Available at <https://www.epilepsy.com/what-is-epilepsy/understanding-seizures>. Accessed June 6, 2024.  
4. US Centers for Disease Control and Prevention. Types of Seizures. Available at <https://www.cdc.gov/epilepsy/about/types-of-seizures.html>. Accessed June 6, 2024.  
5. Ioannou P, Foster DL, Sander JW, et al. The burden of epilepsy and unmet need in people with focal seizures. Brain Behav. 2022;12(9):e2589. doi:10.1002/brb3.2589.