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**ARCION THERAPEUTICS' TOPICAL GEL CANDIDATE, ARC-4558, DEMONSTRATES SIGNIFICANT PAIN REDUCTION IN PHASE 2b TRIAL FOR PAINFUL DIABETIC NEUROPATHY (PDN)**

BALTIMORE, MD - July 20, 2010 - [Arcion Therapeutics](http://www.arciontherapeutics.com), a venture backed clinical stage biotechnology company developing topical therapies for chronic pain, today announced top-line results from a successful Phase 2b double-blind, randomized, placebo-controlled clinical trial of its lead topical pain candidate, ARC-4558, in adult patients with painful diabetic neuropathy (PDN). Arcion recently held an End of Phase 2 meeting with the United States Food and Drug Administration (FDA) and the ARC-4558 program is now poised to enter Phase 3 studies. ARC-4558 is a 0.1% gel formulation of clonidine hydrochloride for topical administration.

The study results successfully demonstrated therapeutic potential for treating PDN with ARC-4558 by targeting abnormal nerve signaling at the level of the skin with a 0.1% topical gel formulation of clonidine. ARC-4558 was most effective in reducing pain in subjects with evidence of preserved nociceptors (nerve fibers responsible for pain signaling) in the skin. In subjects with at least minimal nociceptor function, ARC-4558 was significantly more effective in reducing pain than placebo ( $p < 0.05$ ). The significance of the response increased with higher levels of nociceptors in the subject's skin ( $p < 0.005$ ). ARC-4558 did not demonstrate efficacy in subjects lacking evidence of preserved nociceptor function.

The ITT (intent to treat) population was comprised of a mix of subjects in which about half had little or no nociceptor preservation and therefore the pooled results were not significant. Plasma levels of clonidine were consistently low or undetectable. No serious or severe adverse events were attributable to ARC-4558 treatment and the topical formulation was well-tolerated at the site of skin application.

"The top-line data reported today for ARC-4558 provide strong support for Arcion's fundamental approach of applying therapies topically to relieve neuropathic pain by targeting nerve signaling at the level of the skin," said James Campbell, M.D., President and CEO of Arcion. "Through this study, we identified a simple, predictive clinical test to identify non-responders to ARC-4558, which should enable us to optimize subject enrollment in future studies. Based on our successful End of Phase 2 meeting with the FDA, we believe ARC-4558 will be the first PDN treatment indicated to treat patients who have demonstrable functional nociceptors in the skin. The full Phase 2b results will be submitted for future peer review and we look forward to advancing the ARC-4558 program in Phase 3 studies."

Michael C. Rowbotham, M.D., Adjunct Professor of Neurology and Anesthesia and Director, UCSF Pain Clinical Research Center, commented, "Painful diabetic neuropathy is frequently a

debilitating condition that severely impacts a patient's quality of life and ability to carry out normal day-to-day functions. There are approved therapies to control the pain, but issues of tolerability and efficacy seriously limit their usefulness. A novel mechanism-based topical treatment with a low liability of systemic side effects has promise to advance significantly the treatment of this condition and improve the quality of life for a large number of patients."

### **About the Phase 2b Trial**

The Phase 2b study included an adaptive trial design and enrolled a total of 180 adult patients with PDN. Patients in the study applied ARC-4558 0.1% gel or placebo to the affected area three times a day (3.9 mg clonidine per day) for a 12-week treatment period. Patients were able to continue taking a stable dose of their existing pain medications. The primary endpoint of the study related to the change in pain at week 12 compared to baseline measured by the numerical pain rating scale (NPRS).

### **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](http://www.arciontherapeutics.com)