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ARCION THERAPEUTICS RECEIVES FDA FAST TRACK DESIGNATION FOR ARC-4558 FOR THE TREATMENT OF PAIN ASSOCIATED WITH PAINFUL DIABETIC NEUROPATHY

BALTIMORE, MD - September 14, 2010 - [Arcion Therapeutics](http://www.arciontherapeutics.com), a venture backed clinical stage biotechnology company developing topical therapies for chronic pain, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to ARC-4558 for the treatment of pain associated with Painful Diabetic Neuropathy (PDN). ARC-4558 is a 0.1% gel formulation of clonidine hydrochloride for topical administration. Arcion recently [announced](#) positive top-line results from a Phase 2b double-blind, randomized, placebo-controlled clinical trial of ARC-4558 in adult patients with PDN. The Company also recently held an End of Phase 2 meeting with the FDA and the ARC-4558 program is now poised to enter Phase 3 studies.

The Fast Track program of the FDA is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. Fast Track designated drugs typically qualify for priority review, thereby expediting the FDA review process.

"This Fast Track designation is an important recognition by the FDA of the potential for ARC-4558 to address the unmet need for better agents to control the pain involved in PDN, a serious condition," said James Campbell, M.D., Chief Executive Officer of Arcion. "Having the Fast Track designation will be of great value to Arcion as we work with the FDA to come to an agreement on the final Phase 3 program, as well as open the way to a potential priority review."

About ARC-4558

ARC-4558 is a 0.1% gel formulation of clonidine hydrochloride (HCL) for topical administration to the painful area in order to manage the neuropathic pain associated with painful diabetic neuropathy (PDN). Topical clonidine, through its agonist effects on alpha2 (a2)-adrenergic receptors, is believed to reduce pain in PDN via local actions on the nociceptors that innervate the affected skin. Based on the results of clinical trials to-date, Arcion believes that ARC-4558 has a level of efficacy comparable to systemic therapies in the target population, but with substantially fewer side effects. The 0.1% gel formulation avoids the treatment area limitations and undesirable aesthetic and skin reaction issues associated with analgesic patches. Furthermore, the ARC-4558 gel has been shown to provide analgesia without numbing or anesthetizing the skin.

About Painful Diabetic Neuropathy (PDN)

Neuropathy is a common complication of diabetes mellitus. According to 2008 estimates by the Centers for Disease Control and Prevention, nearly 18 million people in the United States are diagnosed with diabetes. Given a conservative estimate that 15% of people with diabetes have painful neuropathies, approximately 2.7 million Americans experience PDN. Patients with PDN often experience debilitating pain symptoms that affect day-to-day functioning and quality of life. How diabetes causes a length-dependent neuropathy is unknown. Arcion believes the PDN market is highly under-served by existing products and that there is a strong scientific rationale for developing a topical treatment for PDN that delivers analgesia in a way that avoids systemic side effects.

About Arcion

Arcion Therapeutics applies breakthroughs in neuroscience to advance the treatment of chronic pain. The company focuses on innovative topical treatments to provide pain relief with convenient application and reduced systemic side effects. Arcion's product pipeline comprises multiple candidates to treat neuropathic pain. www.arciontherapeutics.com

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