



## PRESS RELEASE

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### **ARCION THERAPEUTICS' TOPICAL PAIN CANDIDATE, ARC-4558, SIGNIFICANTLY REDUCES PAIN CAUSED BY DIABETIC NEUROPATHY**

#### **-Clinical Data Presented at American Pain Society Annual Meeting-**

**BALTIMORE, MD - May 07, 2009** - Arcion Therapeutics, a venture backed clinical stage biotechnology company that develops pain therapies, today announced the presentation of data demonstrating that its lead candidate, ARC-4558, significantly reduced pain caused by diabetic neuropathy in a double-blind, placebo-controlled trial. The abstract will be presented in a poster session on May 8<sup>th</sup> from 4:00-5:30 PM at the American Pain Society Annual Meeting, held May 7-9 in San Diego. ARC-4558 is a 0.1% gel formulation of clonidine hydrochloride for topical administration. Arcion is currently conducting a Phase 2b clinical trial of ARC-4558 for the treatment of painful diabetic neuropathy (PDN).

According to the abstract, patients receiving 0.1% clonidine gel reported significantly greater reductions in pain when compared to placebo ( $p=0.015$ ). This improvement was demonstrated in the first week of the study ( $p=0.003$ ). Participants in the 0.2% group did not differ from those in the placebo group, though a trend was observed ( $p=0.054$ ). The 0.2% results may have been due to the fact that this group received 23% less gel in order to avoid higher systemic dosing. Consistent with this, clonidine blood levels in the 0.2% group were the same as that in the 0.1% group. Responder analysis revealed that 47.2% of patients across both treatment groups combined had 30% or more pain relief compared to 29.3% in the placebo group ( $p=0.031$ ). Blood levels of clonidine varied from non-detectable to levels several-fold below the threshold required to treat hypertension (the original indication for clonidine). Patients with detectable clonidine in the blood experienced significantly greater pain reduction than patients in whom clonidine was not detected ( $p<0.05$ ).

“These data demonstrate that ARC-4558 may offer a new approach to treating the pain associated with diabetic neuropathy. By applying the drug topically to the area of pain, systemic exposure is minimized, and hence, systemic side effects appear to be minimal. Moreover, this approach may be complementary to systemic approaches. We are now in the midst of an additional randomized, controlled Phase 2b trial to confirm the safety and efficacy of topical clonidine,” said James Campbell, M.D., President and CEO of Arcion. “ARC-4558 is a result of Arcion’s expertise in developing differentiated drugs through our understanding of the underlying biology of neuropathic pain.”

Previously published research has shown that in neuropathic pain conditions such as PDN, the signal that triggers pain actually arises at the level of the skin. The data reported today for ARC-4558 provide further rationale for applying therapies topically at the site of the pain. From a treatment standpoint, this approach has the potential to offer multiple benefits over orally bioavailable or patch-

based treatments including more convenient application, uniform coverage of the affected site, lower systemic side-effects and fewer drug interactions.

The abstract, titled, “Topical clonidine gel (ARC-4558) reduces pain caused by diabetic neuropathy: Results of a multicenter, placebo-controlled clinical trial,” was authored by Claudia M. Campbell, Ph.D., Johns Hopkins School of Medicine; Bruce Stouch, Ph.D., BCS Consulting; Kerrie Brady, M.S., M.B.A., Arcion Therapeutics; Bill Schmidt, Ph.D., NorthStar Consulting LLC; and James Campbell, M.D., Johns Hopkins School of Medicine and Arcion Therapeutics.

### **About the Trial**

The double-blind, placebo-controlled trial included 166 patients with chronic, bilateral, lower extremity, painful diabetic neuropathy. Patients were randomized to receive 0.1% or 0.2% topical clonidine gel or placebo gel, and remained on their existing pain management treatments. The gel was applied to both feet twice daily for the first two weeks and three times a day for six weeks. Participants rated their pain throughout the study.

### **About Painful Diabetic Neuropathy (PDN)**

Diabetic neuropathy is one of the most common complications of diabetes mellitus that is associated with a number of painful conditions. According to 2008 estimates by the Centers for Disease Control and Prevention, nearly 24 million people in the United States are affected by diabetes. Given a conservative estimate that 15% of people with diabetes have painful neuropathies, approximately 3.6 million Americans experience PDN. PDN is thought to result from chronic hyperglycemia, which can lead to diabetic microvascular injury involving small blood vessels that supply nerves (vasa nervorum), particularly the sensory, motor and autonomic nerve fibers. Patients with PDN often experience debilitating pain symptoms that affect day-to-day functioning and quality of life.

### **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.

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