**September 14, 2017**

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| **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**

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| **Material Type :** | Social Media | **Material Item# :** | MA1710330-1 |
| **Description :** | ACT14820 UPDATED MJFF Trial Page Study Purpose 9.14.17 | | |
| **Submitted By :** | Sponsor | **Received Via :** | Email |
| **Received Date :** | 09/11/2017 | **Review Date :** | 09/11/2017 |

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 .

PLEASE REFERENCE MATERIAL ITEM NUMBER **MA1710330-1** ON ALL CORRESPONDENCE

**WebPortal/Paperless**

*60-MA171033O-2-7*

All dates in mm/dd/yyyy format

Study Purpose –

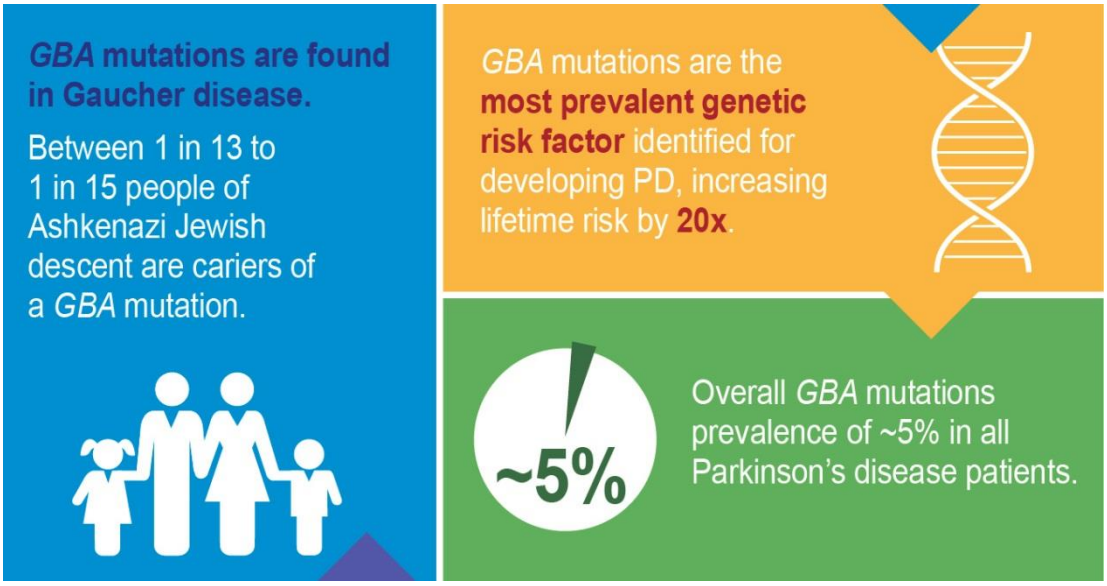
Millions of people live with Parkinson's disease, a condition that causes damage to a part of the brain in ways that make daily life challenging for patients.

While the exact causes are unknown, an estimated 5 – 10% of cases are linked to a genetic mutation (a GBA mutation) that puts them at risk of having an earlier appearance of PD symptoms and faster loss of mental and motor skills than those PD patients with no GBA mutation. However, a study of PD patients with this mutation and treatment has not been done yet. This research study is the first study to identify patients with this mutation (using a saliva sample) and evaluate how they respond to an investigational treatment that targets the pathway of the mutation.

The drug being tested targets the pathway where this mutation is located and 'normalizes' the cell activity. The drug is called SAR402671, and it is an experimental medication (one that has not been approved yet) being developed by the Sponsor of the clinical trial. There will be 2 parts to the study. Part 1 will first evaluate how tolerable the drug is in a small number of patients. Part 2 will then evaluate how effective the drug is in improving symptoms of GBA-mutation positive PD patients. If selected to be in this study, the total study duration in Part 1 will be up to 9 months.

Part 2 will be approximately 42 months that will include 6.5 weeks of screening period, 12 months of treatment period, 26 months of follow-up period, and 6 weeks of post-treatment observation period.

This study will also help further researchers' understanding of GBA mutations, which may be helpful to other patients. If interested in learning more visit: http://mediaroom.sanofi.com/persistence-and-accidental-inspiration-propel-parkinsons-research/



Below you will find some of the inclusion/exclusion points that will help decide if you could participate in this trial. This is not a complete list of criteria. A study nurse would review all study points with you prior to enrolling.

Inclusion –

- Are you aged 18-80?
- Diagnosed with PD ( symptoms for 2 years or more - resting tremor, postural instability (difficulty with balance)
- Known to have GBA mutation or willing to be tested, loss or impairment of the power of voluntary movement, and muscle rigidity
- Are you able to easily swallow pills?
- Willing and able to complete all aspects of the trial
- Able to provide written informed consent

Exclusion –

- Do you have Parkinsonisms due to drugs and/or toxins?
- Do you have the LRRK2 G2019S mutation? (These mutations in the leucine rich repeat kinase 2 (LRRK2) gene are recognized as the most common cause of genetic Parkinsonism to date.)
- Have you been diagnosed with Gaucher disease?
- Have you had past surgical history of deep brain stimulation? (A surgical procedure used to treat a variety of disabling neurological symptoms—most commonly the debilitating symptoms of Parkinson's disease (PD), such as: tremor, rigidity, stiffness, slowed movement, and walking problems.)
- Do you have any medical disorders that would interfere with your ability to complete all aspects of this trial such as inability to swallow pills?
- Are you in another drug trial right now?
- Do you have a history of drug and/or alcohol abuse?