



## **Study Brochure**

Keeping Time with Parkinson's Research



# Introducing the TemPo Studies

If you or a loved one have been diagnosed with Parkinson's disease (PD), you or your loved one may be interested in participating in one of the TemPo Studies. They are a suite of three clinical research studies evaluating an oral investigational drug (tavapadon) to see if it may help improve PD symptoms that impact your movement and daily activities.

If you are interested in learning more about these research studies, please review this brochure and speak with a member of the study team. They will be happy to answer any questions you may have.







## About the TemPo Studies

The TemPo Studies are evaluating the efficacy and safety of the investigational drug in two different groups of patients:

People with early stage PD  
(diagnosis within the past  
3 years) who are not currently  
taking levodopa or dopamine  
agonists to manage symptoms

People who are currently  
taking levodopa to manage  
PD symptoms

Based on your medical history, the study doctor will determine whether you may be eligible to participate in one of the TemPo Studies.

# About the Study Drug



The investigational drug is not approved by the United States (US) Food and Drug Administration (FDA).

Tavapadon is an investigational drug being evaluated for treatment of PD. It is a dopamine receptor agonist designed to target a specific dopamine receptor in the brain that the Sponsor believes may help reduce PD symptoms that affect your movement and daily activities. The Sponsor believes tavapadon may also have less potential to cause some of the side effects commonly associated with currently approved dopamine agonists, which target different types of dopamine receptors.

Each of the TemPo Studies will compare the investigational drug to placebo. A placebo is an inactive material, such as a sugar pill, that looks like the investigational drug, but does not contain any active drug. Placebos play an important role in clinical research studies, as they help researchers determine if an investigational drug works better or is safer than taking nothing.

Participants in the TemPo Studies will be randomly assigned (like flipping a coin) to receive the investigational drug or placebo. Your chances of receiving the investigational drug or placebo will depend on which of the three TemPo Studies you are participating in. Neither you nor the study doctor will know if you are receiving the investigational drug; however, the study doctor can find out this information if he or she feels it is necessary for your health.

**For additional information about the study drug, please speak with a member of the study staff.**

# Who is Eligible to Participate?

You may be eligible to participate in the TemPo Studies if you meet the following criteria:



Have been diagnosed with PD



40 to 80 years of age



Have never received deep brain stimulation treatment

# About the Informed Consent Process

If you are interested in participating in the TemPo Studies, you will be asked to first read and sign an Informed Consent Form.

This form contains information about the TemPo Studies, including a summary of what you may expect during study participation, potential risks and benefits, the rights of study participants, and other options that may be available to you.

Once you have read and signed the Informed Consent Form, your study participation will begin.

Participating in the TemPo Studies is completely voluntary. You may choose to stop participating at any time and for any reason.

For a full list of eligibility criteria, please speak with a member of the study staff.

# Study Participation Overview

Study participation will take approximately 35 weeks.

## Screening Period

UP TO 4 WEEKS

The study doctor and study staff will review your medical history and conduct a number of tests and be asked questions to determine if you are fully eligible to participate. This visit will last approximately four hours.

## Study Treatment Period

27 WEEKS

You will begin taking your assigned study drug (investigational drug or placebo) as directed by the study doctor. You will be asked to attend ten study visits where you will take part in study-related tests and be asked questions to monitor your health and the effects (if any) of your assigned study drug. These visits are expected to last approximately one to two hours.

All eligible study participants will receive at no cost:



Study-related consultation and care



Study visits, tests, assessments, and procedures



Study drugs (investigational drug or placebo)

In addition, reimbursement for travel-related expenses (e.g., gas, parking, tolls) may also be available. Speak to a member of the study team for more details.

## Safety Follow-up Period

UP TO 4 WEEKS AFTER YOUR FINAL STUDY VISIT

A member of the study team will contact you by phone for a final check-in.

## Open-label Extension

OPTIONAL


Following the Study Treatment Period, you may have the option to participate in an Open-label Extension study.

During the Open-label Extension, all study participants will receive the investigational drug for an additional 58 weeks. There is no placebo in the extension. You will also be asked to attend regularly scheduled study visits to monitor your health.

# Coming Together for PD Research

As a study participant there is no guarantee that you will receive any benefits from being in this study. However, the information gathered through your participation may help researchers learn new things about the investigational drug, which could potentially benefit future generations of people affected by PD.

The study doctor and study team are helping to conduct the TemPo Studies as part of their commitment to advancing potential treatment options for PD. What comes first, however, is their commitment to you – and to helping you make a choice that's right for you.



Interested in learning more  
about TemPo?  
Contact the study doctor and staff  
and they will provide you  
with more information.



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