### What is the ARTIOS Study?

The ARTIOS study is looking at the safety and effectiveness of a medicine called **ofatumumab** in adults 18 years of age and older with relapsing MS who show disease activity while on dimethyl fumarate or fingolimod.

### Who can take part in the study?

In order to be considered for the clinical study, you must:



Be 18 to 60 years old



Have a relapsing form of MS



Have disease breakthrough activity like a confirmed relapse, or MRI lesions while taking oral medicine dimethyl fumarate or fingolimod for at least 6 months By joining a clinical study, you can contribute to advancements that may help improve the health of others in the future. You may also have a chance of benefiting from a new treatment before it is available to the public.

Being in a clinical study is voluntary and you can stop participation at any time.

For more information on the ARTIOS study, contact:

## UNDERSTANDING THE ARTIOS STUDY

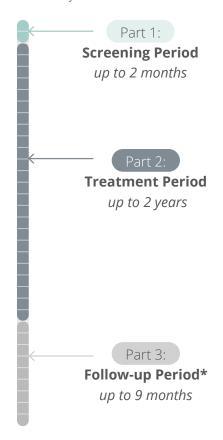
Ofatumumab for adults with relapsing multiple sclerosis (MS)

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#### How long is the ARTIOS study?

If you decided to join, you would be in the study for about 2 years. There are 3 parts to the study.

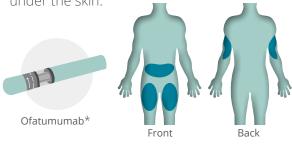


# Will all participants receive the study medicine?

Yes, all study participants will receive ofatumumab during the Treatment Period.

### How is the study medicine given?

The medicine is given as an injection with a small needle into the fatty layer right under the skin.



You would have your first injection at the study site and the rest at home. The study team would show you and a family member how to give the injection at home.

### How often would I take the study medicine?



<sup>\*</sup>Using an autoinjecter pen means that you can inject the medicine under the skin yourself. An injection into the upper arm is only to be performed by a caregiver or health care provider.

### What happens during the study?

- A You would visit the study site 14 times over 2 years for tests to check on your health.
- Between clinic visits, the study team would also call you to ask questions about your health and to make sure you are taking the study medicine correctly.
- A If you agree to be in the study, you may also receive a couple of electronic devices to wear or carry with you so that the study team can monitor your physical activity throughout the day:

#### » Electronic diary (smartphone):



To answer surveys and to track and note when you take your medication.

#### » Floodlight app:



An app on a smartphone that you may receive to answer questions about your health and to track how you move throughout the day.

