Information about the FUSION study

for people with relapsing forms of multiple sclerosis

Biogen-191249

FUSION

WELCOME!

An estimated 2.8 million people around the world have multiple sclerosis (MS). But despite advances over the years, many people with MS still experience disease progression or side effects from their treatment that they're unable to tolerate. That's why we're conducting the FUSION clinical study.

This brochure will tell you about clinical research in general and describe what taking part in this study would involve. If you have any questions or would like to learn more, please contact us using the details on the last page.

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FUSION consists of two parts and we're currently looking for people to join Part 1. Part 1 is asking whether our investigational drug could be effective in treating MS. Part 2 is asking whether our investigational drug, a type of B cell modulator known as a Bruton's tyrosine kinase (BTK) inhibitor, could be effective in treating MS when combined with an approved T-cell modulator called diroximel fumarate (DRF). The potential for combination therapy in treating MS would be a novel approach, and both Part 1 and Part 2 are essential in understanding our investigational drug.

But in Part 1 we will be assessing the safety and effectiveness of our investigational drug as a therapy on its own first (known as 'monotherapy'). We're looking for people who:

- Are aged 18–55
- Have a diagnosis of a relapsing form of MS (relapsing-remitting MS or active secondary progressive MS)
- Have a baseline EDSS score of 0 to 5.0 (able to walk without aid for 200 meters)
- Have evidence of disease activity, as shown by an MRI scan in the last 6 to 12 months, and/or clinical relapse(s) in the last 24 months

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What are clinical studies?

Clinical studies (also known as 'clinical trials') are carefully controlled scientific investigations that help find:

- Potential new medications
- New versions of medications already being used
- New uses for medications already being used

Participant safety is the top priority of every study. In fact, governments have strict rules to protect the safety and privacy of volunteers. What's more, by law, participants must be told about all the potential risks and benefits of taking part. This is called the 'informed consent' process, and the study team will tell you more if you want to join. Scan the QR code below to learn more about clinical studies.

PLACE HOLDER

How does the investigational drug work?

1

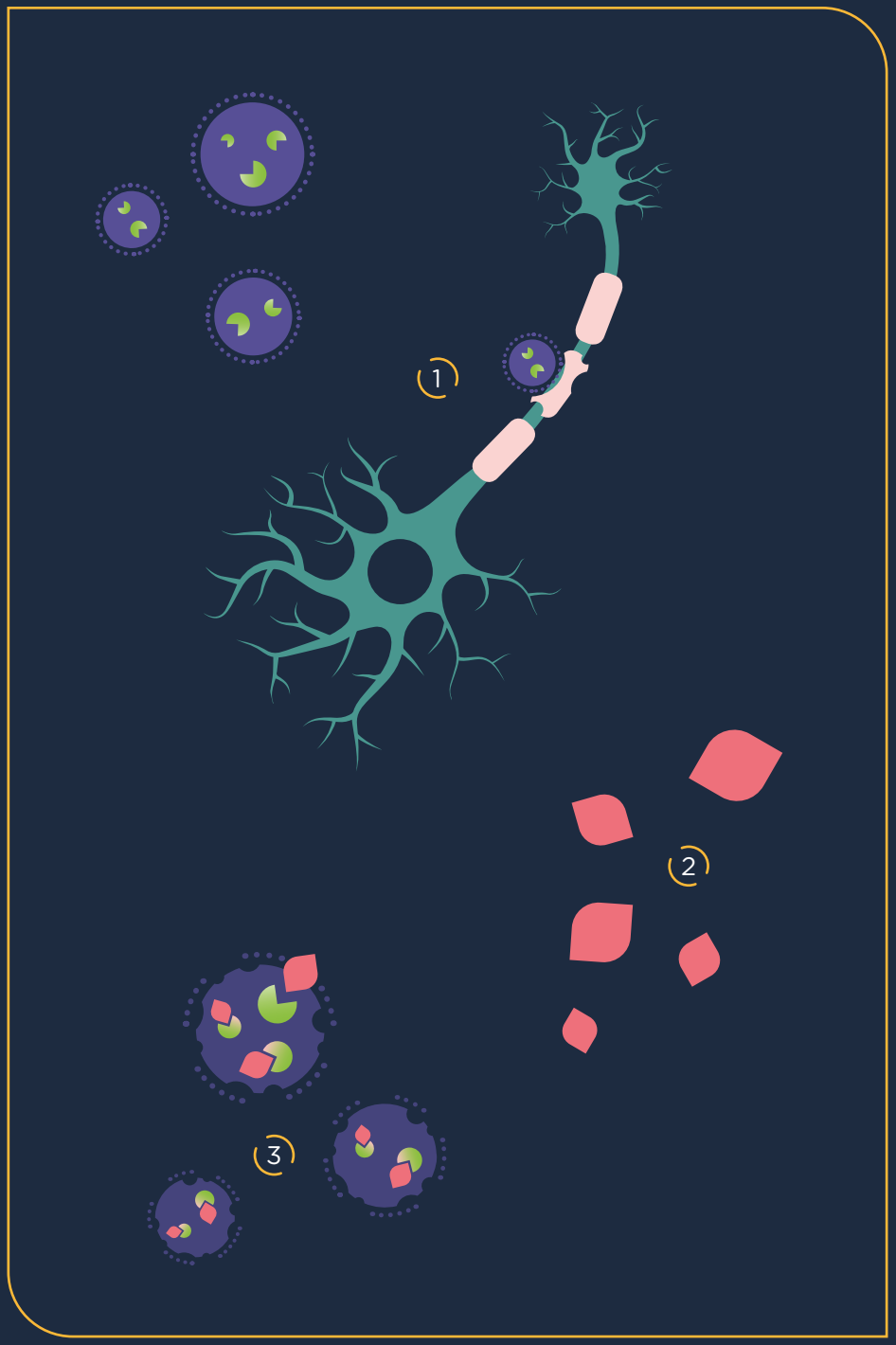
B cells play an important role in the immune system. However, in people with MS, B cells don't always work as they should – damaging the nerve cells responsible for communication between the brain, spinal cord, and other areas of the body.

