A Phase II, randomised, double-blind, placebo-controlled clinical trial to assess the safety and efficacy of AZD1656 in diabetic patients hospitalised with suspected or confirmed COVID-19 (The ARCADIA Trial) – sponsored by St. George Street Capital.

SUMMARY PATIENT INFORMATION SHEET

WHY AM I BEING ASKED TO TAKE PART IN THIS STUDY?

You have Type 1 or Type II Diabetes Mellitus and you are in hospital with suspected or confirmed COVID-19.

AM I ELIGIBLE TO TAKE PART IN THIS STUDY?

If you test positive for COVID-19, or the study doctor strongly suspects your symptoms are COVID-19 related, you may be eligible to take part in this study. You will have to undergo some procedures and answer some questions before the study doctor will confirm if you can take part.

DO I HAVE TO TAKE PART?

No. You can decide not to take part. Even if you do take part, you can change your mind at any time and withdraw from the study. You don't even have to give a reason for this. You will still receive the usual hospital treatments and care no matter what you decide to do.

WHAT WILL I HAVE TO DO IF I DO TAKE PART?

You will have to take the study medication during your hospital stay only. If you get better and are discharged from hospital, you will stop the study medication as you will no longer need it. If your symptoms worsen, then you may have to stop the medication depending on the treatments or procedures that are needed to treat you.

You will also have to agree to the study procedures. Most of these will follow the routine hospital care. However, the study does include additional blood samples to look at how the study drug is working in your body. Please refer to section 5 of the full Patient Information Sheet for information on the study procedures and additional samples. Your study doctor may specifically ask that you agree for two clotting factor blood samples to be taken on Day 1 (V2) and Day 8 (V9). This sample is optional. Therefore, you may opt out of this if you want to. Please confirm to the study doctor if you are happy for this sample to be collected.

HOW WILL THIS STUDY AFFECT HOSPITAL TREATMENT AND MY DIABETIC TREATMENTS?

This study will not interfere with any of the treatments and care you need while you are in hospital. You will also be able to take any medications you took before you came into hospital. Some of your diabetic medications may need adjusting. However, this may also be because you have COVID-19 which can affect your blood glucose. If you must stop any of your usual drugs, the study doctor will explain the reasons for this.

WHAT IS THE STUDY DRUG?

This study will investigate a drug called AZD1656. This drug was developed as a treatment for diabetes. Approximately 960 people have taken this drug in 25 previous clinical trials. In these trials AZD1656 was shown to help control blood sugar levels for up to 4 months. As the effects did not last beyond 4 months, it was not considered useful as a long-term treatment for diabetes. However, a short course of AZD1656 whilst you are in hospital with COVID-19 may help to better control your glucose

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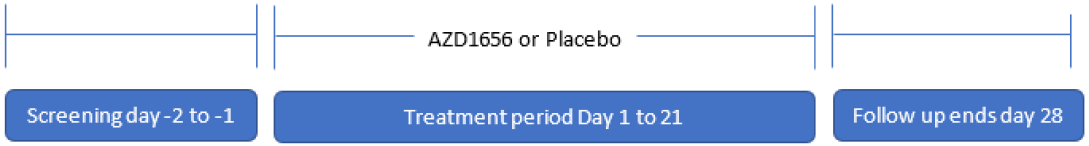
levels. In addition, AZD1656 may have a positive effect on your immune system, reducing excessive inflammation in the lungs and other organs, which is sometimes seen in patients with COVID-19. This effect has not yet been proven and will be studied in this trial.



Total Duration of Study: 30 days (Screening, Treatment and Follow-Up)

- **Before you enter the study (Screening):** To ensure that you can safely enter the study it will be necessary for some blood tests and physical examinations to be taken by your doctor.
- **Once you have entered the study (Treatment):** You will receive the study drug or placebo 2 times a day on each day from day 1 to day 21.
- **After you have completed the study treatment (Follow-Up):** You will continue to be assessed up to 7 days after stopping study treatment. If you have been discharged from hospital you will receive a phone call 7 days after discharge to check on your health.

WILL I GET THE STUDY DRUG?

If you do agree to participate and meet the entry requirements of the study, you will be assigned to one of two treatment groups. The treatment group that you will be in is selected by chance, like tossing a coin. Half of the study patients will receive AZD1656 (the active drug) and half will receive placebo (a dummy pill that looks the same as AZD1656 but does not contain the active drug). This study is "double-blinded". This means that neither you nor your study doctor will know whether you are taking AZD1656 or placebo. If required for medical reasons, the doctor is able to find out which treatment you are receiving.

WHAT WILL HAPPEN TO MY DATA?

You and your data will be identified only by a unique study code, so your taking part will be confidential. Your personal information, collected during the study, will be processed to monitor your safety and the safety of others participating in the study and to ensure the study is running according to the protocol and to ethics committee and regulatory authority guidelines. For more information on how your data will be protected, please refer to section 16 of the full Patient Information Sheet. The study doctor can review this with you.

WHAT WILL HAPPEN NEXT?

If you have any questions you should discuss these now with the study doctor. You will be provided with the full Patient Information Sheet and Informed Consent Form to review and sign. However, if you are happy to tell the study doctor that you would like to take part now, he will document your decision in the study records that you have given your ORAL consent to take part in the study.

Thank you for reviewing this summary of the Patient Information Sheet.