The PATH Study - CIDP Treatment with Subcutaneous Immunoglobulin (IgPro20)

CSL Behring is currently recruiting patients for the PATH study, an international clinical trial designed to evaluate the effectiveness of IgPro20 compared with placebo in the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). The study will also look at the safety and tolerability of two different doses.

Intravenous immunoglobulins (IVIG), steroids and plasma exchange are recommended treatment options for CIDP. IVIG have to be administered by intravenous injection (through a needle inserted in your vein). In contrast IgPro20 is a subcutaneous immunoglobulin (SCig), which means that it can be administered by injection under the surface of the skin. It may, therefore, offer another treatment option for CIDP, possibly allowing patients to administer the medication at home, or wherever and whenever it suits them, and to integrate the treatment into their lifestyle.

What does the study involve?

The study is made up of 4 different periods that all together will last about 52 weeks. The study doctor will decide if you are eligible to continue in the study at the end of each study period.

1. Screening period
   In the Screening period some medical assessments and a blood draw will be done. The study doctor will use the results of these tests to decide if you are eligible to participate in the study.

2. Ig dependency period
   Some patients do not need the same amount of IVIG throughout their treatment of CIDP, and some may not need IVIG anymore because they are in remission. The purpose of the Ig dependency phase is to be sure patients still need IVIG treatment before treating them with the study drug. To do this the study doctor will ask you to delay (pause) your next regular IVIG treatment and closely monitor you to look for signs of IgG dependency. You will be trained to check your own symptoms at home by using tools to measure any change in your ability to perform certain daily activities. You will be asked to come into the office as soon as your symptoms start to get worse. If your symptoms do not worsen after 12 weeks, you may not need IVIG anymore or only a reduced dosage.

3. IVIG Re-stabilization period
   You will quickly be treated with IVIG again as soon as the study doctor confirms that your symptoms do get worse during the Ig dependency period. In this case you will continue in the study and receive IVIG over a period of 10 to 13 weeks to improve your symptoms.

4. Subcutaneous (SC) treatment period
   For the final period of the study, you will receive either the study drug IgPro20 or placebo as weekly subcutaneous infusions over 25 weeks. The study team will teach you how to administer the subcutaneous infusions at the beginning of this period, after which you can do the weekly infusions yourself.

   To make the comparison between IgPro20 and placebo as fair as possible, this study is “double blinded.” This means that neither you nor the study doctor will know which treatment you are taking. The study doctor will closely monitor your symptoms during this period. If there is any sign that your symptoms get worse, you will again be given IVIG and will stop with the study.

Who can take part?

To be eligible for the study, patients diagnosed with CIDP should:
- Definite or probable CIDP according to the EFNS/PNS 2010
- Have had repeated treatment with IVIG (≥ 4 infusions) within the last 9 months prior to enrollment.
- Have had an IVIG treatment during the last 8 weeks prior to enrollment.
- Be ≥18 years of age.

Patients with any of the following are not eligible to participate:
- Any polyneuropathy of other causes
- Any other disease (mainly neurological or chronic orthopedic) that has caused neurological symptoms or may interfere with treatment or outcome assessments
- Severe diseases and conditions that are likely to interfere with evaluation of the study product or satisfactory conduct of the study
- History of thrombotic episodes within the 2 years prior to enrolment
- Known allergic or other severe reactions to blood products including intolerance to previous IVIG

Where can I find more information about taking part in the study?

You can find more information about the study and where we are currently recruiting patients published on the US website www.clinicaltrials.gov.

To find out if there will be a study site open near you, you can also send an email to clinicaltrials@cslehring.com and the study team will provide you with information on how to contact a participating investigator.