

NEWS RELEASE

Araim Pharmaceuticals Given FDA Fast Track Designation to ARA 290 for the Treatment of Sarcoidosis-associated Small Fiber Neuropathy

Tarrytown, NY – October 28, -- [Araim Pharmaceuticals](#), a privately held company engaged in developing novel treatments for devastating injuries and chronic diseases underserved by current therapies, today announced a Fast Track Designation from the FDA for its lead compound ARA290, for treatment of Sarcoidosis-associated Small Fiber Neuropathy (SFN).

Small nerve fiber loss and damage causes autonomic and sensory symptoms, which are often disabling, with neuropathic pain being the most common patient complaint. There is currently no approved treatment of Sarcoidosis-associated SFN.

Sarcoidosis, an orphan disease, is diagnosed by the presence of granulomas, typically in the lung, in adults between 20 and 40. Most patients resolve spontaneously or with available treatment options, but 30 percent go on to develop a chronic condition with SFN the most common problem.

Araim Pharmaceuticals' ARA 290 is a first in class compound which activates the natural repair system of the body by activating the Innate Repair Receptor and thereby turning off systemic inflammation and turning on repair.

Araim Pharmaceuticals has completed exploratory trial and phase 2a trials, and is currently conducting a phase 2b dosing trial at [Cleveland Clinic](#) and Leiden Medical Center in the Netherlands.

“Typically, the effect of small fiber neuropathy on the quality of life of affected patients is very severe,” said Dr. Daniel Culver the lead investigator at the Cleveland Clinic.

“The fast track designation of ARA 290 offers new hope for patients suffering debilitating pain and severe dysautonomia, who frequently are forced to stop working and may even be confined to a wheelchair,” he added.

The FDA has created the Fast Track Designation for new therapies that have the potential to treat serious conditions for which there is no approved treatment option. Through this program the FDA offers streamline procedures and more regular communication to support a compound through the regulatory process.

Unfortunately, there are no approved medical therapies for sarcoidosis-associated small fiber neuropathy, so that currently individuals who experience it are treated only with largely ineffective medications that target symptoms, or must bear the illness with no treatment at all.

In the past ten years, researchers have recognized a potentially devastating complication of sarcoidosis--small fiber neuropathy. Small fiber neuropathy is a form of sarcoidosis

that occurs as a consequence of sarcoidosis due to an unknown mechanism; it does not respond to steroids and other immunosuppressive medications, and it may occur even years after the inflammatory manifestations of sarcoidosis have abated.

Anthony Cerami PhD, the CEO of Araim Pharmaceuticals, identified the potential for anti-TNF therapies and developed the hemoglobin A1c diagnostic test. The HbA1c Diagnostic test is the gold standard worldwide to diagnose and monitor diabetic patients.

Anti-TNF therapies have sold over \$100 billion, and have successfully treated rheumatoid arthritis, psoriasis, and Crohn's disease.

"ARA 290 is a novel first in class drug that has the potential to be the next generation of anti-cytokine therapies -- it turns off all damaging cytokines we have tested, and in animal and preliminary human trials promotes the repair of small nerve fibers--demonstrating real disease modification," stated Dr. Cerami.

Clinical trials have shown potent anti-inflammatory and tissue protective properties. ARA 290 demonstrated significant improvements in the symptoms of SFN along with improved functional capacity and improvements in sensory function and nerve fiber density.

ARA 290 was safe and well-tolerated, and seems to have long-lasting beneficial effects on both pain-related and non-pain-related symptoms.

ARA 290 has also received orphan status with the FDA and by the European Regulatory Agency. Phase 3 trials are slated to begin 4Q 2015.

About Araim Pharmaceuticals, Inc.

[Arim Pharmaceuticals, Inc.](http://www.araimpharma.com) is a privately held biotech company founded in 2006 engaged in developing novel treatments for devastating injuries and chronic diseases underserved by current therapies. Their lead compound, ARA 290, is a novel 11 amino acid peptide engineered to specifically activate the body's natural repair system via the innate repair receptor that is present only following injury. ARA 290 activates anti-inflammatory, tissue protective, and reparative signaling pathways. The short half-life of ARA 290 coupled with the restricted expression of the innate repair receptor functions as a dual safety system to avoid potential side effects. Clinical trials evaluating ARA 290 for treatment of neuropathic symptoms associated with diabetes and the orphan disease sarcoidosis are currently ongoing in the US and Europe. ARA 290 has received orphan drug designation in the US and in Europe, as well as Fast Track designation in the US for treatment of small fiber neuropathy in sarcoidosis. www.araimpharma.com

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