



February 09, 2018

**FROM :** Schulman IRB ("Schulman" or the "Board")  
**TO:** All sites that receive Schulman approval to conduct this protocol  
**SUBJECT:** Recruitment/Study-Related Material  
**IRB NO.:** 201605129;  
**SPONSOR :** Sanofi US Services Inc., an affiliate of Genzyme Corporation  
**PROTOCOL NO.:** ACT14820

The following item was reviewed by Expedited Review, as referenced below, and received a decision of

**Approved for use ONLY in its entirety**

<b>Material Type :</b> Flyer	<b>Material Item# :</b> MA1801631-0
<b>Description :</b> 5.0 ACT14820 Patient Flyer_02Jan2018	
<b>Submitted By :</b> Sponsor	<b>Received Via :</b> eSubmission
<b>Received Date :</b> 02/04/2018	<b>Review Date :</b> 02/08/2018

Approved and/or Acknowledged Recruitment/Study-Related materials should not be used or distributed to study subjects until you have received an approval letter from Schulman to conduct this study.

Acknowledged material includes, but is not limited to, copyrighted documents, some subject instructions, standardized questionnaires, etc.

Any variation of approved or acknowledged materials must be resubmitted as outlined in the Recruitment Guidance available at [www.sairb.com](http://www.sairb.com).

PLEASE REFERENCE MATERIAL ITEM NUMBER **MA1801631-0** ON ALL CORRESPONDENCE

**WebPortal/Paperless**



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***MOVES – PD  
PARKINSON  
DISEASE STUDY***

**A Clinical Trial for  
Parkinson's Disease  
Patients With GBA  
Mutation.  
Find Out More!**

*Version 2.0, January 02, 2018 - Property of Sanofi US Services, Inc.  
SGUSMA.GZ.17.03.0226*

**PATIENT FLYER**

**BE INVOLVED - WE WOULD LIKE TO INVITE YOU TO PARTICIPATE  
IN A RESEARCH STUDY FOR PATIENTS WITH PARKINSON'S DISEASE  
AND A GBA MUTATION**

Sanofi US Services, Inc. is seeking patients who have been diagnosed with Parkinson Disease (PD) and who are known heterozygous carriers of a glucocerebrosidase gene (GBA) mutation to participate in this clinical research study. If you are a heterozygous carrier, it means that you have two different forms of a gene (for example, one from mom (B) and the other from dad (b) that is different).

**WHAT IS THE STUDY?**

The short name for the study is MOVES-PD and the study medication is GZ/SAR402671. This is an international study that will be run in 2 parts at sites located in the United States, Canada, Europe, Asia and Israel.

*Part 1 of the study recently began enrolling people with PD and a GBA mutation.* Patients are randomly assigned (like the flip of a coin) to one of 3 treatment groups (cohorts). Each group (cohort) receives a different dose (4mg, 8mg or 15mg) of the study medication (GZ/SAR402671) or a matching placebo (no active medication). If you are one of the people who will be participating in Part 1, you may be taking 1 or 2 capsules a day (depending on the group you are in); all will be oral daily dosing and self-administered. You will also have a chance to continue in the second part of the study (Part 2), if you continue to meet eligibility requirements and are willing to remain in the study.

Once Part 1 of the study is finished, if the data is acceptable, we will move on to Part 2 with a much larger patient population. Patients from Part 1 may also be included if they meet eligibility requirements. Patients will take a single oral dose of GZ/SAR402671 that was chosen in Part 1 or take matching placebo and self-administer the dose once daily.

If you are assigned to a group that receives placebo, at some point in this study, if you stay in the entire time, you will receive GZ/SAR402671.

### WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to evaluate the possible risks and the effectiveness of the study medication GZ/SAR402671 in the treatment of PD patients carrying a (GBA) mutation.

### DURATION OF THE STUDY

The study will last for up to 4.5 years. Part 1 of the study is anticipated to last up to 48 weeks.

Part 2 will include 4 main periods: a 45-day screening period (Period 1), the 52 week blinded treatment period (Period 2), following the 52 week treatment period patients will be further evaluated for participation in the 104 week duration long term follow up (LTFU) period (Period 3), and all patients will be followed for an additional 6 weeks, post-treatment observation period (Period 4). Your decision to remain in the study for the entire time is voluntary.

### ABOUT THE INVESTIGATIONAL MEDICATION

GZ/SAR402671 is an oral medication in development for GBA associated PD. It has not been approved by the U.S. Food and Drug Administration (FDA) or by any other responsible regulatory agencies around the world **OR ([insert your HA] yet).**

PD medications act differently in the body and are only approved for use in certain patients. If you are eligible to receive GZ/SAR402671, the study doctor can help you to decide if the medication is right for you.

### PARTICIPANT ELIGIBILITY

You may be eligible to participate in this study if you meet several criteria include the following:

- Diagnosis of PD and are a known heterozygous carrier of a GBA mutation associated with PD
- Age 18 to 80 years
- Have symptoms of PD for  $\geq 2$  years
- If taking levodopa or any other PD medication, must be on a stable dose for at least 30 days prior to randomization.

#### **WHAT TO EXPECT DURING THE STUDY**

If you agree to take part in the study, you will sign the consent form and proceed with several screening activities. We will ask you some questions about your medical history, medications and perform blood tests. We will record your height, weight and blood pressure. You will undergo a physical and neurological exam, eye exams, neuroimaging assessments (magnetic resonance imaging (MRI)), DaT scan (brain scan), and a lumbar puncture to obtain cerebrospinal spinal fluid (the fluid that runs next to the spinal cord).

We will measure the severity of your Parkinson's disease with a common clinical test called the Movement Disorder Society United Parkinson's Disease Rating Scale, or MDS-UPDRS and complete other scales and questionnaires.

Patients can opt to send an extra blood sample to a repository for future study (genetic & biomarker assessments).

You will be asked to complete some assessments before you take your study medication the morning of your clinical visit and then some more assessments after you take your study medication.

You will bring your remaining medications and patient diary with you to each on site visit.

We will also ask if it is OK for us to contact the physician who treats your Parkinson's disease to notify them that you are participating in this study.

#### **WHAT ABOUT MY CURRENT TREATMENT?**

You will be allowed to start on Parkinson's disease (PD) therapy (as needed) or to continue to take your medication as usual (if already taking PD medication at study start). The study doctor can review the medications that are permitted with you.

#### **WHAT IF I DO NOT KNOW MY GBA STATUS?**

If you do not already know your status, you can speak with the site personnel to find out how to get tested for the GBA gene. You may consult with a qualified genetic counselor to learn your Parkinson's genetic status and speak to your physician both before and after receiving your results to understand all of the issues involved.

**IF YOU QUALIFY TO PARTICIPATE IN THIS STUDY:**

- You will receive your study-related care at no cost to you.
- You will be seen by a doctor who will closely monitor your Parkinson's symptoms.

It's okay if you don't know if you qualify, the study doctor can tell you if you do. To learn more about the MOVES-PD study, or see if you or someone you know may qualify for participation, please contact:

**Principal Investigator**

PI Name

Title

Center/Department

Phone

Fax

E-mail