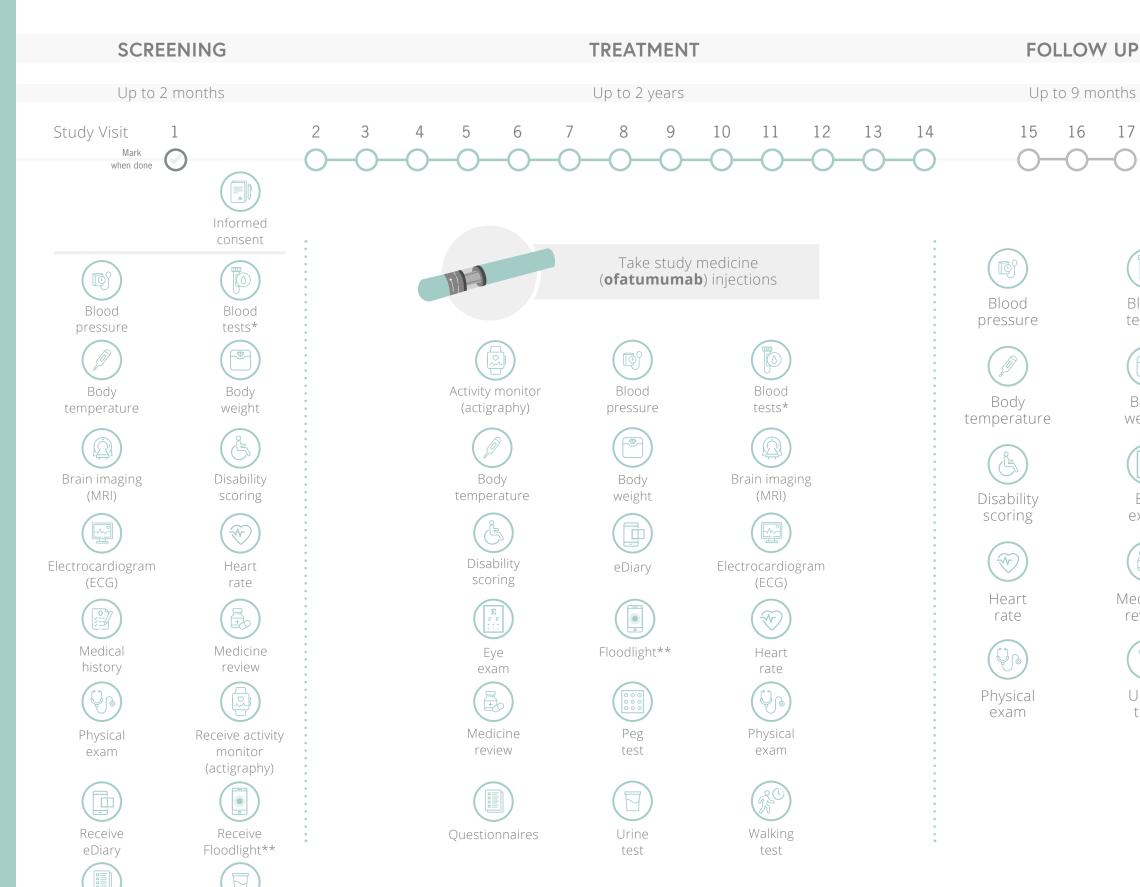


Activity monitor (actigraphy): Records your daily physical activity and how well you sleep.

You will find a summary of what to expect at your scheduled study visits, including some of the tests that would take place. You wouldn't have all of the tests at each visit. Speak with the study doctor to learn more about the study visits and tests.

<sup>\*</sup>There may be a possibility to enter an ofatumumab extension study after completion of the treatment period.

#### Visit schedule summary



Urine

test

QuestionnaireS

**GLOSSARY** 

#### **Activity monitor (actigraphy):**

A device like a smartwatch that records your daily physical activity and how well you sleep.

**Blood pressure:** This measures how your heart is pumping and how blood is flowing through your blood vessels. The study doctor or nurse will wrap a cuff around your upper arm that gently squeezes it.

16

17

Blood

tests\*

(W)

Body

weight

Eye

exam

Medicine

review

Urine

test

**Blood test:** Small samples of your blood will be taken to look at types of blood cells and how the study medicine may be affecting your body. They can also look at how your kidneys and liver are working. Certain markers in the blood will be looked at to see how you may be responding to treatment and to see if your MS is getting worse. Women will have their blood tested for pregnancy at the start

**Body temperature:** Your temperature will be taken by mouth by placing a digital thermometer under

of the study and then once a year.

your tongue. **Body weight:** Your body weight will be measured without shoes and while

wearing light clothing.

Brain imaging (MRI): You will have a scan called an MRI scan that uses magnets to take pictures of the insides of your body. In this study, a special dye will be used to look at parts of your brain that may be affected by MS. The

test takes about 40 to 45 minutes.

**Disability scoring:** A special scoring system is used to measure the level of disability caused by your MS. The study doctor will check your ability to walk and balance, your reflexes, muscles, eye movement, and coordination. This exam takes about 15 to 30 minutes.

Electrocardiogram (ECG): An ECG is a painless test that measures the heart's electrical activity (heartbeat). For this test you will lie down. Small metal discs called electrodes that are connected to a computer will be placed on your chest.

**Electronic diary (eDiary):** A device like a smartphone used to answer surveys and to track and note when you take your medication.

**Eye exam:** The study doctor will check your vision by assessing how well you can recognize various letters of different sizes.

**Floodlight app:** An app on a smartphone that you may receive to answer questions about your health and to track how you move throughout the day.

**Heart rate:** The study doctor or nurse will check the rate of your heartbeat by taking your pulse at your wrist while sitting for 1 minute.

**Informed consent:** After the doctor explains the study, you will sign forms to give your permission to join.

**Medical history:** The study doctor will discuss and review your past and current health.

**Medicine review:** The study doctor will review any medicine you have taken in the past and are

currently taking.

Peg test: This test looks at your hand movement and coordination. The study doctor will look to see how long it takes you to insert and remove 9 pegs from a small board with holes. You will do

**Physical exam:** The study doctor will check the health of your body, including your heart, lungs, stomach, head, neck, and

this test for each hand.

nerve function

a month.

Questionnaires: You will answer different questions about your MS symptoms and how they may affect your everyday life, daily activities, mood, thinking, and movement.

**Urine test:** These tests can measure the amount of sugar, protein, and blood in the urine. Women will have their urine tested for pregnancy once

**Walking test:** This test measures how fast you can walk. The study team will look at how many seconds it takes you to walk 25 feet.

During the study, you would also be checked for any side effects that may happen.

\*Certain markers in the blood will be looked at to see how you may be responding to treatment and to see if your MS is getting worse \*\*Floodlight is not available in all countries and for all patients.