

## **Resolvix Announces Positive Data from Phase 2 Clinical Trial of the Resolvin RX-10045 in Patients with Dry Eye Syndrome**

*First Demonstration of Clinical Efficacy for Novel Class of Resolvin Therapeutics*

**BEDFORD, MA — August 24, 2009** -- Resolvix Pharmaceuticals, Inc., the leading resolvin therapeutics company, today announced positive data from a Phase 2 clinical study evaluating RX-10045, a resolvin administered as a topical eye drop for the treatment of patients with chronic dry eye syndrome. In this 28-day, randomized, placebo-controlled, 232-patient trial, RX-10045 produced dose-dependent, statistically significant improvement on the primary endpoints for both the signs and symptoms of dry eye, and was generally shown to be safe and well tolerated. These Phase 2 results represent the first demonstration of clinical efficacy for the novel class of resolvin compounds and suggest that resolvins have the potential to treat a broad range of inflammatory diseases.

"There is an urgent need for new treatment options in dry eye and the results of this Phase 2 study are as strong as any I have seen," said Stephen Pflugfelder, MD, an expert in dry eye at Baylor College of Medicine. "Based both on these clinical results and on its unique mode of action, I am confident that RX-10045 can be an important new treatment modality for these patients."

The 28-day, randomized, multi-center, placebo-controlled study in 232 patients with moderate dry eye patients was designed to evaluate the safety, tolerability and efficacy of RX-10045 administered twice daily. The Phase 2 study examined three doses of RX-10045 and utilized a controlled adverse environment (CAE) to measure corneal staining in a stressful drying environment, as well as daily patient diaries using a standard visual analog scale to assess symptom improvement over the course of the study.

RX-10045 produced a significant dose-dependent improvement from baseline in symptoms recorded in daily patient diaries. The improvement was observed across all symptoms evaluated in the study, including dryness, stinging, burning, grittiness, ocular discomfort and the composite of each patient's most severe symptom (Worst Symptom Score). RX-10045 was superior to placebo on the primary symptomatic endpoint of Worst Symptom Score ( $p < 0.02$ ), as well as on several individual symptoms. The onset of symptom relief occurred within the first week of treatment, and symptoms continued to improve over the course of the 28-day study, suggesting the potential for even greater benefit with longer treatment durations.

"I am very encouraged by the symptom relief achieved with RX-10045," said Ira Udell, M.D., Chairman of the Department of Ophthalmology at the North Shore-Long Island Jewish Health System and Professor of Ophthalmology and Visual Sciences, Albert Einstein College of Medicine. "Symptomatic improvement is what really matters to patients."

RX-10045 also produced a 75% reduction from baseline in CAE-induced staining of the central cornea ( $p < 0.00001$ ), the primary sign endpoint in the study. This improvement was greater than that observed for placebo, the difference approaching statistical significance ( $p = 0.11$ ). RX-10045 also produced a significant improvement in CAE-induced staining in the inferior cornea and in the composite of central and inferior cornea, which also approached statistical significance over placebo ( $p = 0.09$ ).

"We are very enthusiastic about the results of this Phase 2 study which, in only a 28-day study, achieved what we believe is unprecedented dose-dependent improvement in the symptoms of dry eye, as well as strong improvement in the signs of dry eye. The results of this study will help Resolvix design the pivotal trials for RX-10045, which are currently targeted to begin in the first half of 2010," said Greg Weinhoff, Executive Chairman of Resolvix. "In addition to demonstrating the potential of RX-10045 to treat dry eye patients, this study also shows the potential of the entire resolvin class to treat a range of inflammatory diseases."

Resolvix is also currently conducting a Phase 1 study with a second resolvin, RX-10001, an orally-administered drug candidate for the treatment of systemic inflammatory diseases such as asthma, inflammatory bowel disease and other inflammatory diseases.

### **About RX-10045**

RX-10045 is Resolvyx's lead resolvin therapeutic, and is a synthetic analog of RvE1, a naturally occurring resolvin. RX-10045 has been shown to have potent anti-inflammatory and cell-survival benefits in laboratory testing. In preclinical studies, RX-10045 was highly effective in preventing signs of dry eye, including decreasing corneal inflammation, reducing corneal epithelial damage, preventing loss of goblet cells (cells that play an important role in maintaining tear film integrity) and improving tear volume. In addition, those studies demonstrated that RX-10045 potentially inhibited the release of several key pro-inflammatory mediators from corneal epithelial cells and accelerated corneal tissue repair with an effect level comparable to that seen with epidermal growth factor, the most potent previously-known mediator of corneal tissue repair. RX-10045 is formulated as a clear, aqueous, preservative-free solution for ocular administration.

### **About Dry Eye Syndrome**

Dry eye syndrome is one of the most common problems treated by eye physicians; an estimated 25-30 million Americans suffer from dry eye and the worldwide prevalence closely parallels that of the United States. Dry eye is a chronic, multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface. Dry eye can make it more difficult to perform some visual activities for an extended period of time, and it can decrease tolerance for dry environments.

### **About Resolvins**

Resolvins are a recently discovered family of naturally-occurring, small molecule lipid mediators that can be targeted to treat a wide range of diseases. In particular, resolvins act to protect healthy tissue during an inflammatory response to infection, injury or other environmental challenge, and then act to resolve inflammation and promote healing after the insult has passed. Resolvins are shown to be highly potent and efficacious in pre-clinical models of asthma, atherosclerosis, rheumatoid arthritis, inflammatory bowel disease, dry eye and retinal disease, among others.

Resolvins are potential drug candidates to treat a broad range of acute and chronic diseases caused by a failure to resolve the inflammatory response and restore immune homeostasis. Such diseases include autoimmune diseases (like Crohn's disease, psoriasis and rheumatoid arthritis), allergic diseases (like asthma) and chronic inflammatory diseases (like atherosclerosis, degenerative retinal diseases, chronic dry eye and Alzheimer's disease). Resolvins offer an entirely novel biological approach to treating significant inflammatory diseases, with a decreased potential for immuno-suppression.

### **About Resolvyx Pharmaceuticals**

Resolvyx Pharmaceuticals is a privately-held biopharmaceutical company dedicated to the discovery, development and commercialization of resolvins, a novel class of therapies to treat inflammatory diseases and their complications. Resolvyx's drug R&D programs are focused on characterizing and developing resolvin-based compounds. With its experienced management team, world-class scientists and leading investors, Resolvyx is well-positioned to capitalize on its extensive portfolio of 69 patents and applications. The company's headquarters are in Bedford, Massachusetts. For additional information, please visit <http://www.resolvyx.com>.