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Macular Degeneration Partnership

September 2017 Newsletter

Disappointing News about Dry AMD Study

On September 11, a press release from Genentech disappointed millions of individuals anticipating an effective treatment for dry AMD.

The company revealed that the results from *Spectri*, their Phase III study, did not meet the primary endpoint and the study has been halted until the results can be further evaluated.

The *Spectri* study enrolled close to 1,000 study subjects in 300 locations worldwide. The treatment protocol for the study was similar to treatments now available to patients with wet AMD. Subjects would be given an intravitreal injection every 4 to 6 weeks. The injections were either the drug, Lampalizumab, or a sham treatment.

Lampalizumab is an antigen fragment that binds to Complement factor D, which is believed to play an important role in generating inflammatory responses in the eye. Complement factor D contributes to the development and progression of geographic atrophy, an irreversible disease that impairs vision, resulting in dry AMD. Lampalizumab is thought to slow the process.

Patients in the clinical trial were expected to be enrolled in the study for two years. At the end of year 1, the progression in geographic atrophy lesions would be evaluated. At the end of year 2, changes in geographic atrophy as well as quality of life, visual acuity, and functional skills like reading would be evaluated.

At the end of year 1, the patients who received the lampalizumab injections were not found not to have a significant change in the area affected by geographic atrophy compared to the patients who received the sham treatment. Given the lack of efficacy, the trial was suspended.

This study was the largest interventional clinical trial ever conducted for geographic atrophy and the largest ophthalmology clinical trials run by Genentech, a division of the international company, Hoffmann-La Roche. An earlier, smaller Phase 2 study appeared to show reduction in disease progression with the lampalizumab injections.

Genentech is running an identical parallel study (*Chroma*) with another 1,000 patients suffering from late-stage dry AMD. These study participants will receive the identical protocol as the *Sprectri* study (sham or lampalizumab injection every 4-6 weeks).

The results of the *Chroma* study are expected in the next several weeks. It will be a major set-back for treatment of dry AMD if the *Chroma* findings are the same as *Spectri*.

While this is a disappointment, there are many biotech and pharmaceutical companies devoting considerable resources and treatments for dry AMD which affects over 1 million people in the U.S.