

## **Resolvix Initiates Phase I Clinical Trial of Novel Resolvin, RX-10001, for Asthma and Inflammatory Diseases**

### **First Clinical Trial of Orally-Administered Resolvin Therapeutic**

**BEDFORD, MA — May 5, 2009** -- Resolvix Pharmaceuticals, Inc., the leading resolvin therapeutics company, today announced that it has initiated the first human clinical trial evaluating an oral resolvin therapeutic, RX-10001, in a Phase I clinical trial in healthy volunteers. RX-10001 is a synthetic form of RvE1, a naturally occurring resolvin, which in animal studies has been shown to activate the body's own off-switch mechanisms for inflammation and to promote healing for normal tissue function. In preclinical testing, RX-10001 and analogs have shown high potency across a range of inflammatory disease models, including asthma, colitis, rheumatoid arthritis, and atherosclerosis.

"This is an important milestone for Resolvix, as initiation of this first trial of an orally-administered resolvin offers Resolvix the opportunity to demonstrate the broad clinical potential of resolvins as a new class of therapeutics," said Paul Rubin, M.D., Chief Executive Officer of Resolvix. "We are delighted to have successfully initiated this study, and, upon the successful completion of this Phase I trial, we anticipate evaluating RX-10001 in an exercise-challenge asthma clinical trial and subsequently testing its potential across multiple inflammatory diseases."

The randomized, placebo-controlled, double-blind study is designed to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamics of RX-10001. 56 healthy volunteers will be enrolled in the trial which will evaluate a single as well as a multiple ascending dose of RX-10001 which will be administered orally.

"Based on its unique mechanism of action and compelling preclinical data, we are hopeful that RX-10001 will offer a novel therapeutic approach for a broad number of inflammatory diseases, beginning with asthma," said Per Gjorstrup, M.D., Ph.D., Chief Medical Officer of Resolvix. "In contrast to existing treatment approaches to asthma that primarily tamp down inflammation and provide incomplete resolution of an inflammatory response, resolvins have the potential to engage a natural mechanism to turn off inflammation as well as restoring normal tissue function."

#### **About RX-10001**

The resolvin RX-10001 is a naturally occurring, small molecule lipid mediator. RX-10001 acts to protect healthy tissue during an inflammatory response to an environmental insult and to resolve inflammation once the environmental insult has passed. Preclinically, RX-10001 is active with very high potency across a range of inflammatory disease models, including asthma, colitis, rheumatoid arthritis, atherosclerosis, dry eye and retinopathy, and is active by oral, intravenous and subcutaneous routes of administration. As an active metabolite of the omega-3 fatty acid called EPA (eicosapentaenoic acid), RX-10001 may account for the proven health benefits of omega-3s and is anticipated to have an exceptional safety profile in the clinic. To prove concept, RX-10001 will be evaluated initially in an exercise-challenge asthma clinical trial and will subsequently be tested broadly across multiple inflammatory diseases.

#### **About Asthma**

Asthma is a condition characterized by inflammation of airways in the lungs resulting in chronic wheezing, coughing and difficulty breathing. Asthma has a significant impact on both individual lives and society, including:

- More than 4,000 deaths annually (1),
- Accounting for more than 10 million outpatient visits and 500,000 hospitalizations annually (2),
- Over 10 million missed days of work for adults each year (1) and over 14 million missed days of school for children (2),
- 2 million emergency room visits each year (2), and
- An estimated \$18 billion in medical expenses and indirect costs each year (2).
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#### **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 immuno-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 auto-immune 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 resolvins-based compounds. With its experienced management team, world-class scientists and leading investors, Resolvyx is well-positioned to capitalize on its extensive portfolio of more than 55 patents and applications.

#### **References:**

The company's headquarters are in Bedford, Massachusetts. For additional information, please visit <http://www.resolvyx.com>.

1. Centers for Disease Control. "Asthma Prevalence, Health Care Use and Mortality, 2003-2005" Available at <http://www.cdc.gov/nchs/products/pubs/pubd/hestats/ashtma03-05/asthma03-05.htm> (accessed 5/26/09)
2. Asthma and Allergy Foundation of America. "Asthma Facts and Figures." <http://www.aafa.org/display.cfm?id=8c=42> (accessed 5/26/09)

Source: Resolvyx Pharmaceuticals