

## Optional Sub-Study Information Related to Pharmacogenetics (DNA Research) and Consent Form

**Main study title:** A 52-week randomized double-blind placebo-controlled phase III study to evaluate the efficacy and safety of Etrasimod in people with moderate to severe cases of active ulcerative colitis

**Study protocol:** APD334-301

**Study drug:** Etrasimod (APD334), referred to in this document as the "study drug"

### Introduction

You have previously agreed to participate in the main study, mentioned above, by signing the [information sheet and consent form](#). We now invite you to participate in a separate, **optional** part of the study (sub-study) that includes (genetic) DNA research.

This form provides additional information to help you decide if you wish to participate in the optional sub-study. You can remain in the main study even if you decide not to participate in the sub-study. Before agreeing to participate in the sub-study, please read this form.

### What is the purpose of this sub-study?

In drug studies, the main reason for DNA testing is to help doctors, in the future, choose the most appropriate drug for each person. DNA, or deoxyribonucleic acid, is the genetic material in humans and almost all other living things. DNA is found inside all cells in the body, including blood. You can liken DNA to a huge book of guidelines (genes) that your body uses to figure out how to build you the way you are now. There are guidelines on eye and hair color, and guidelines that tell your body how to interact with drugs. As with any drug, some people may react well to the study drug while others may react poorly or not at all. Researchers would like to know how differences in your genes can affect how much you and others interact with the study drug. This type of research may help doctors in the future find out if a patient will react or not to this potential new drug before prescribing it.

This sub-study will examine the DNA in a sample of your blood. With the aim of learning more information about the disease, the extent of interaction with treatment, and the study drug.

### What will happen to your blood sample taken in this sub-study?

In this sub-study, we will examine the DNA in your blood. For this reason, a 2.5 ml blood sample (about half a teaspoon) will be collected at week 0/day 1 visit during the main study. We may request that a new sample be collected later if we cannot obtain DNA from the first sample you submitted. The sample will be collected using a needle inserted into a vein in the arm. This procedure will take 2 to 3 minutes. Your sample will be identified by your participant identification number. Some samples will be analysed in this laboratory in the UK, and some will be sent to other qualified laboratories for testing.

The code key that identifies your sample will be kept secure to protect your identity.

The sponsor or its representatives, as well as the principal researcher, will be subject to the provisions of Egyptian law if this study is conducted. The country and the participant in the study have the right to resort to international arbitration.

### Will the information collected from this sub-study be kept confidential?

Your information collected from this sub-study will be processed and used in this sub-study to learn more information about the study drug and ulcerative colitis. Your personal information collected during the main study will also be processed and used in this sub-study.

### Will your DNA sample be re-identified?

To destroy your sample, it will be necessary to link the code assigned to your DNA sample to your participant identification number. This process is called "re-identification." Your DNA sample will only be linked to your participant identification number, never your name.

### What will happen to the results of this sub-study?

The results of this sub-study will be used to make informed clinical decisions about the development of this potential new drug. They will not be shared with you, the study doctor, any insurance company, employer, your family, or any other doctor who treats you or may treat you in the future. Information obtained from this sub-study will not be entered into your medical records. The results of this sub-study may be published in scientific journals or discussed in scientific meetings; you will not be identified in such publications or discussions.