RESET-RA

The RESET-RA study is designed to evaluate the safety and effectiveness of vagus nerve stimulation (VNS) for treatment of adult patients with active, moderate-to-severe rheumatoid arthritis who have had an inadequate response or intolerance to biologic or targeted synthetic Disease-Modifying Anti-Rheumatic Drugs (DMARDs).

All eligible subjects in the study will undergo an implant procedure to place the investigational device on the left vagus nerve. Subjects will be randomized 1:1 to receive either active doses of stimulation (study treatment) or non-active doses of stimulation (control). Stimulation will be delivered for 1 minute once per day for 12 weeks – the primary time endpoint of the study.

All subjects completing Week 12 assessments will be crossed over to active stimulation arm in a long-term follow-up period. Subjects not achieving ACR20 improvement at Week 12 will be eligible for rescue therapy.

STUDY ELIGIBILITY CRITERIA:

- 22-75 years of age
- Active moderate-to-severe RA – at least 4/28 tender and 4/28 swollen joints
- Currently receiving treatment with at least 1 conventional synthetic DMARD for at least 12 weeks, with non-changing dose for 4 weeks prior to study screening
- Demonstrated an inadequate response, loss of response, or intolerance to 1 or more approved for RA biologic DMARD
    - Ideally, no exposure to JAKi
- Willing to undergo a vagus nerve stimulation implant procedure

THE MICROREGULATOR IMPLANT

The study will evaluate a miniaturized stimulator that is surgically implanted on the left vagus nerve during a 60-90 minute outpatient procedure performed by an experienced surgeon while the subject is under general anesthesia.

The implant delivers a stimulation of 1 minute once per day to the nerve to activate the body's inflammatory reflex to potentially reduce inflammation.

Learn more about the study:
www.RESET-RA.study or
https://clinicaltrials.gov/ct2/show/NCT04539964

CAUTION - Investigational device. Limited by United States law to investigational use.