PATIENT INFORMATION SHEET SUMMARY

Protocol Title:	A Phase 1/2, Open-label Study to Evaluate the Safety and Efficacy of Autologous CD19-specific Chimeric Antigen Receptor T cells (CABA-201) in Subjects with Active Idiopathic Inflammatory Myopathy
Study Number:	CAB-201-002
IRAS ID:	10008852
Sponsor:	Cabaletta Bio, Inc.
Investigator	Dr. [Principal Investigator]
Site:	[Site Name] [Site Address] [Site City], [Province/State], [Country] [Postal Code] [Telephone] (business hours) or [Telephone] (after hours)
Version:	Template 1.0 (UK), 02Jun2024

Dear Patient,

As a result of your Idiopathic Inflammatory Myopathy, you have been invited to take part in a research study. This document is a simplified summary of the Patient Information Sheet and Consent Form which will provide an overview about this research study. If you are interested in participating in this clinical trial, a full patient information sheet will be provided to you.

1 WHAT IS THE PURPOSE OF THIS STUDY?

Cabaletta Bio, Inc. has developed a therapy called CABA-201. CABA-201 is a chimeric antigen receptor T cell therapy (CART) in which we take some of your T cells, a type of blood cell, and genetically change them (put in a "code") so that the cells may find and remove the B cells in your body that are thought to be involved in causing your disease. CABA-201 is an investigational treatment, meaning it has not yet been approved for use outside of clinical trials.

All clinical research is looked at by an independent group of people called a Research Ethics Committee who reviews research studies to protect the rights and wellbeing of the people taking part.

2 WHAT WILL HAPPEN TO ME IF I AGREE TO TAKE PART?

If you qualify for this study, your participation can last over 3 years, with additional routine long term follow up that will last for at least 15 years following CABA-201 infusion. You will be asked to attend 4 visits prior to your CABA-201 infusion. After CABA-201, you may receive a false positive result to a HIV test, which should be temporary. .

In this study, we will take some of your T cells, a type of white blood cell, and genetically change them (put in a "code") so that they may find and remove the B cells in your body, including the B cells that that are involved in causing your disease.

You will be given preconditioning medications to help the CABA-201 cells to work. These include fludarabine, which is given once per day on three consecutive days, and cyclophosphamide which is given once on the same day as the last dose of fludarabine. Then the CABA-201 cells will be re-infused into your body intravenously (through the vein).

This study will start with testing a single dose of CABA-201 cells given once after pre-treatment with cyclophosphamide and fludarabine. Your study doctor may require you stay overnight or longer in the hospital to have the preconditioning regimen, and for at least 4 days in the hospital following CABA-201 infusion. After your infusion, you will be required to attend visits 6 times within the first month, then once a month for the first year. During the second year, visits will be every 3 months, and during the third year, visits will be every 6 months.

3 WHAT ARE THE POSSIBLE BENEFITS OF BEING IN THIS STUDY?

You may not get any benefit from being in this research study. Although it is possible that the CABA-201 cells used in this study may help control your IIM, it is not known whether you or any other participant will benefit from the treatment. Taking part in this study may help the Sponsor and doctors learn more about the study drug and your disease.

4 WHAT ARE THE POSSIBLE DISADVANTAGES OF TAKING PART IN THIS STUDY?

You may experience discomfort and side effects from the treatment in the study and the study procedures. There may be risks to being in this study that we cannot predict. Rare or unknown side effects could occur.

This is the first time CABA-201 will be tested in people, either alone or following cyclophosphamide and fludarabine. Similar products, known as CART cells, have been given to many patients with cancer. Based on past experiences, the most common side effects observed with CART cells in cancer patients are altered taste, infusion reactions, and cytokine release syndrome. The most common risks associated with fludarabine and cyclophosphamide are low blood counts, nausea, vomiting, diarrhea, loss of appetite, cough, infection, fatigue, weakness, hair loss, skin rash, skin discoloration and changes to the nails.

A full list of known side effects are outlined within the full patient information sheet, along with the risks of the preconditioning treatments and those risks associated with some of the study procedures.

5 WILL MY INFORMATION BE KEPT CONFIDENTIAL?

During this study, all of your data will be anonymized meaning only the study site will know who you are. All personal information sent to the sponsor will be coded. The sponsor will be using information from you and/or your medical records in order to undertake this study and will be responsible for looking after your information and using it properly. Please refer to the full Patient Information Sheet for further details regarding how your personal information will be protected.

6 FURTHER INFORMATION

If you are interested in participating in this study and would like to receive more information, the study doctor will provide you the full Patient Information Sheet which contains detailed information about the study.

Thank you for taking the time to read this information and please inform your study doctor if you are interested in the study.