2

Our investigational drug targets a protein found in B-cells called BTK. The BTK protein functions as a key molecule to regulate B cell function.

3

Our investigational drug is a BTK-inhibitor and is designed to work by blocking BTK in B cells, to see if this could prevent the damage they can cause in people with MS.



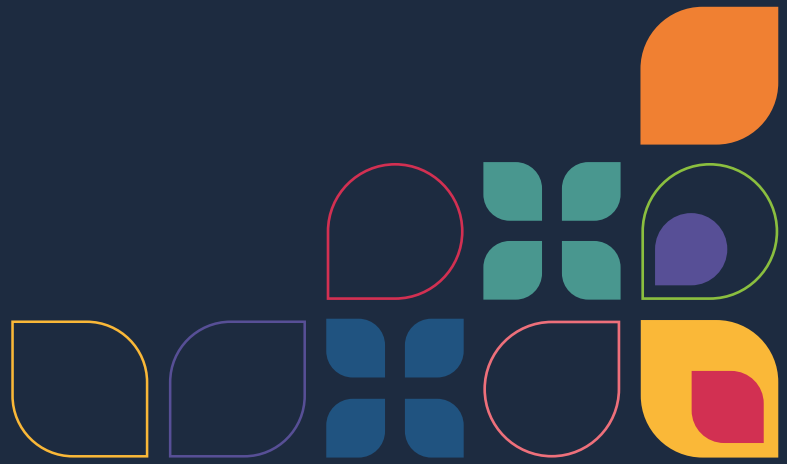
What are the potential benefits of the investigational drug?

- Unlike other B-cell modulators, BTK inhibitors are selective in the cells they target, meaning they don't wipe out other cells by accident
- Other available (or approved) MS drugs that target B-cells are given as an injection or infusion, while BIIB091 is taken orally (by mouth)
- Many treatment options for MS can have lengthy wash-out periods of up to several months (the time it takes for a drug to be eliminated from the body). However, the wash-out period for BIIB091 has been shown to potentially occur within days

How do Parts 1 and 2 fit together?

Part 1 is assessing the safety and effectiveness of our investigational drug as a monotherapy, but it will also be used to determine whether we run Part 2. At Week 16, an independent board will conduct a safety review of the investigational drug. We'll then either give the go-ahead for Part 2 or halt the study. If Part 2 goes ahead, we'll use the data collected during Part 1 to decide what dose of the investigational drug will be used in combination with DRF.

We're currently recruiting for Part 1 of FUSION. If you join Part 1 of FUSION, you'll be unable to join Part 2.



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What will Part 1 involve?

Screening period
(up to 4 weeks)

We'll carry out some initial assessments to make sure that you and the study are a good fit.

Blinded treatment period
(48 weeks)

If the study is right for you, you'll randomly (by chance) be assigned to receive either:

- The investigational drug (4 in 5 chance)
- A standard dose of DRF (1 in 5 chance)

Both study drugs will be given orally (by mouth).

Follow-up period
(approximately 2 weeks after last dose)

You will be asked to attend a final check-up.

A 'blinded' treatment period means that neither you nor the study team at the site will know which study drug you have been assigned. We do this to ensure any benefit seen is due to the effectiveness of the investigational drug and not due to bias.

How would my health be monitored?

During the study, you'll be given a diary to record each dose of study drug you take or any doses you miss. You'll also need to visit the clinic approximately 20 times (including screening and follow-up). This is so that we can closely monitor your general health and see how your body is responding to your assigned study drug. Health assessments will vary between visits, but may include:


Blood tests


Brain MRI scans


Vital signs


Electrocardiograms (ECGs)


Urine tests


Smartphone assessments


Questionnaires

So that we can monitor new disease activity, you'll have brain magnetic resonance imaging (MRI) scans at some of your study visits. At each of these visits you will have an MRI scan that will involve using a contrast agent called gadolinium (Gd)*. The contrast agent will be injected into your vein during the MRI. The contrast agent can help us learn different and important things about your disease progression. If you're interested in taking part and want to learn more, the study team will be happy to answer your questions.

*Gd is a commonly used contrast agent and is considered safe, but like all medical procedures, there is the potential for risks and side effects. The most common side effects include headache and nausea. Most side effects are mild to moderate in intensity, but very rare side effects include cardiac arrest and severe allergic reaction (which can arise from hours to days after the scan). But please be reassured that your health will be monitored throughout the study.

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Frequently asked questions

Would I have to pay for anything?

No. All study-related drugs and procedures will be provided at no cost to you. A service may also be available to support you with study-related travel, including transport and accommodation.

Is the study voluntary?

Taking part in a clinical study is a personal decision and no one has to join if they don't want to. It's also important to know that if you join the study and then change your mind, you can leave at any time without any impact on your usual healthcare.

How will my data be kept secure?

Your study data and samples will be labeled with a participant identification (ID) number that is unique to you and not related to or derived from information that identifies you. This means that people who have access to the study data will not be able to identify you.

Will I get better if I take part?

Because studies test investigational therapies, we can't promise that your health will improve if you join. You may feel better, you may feel the same, or you may feel worse. But please be reassured that each and every participant will be monitored closely.

For more information, please see our website **www.fusionclinicaltrial.com** or contact us using the details below. We'll be happy to tell you more.

CONTACT DETAILS

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