What is the AFFIRM-AL clinical trial?

AFFIRM-AL is a confirmatory phase 3 clinical trial evaluating an investigational drug called birtamimab for the treatment of adults who are diagnosed with Mayo Stage IV AL amyloidosis and are treatment naïve.

What is AL Amyloidosis and Mayo Stage IV?

AL amyloidosis is caused by amyloid deposits composed of misfolded light chains (proteins made by plasma cells) that build up in multiple organs and tissues, leading to damage.

There are several staging classification systems used to stage the prognosis of AL amyloidosis. Among these include the Mayo 2012 Staging system, which uses specific laboratory tests to determine the stage. This particular staging system classifies Mayo Stage IV as the most severe stage of disease.

Who is eligible to participate in the AFFIRM-AL clinical trial?

People ages 18 and over who have been diagnosed with Mayo Stage IV AL amyloidosis and have not yet received any medical treatment for the condition. Additional eligibility criteria will be assessed by the study team to determine eligibility prior to enrollment.

What does clinical trial participation look like?

All participants will receive standard of care chemotherapy treatment, and 2/3 will receive birtamimab plus standard of care chemotherapy. The trial will be double-blinded, which means neither the participant, nor the clinical trial team, will know who is receiving birtamimab in addition to the standard of care.

Once study eligibility is determined and the patient chooses to participate, all therapies, including either the investigational drug and/or chemotherapy, study-required visits, tests and assessments will be provided at no cost to the patient for the duration of the trial. Clinical trial participation is estimated to span approximately 2.5 years.

What can patients expect during the trial?

The first step is to determine if this trial is appropriate for patients based on the eligibility criteria and each person's diagnosis. This process consists of two clinic visits and may take up to four weeks.

For those who enroll in the trial, the trial is divided into the following parts:

- **Treatment Period:** During this time, participants will receive either birtamimab or placebo in addition to standard of care chemotherapy each month.
- **End of Treatment/Early Treatment Discontinuation**: In the 4 to 5 weeks following the last treatment administration, trial participants will receive laboratory tests and health assessments.

Birtamimab is under investigation and is not approved by any regulatory agency.

For more information about the clinical trial visit: https://affirm-al.com or https://clinicaltrials.gov/study/NCT04973137