To be printed on hospital headed paper

SUMMARY PARTICIPANT INFORMATION SHEET

Study Title:	An Open-Label Randomized Crossover Trial, utilizing a Single Blinded Rater to evaluate APL 130277 compared to s.c. Apomorphine in Levodopa Responsive Subjects with Parkinson's Disease Complicated by Motor Fluctuations
Short Title:	Sunovion CTH-302
Protocol Number:	CTH-302
Sponsor:	Sunovion Pharmaceuticals Inc. ("Sunovion")
Address of Sponsor:	84 Waterford Drive, Marlborough, Massachusetts 01752 United States of America
Investigator:	(PI_FIRST_NAME) (PI_LAST_NAME)
Study Centre Address:	(CENTRE ADDRESS)
Daytime Telephone Number(s):	(PHONE_NUMBER)
24-Hour Contact Numbers:	(PHONE_NUMBER)
EudraCT Number:	2016-003456-70
IRAS ID:	220795

Sunovion is the sponsor of the study developing the study drug called APL-130277, a fast-acting thin film formulation of apomorphine that is placed under the tongue and is intended to be an alternative to the injectable form of apomorphine which is currently in use. The trial is part of a development program to formulate a medication that provides Parkinson's disease (PD) patients with an easier way to take apomorphine. Parkinson's disease (PD) affects about 127000 people in the UK. Up to 50% of those affected experience daily changes in performing motor activities, called "OFF" episodes. It is thought that this new formulation will be easier to use, and be more readily accessible to patients when unpredicted "OFF" episodes occur during activities of daily living. It may also allow quicker control over predicted "OFF" periods, and potentially be used by the milder PD patient when "OFF" episodes begin during the advancement of the disease.

This study is a comparator study to show the preference of APL-130277 as a therapy for management of "OFF" episodes in patients with Parkinson's Disease compared to subcutaneous (s.c.) apomorphine (injectable apomorphine).

All participants who qualify for this study will receive study drug, APL-130277 and s.c. apomorphine. You can only be in this study if you meet certain criteria related to your health and medical condition. Before you can receive any study drug, some information will be collected and you will have some medical tests done (screening procedures). These tests and procedures will help the study doctor decide if you can be in the study. This portion of the study is called the Screening Period.

This is a two-part study. PART A is the titration phase where you will be randomly assigned to first take APL-130277 and then take s.c. apomorphine or the reverse order. You will take increasing doses of study medication until a dose is found to turn you from the "OFF" state to the "ON" state (When people with PD are properly medicated and their stiffness, slowness and walking are improved, they are said to be "ON").

This process is known as Dose Titration. You will then be crossed over to the other delivery system and similarly titrated to the dose that provides a full "ON" state. In this study, the doses of APL-130277 will be 10 mg, 15 mg, 20 mg, 25 mg and 30 mg and the dose of s.c. apomorphine will be 2

mg, 3 mg, 4 mg, 5 mg, and 6 mg. APL-130277 will be titrated partly in-clinic and partly at home, with the final dose being confirmed by the study doctor/nurse in an in-clinic visit. The s.c. apomorphine will be titrated during a maximum of two days in-clinic visit.

Following a three to five-day washout, you will then enter into PART B of the study, where you will be randomly assigned to four weeks of at home and in clinic treatment of "OFF" episodes with either APL-130277 or s.c. apomorphine at the dose selected during PART A of the study. After a three to five-day washout period, you will then be assigned to the other treatment for an additional four weeks of treatment. During this part of the study, you will continue to take your standard anti-parkinsonian drugs. You can treat up to 5 "OFF" episodes per day with APL-130277 or s.c. apomorphine during the waking day using the dose selected during PART A.

During Part B, assessments to evaluate how well the medication is working will be completed by a study doctor/nurse. These assessments will include a rating on the MDS-UPDRS Part III scale. You will be assessed by a blinded rater (this means that the rater will not be allowed to know which of the study treatments you have received during PART B). Blood and urine samples will be collected to monitor your health. Blood collection for pharmacokinetic (PK) analyses will be completed during PART B but only at selected hospital sites.

Within 7 days following the completion of PART B, you will be asked to return for a final safety assessment visit or End of Study Visit.

All drugs may cause side effects in some people. Side effects are unpleasant feelings or conditions that people may get when they take a medication. Side effects seen with apomorphine are described in the Participant Information Sheet and Consent Form. Very common side effects (seen in more than 1 in 10 patients) include Nausea. Common side effects (seen in fewer than 1 in 10 patients but more than 1 in 100 patients) include Vomiting, Sleepiness, Dizziness, Fainting, Yawning, Feeling tired, Increased sweating, Headache, Drop in blood pressure when standing, Joint pain, Involuntary muscle movements, Sudden changes in Parkinson's symptoms (called "on-off phenomenon"), Anxiety, Fall and Runny nose. Side effects related to the mouth include: Mouth ulcers, Bad taste in the mouth, Loss of taste, Dry mouth, Inflammation / Irritation / Infection in the mouth, Burning in the mouth, Tongue soreness, Swelling of the lips or tongue and Pain in the mouth or throat. You should read about all the side effects in the Participant Information Sheet and Informed Consent Form and ask the study doctor to explain anything you do not understand.

As apomorphine can cause drowsiness; participants should exercise caution during treatment when driving or using machines. Participants with a history of drowsiness and/or sudden sleep episodes should not drive themselves and should refrain from using machines.

Apomorphine often requires the use of anti-nausea medication, taken along with study medications. The anti-nausea medication prescribed in the study is domperidone and this may be provided to you at you study doctor's discretion. Domperidone is not typically taken for longer than 7 days of continuous use. It should be noted that domperidone may be associated with an increased risk of serious heart rhythm abnormalities. ECG testing will be performed regularly during the study duration for monitoring purposes.