



## Media Release

### IMMEDIATE RELEASE

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### **Amira Pharmaceuticals Announces Favorable Phase 1 Clinical Trial Results for Lead Product Candidate AM103 and Initiates Clinical Studies for the 2<sup>nd</sup> Entry Molecule for the Treatment of Respiratory and Cardiovascular Disease**

**SAN DIEGO, November 1, 2007** -- Amira Pharmaceuticals, Inc. announced completion of the company's Phase 1 clinical trial of AM103, Amira's internally discovered oral drug candidate for the treatment of inflammatory diseases linked to the leukotriene pathway. Amira also announced the start of a Phase 1 trial for AM803, a second oral drug candidate that targets the same inflammatory response.

AM103 and AM803 are novel inhibitors of 5-lipoxygenase-activating protein (FLAP) that have demonstrated potential to treat asthma and cardiovascular disease (CVD) by preventing the synthesis of leukotrienes (LT), which trigger inflammation. The recently completed AM103 trial was designed to assess the safety and tolerability of an escalating single dose of the compound and escalating multiple doses in healthy volunteers who received AM103 or placebo for up to 11 days. The trial also assessed the pharmacodynamic properties of AM103, specifically its ability to inhibit LT production.

Results from the Phase 1 trial show that AM103 is safe and well-tolerated at doses up to 1,000 mg per day with no evidence of significant side effects. The systemic exposure of AM103 increased linearly from 50 mg to 1,000 mg.

Pharmacodynamic data demonstrated a robust and statistically significant reduction of LTB<sub>4</sub> and LTE<sub>4</sub> in a dose-dependent manner. "The results from this trial meet and even exceed our expectations for safety, and provide pharmacodynamic evidence consistent with this mechanism of action," said Peppi Prasit, Amira's chief scientific officer. "The half-life of up to 10 hours also gives us the opportunity to evaluate once-daily dosing in a Phase 2 trial, which we expect to start in 2008."

"Based on this very favorable profile, the excellent tolerability and the high levels of exposure obtained with oral dosing in Phase 1 studies, we are moving forward to conduct a Phase 2 study with AM103 in

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asthmatic patients," said Bob Baltera, Amira's chief executive officer. "In addition, we have initiated a Phase 1 study with our second FLAP inhibitor, AM803, using a similar trial design to AM103. These are exciting times at Amira as our team continues to demonstrate world-class capabilities in drug discovery and development, particularly through the impressive progress of these two drug candidates."

Discussions are continuing with a number of potential pharmaceutical partners interested in Amira's FLAP program.

### **About FLAP Inhibitors**

FLAP is a key component early in the leukotriene pathway, a complex signaling process that exerts control over biological processes, such as inflammation and immunity. Excessive activity of FLAP exacerbates inflammatory diseases, such as asthma; the FLAP gene has also been linked to a significant increase in the risk of myocardial infarction and stroke. AM103 binds to FLAP, inhibiting the synthesis of leukotrienes that cause inflammation.

A FLAP inhibitor is active at a point higher in the leukotriene pathway than a CysLT1 receptor antagonist, enabling it potentially to inhibit the production of all leukotrienes. Leukotrienes, prostaglandins and other arachidonic acid-derived lipids make up the eicosanoid family of inflammatory mediators.

### **About Amira**

Founded in 2005 and headquartered in San Diego, Amira Pharmaceuticals is a small molecule pharmaceutical company focused on the discovery and early development of compounds to treat inflammatory disease linked to the eicosanoid pathway.

The company combines the rigor of a big pharmaceutical company with the ingenuity and energy of a small company, creating an environment for efficient and effective pre-clinical and clinical program decisions. Its scientific founders have successfully worked together for more than a decade and were pivotal in the discovery of a number of inflammatory drugs, including Singulair®. The drug hunters at Amira are now actively leveraging their history of success to create high-value compounds for the future.

In January 2006, Amira signed a collaboration with Roche to establish a research alliance and an option for Amira to license two clinical-stage compounds from Roche. Amira has yet to exercise its option.

Amira has raised \$40 million to date from investors including Novo A/S (Copenhagen, Denmark), Avalon Ventures (San Diego, CA), Prospect Ventures (Palo Alto, CA) and Versant Ventures (Menlo Park, CA). For more information, visit [www.amirapharm.com](http://www.amirapharm.com)