Research Progress for Dry AMD Treatments

There is good news on the research horizon for “dry AMD” as a number of promising treatments are currently in clinical trials. So what exactly is “dry AMD” and why have treatments for this widespread disease been slow to market?.

If you are one of the many people affected by age-related macular degeneration (AMD), you may know that the disease has two forms. The “dry” form and the “wet” form, the latter a typically more serious form of the disease. Dry AMD affects 85 to 90 percent of all people with macular degeneration. The disease is characterized by the presence of small, white-yellow, fatty deposits called drusen in the central part of the retina. The disease can eventually damage the layer of photoreceptor cells (the cells that receive visual images from outside your eye), resulting in decreased central (macular) vision. The most common symptom of dry AMD is blurred and distorted vision. Blind spots may become apparent. Dry AMD generally affects both eyes, but vision can be worse in one eye while the other eye seems unaffected. In most cases, dry AMD does not progress to the wet form of the disease, but progression is possible, so regular screening by an eye care professional is critical.

There are a number of eye-healthy habits that patients with dry AMD can adopt to slow the progression of their disease. These lifestyle habits include eating a diet of fatty fish, nuts, colorful fruits and vegetables, exercising, and quitting smoking. And for those with intermediate to advanced dry AMD, taking specially formulated anti-oxidant vitamins

and zinc can also help slow the progression of the disease. This “AREDS antioxidant treatment” is the only approved treatment to date for those with AMD.

But while there are clinically-approved treatments that are available to patients with wet AMD, people living with dry AMD are anxious to find out when there will be medical treatments available to them that can stop vision loss.

Macular degeneration is a complex disease that is caused by a combination of genetic and environmental factors. One of the reasons that treatments for dry AMD have been slower to market than wet AMD treatments may be because of its complex causative basis. It is also harder to investigate because it typically has a slower progression, making it difficult and expensive for scientists to study it. Demonstrating efficacy for a prospective treatment in the early stages of the disease, before vision loss has occurred, has been challenging. In other words, how do you measure success when success cannot be measured by improvement on an eye chart? In the case of dry AMD, ideally, treatments would halt the disease before it can progress to noticeable vision loss.

Fortunately, some recent government regulatory changes for research into AMD have opened the door for more proactive research. Scientists also now have a better understanding of the pathogenesis (origins and effects) of the condition, clearing the way for pharmaceutical companies to develop therapies for dry AMD.

Most new therapies being developed are based on an attempt to protect the critical photoreceptor cells of the retina, i.e., maintaining their lifespan and function. This can be accomplished in several ways - for example, through the use of proteins called “neuron-survival agents” which prolong the life of the photoreceptor cells. This can also be done by using agents that help to prevent oxidative damage or damage by inflammation – both processes that have been shown to lead to photoreceptor cell death. Importantly, efforts are being made to limit toxic waste products that can accumulate in

the AMD retina and severely damage photoreceptor cells. Researchers at one company are studying the use of a tiny capsule that is implanted into the eye, where it provides long-term, sustained release of a special neuron-survival agent that helps to maintain photoreceptor function and thus preserve vision. Still other research is focusing on an anti-oxidant eye drop.

But what about taking a pill to help prevent dry AMD or stop its progression?

For many patients, simply taking a pill would be ideal. AMDAI's Vice President of Global Communications, Allie Laban-Baker, recently sat down with Dr. Ryo Kubota, Chief Executive of Acucela, to talk about his company's current clinical trial underway for ACU-4429, an innovative compound that can be taken in a pill form.

Dr. Kubota explained that ACU-4429 works to regulate the eye's visual cycle for processing light. By slowing this cycle, ACU-4429 has demonstrated the ability to decrease the levels of toxic by-products in the eye. The specific target of ACU-4429 will regulate what is called A2E, a toxic by-product formed during the visual process whose accumulation is thought to lead to AMD.

While this may sound complicated, Dr. Kubota described it this way. "When someone's heart beats too fast, it can cause free-radical generation and oxidative stress on the body that could lead to cardiac failure. You need to find a way to slow the heart rate. In the eye, we are finding a way to regulate the visual cycle to reduce the buildup of toxic by-products that cause AMD without damaging the retina."

The key says Dr. Kubota, who is an ophthalmologist by training, will be early diagnosis. "If we can intervene in the earliest stage of AMD, then we can better preserve visual function."

The good news says Dr. Kubota is that AMD is easily diagnosed and he expects that the technology to identify the disease will become even easier in the years ahead. In fact, Dr.

Kubota envisions a day when there might be an easy at-home test or a hand-held device that could detect AMD.

ACU-4429 is now being tested in humans. It has completed a Phase I clinical trial and is now recruiting for its Phase II trial. Earlier this year, ACU-4429 was granted Fast Track Status by the U.S. Food and Drug Administration for the treatment of dry AMD. The FDA's Fast Track Program is designed to expedite the review of new drugs that are intended to treat serious conditions like AMD and demonstrate the potential to address unmet medical needs.

While a pill or other treatment for dry AMD is still a few years off, patients with the disease, and those at-risk, should feel hopeful about all of the current research being explored. With so many companies looking into the disease, the future is looking very bright for combating dry AMD.

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