



## Media Release

### IMMEDIATE RELEASE

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### Amira Pharmaceuticals and GlaxoSmithKline enter global agreement for FLAP inhibitor program

#### Deal follows positive phase I data from novel product candidate AM103 for the oral treatment of respiratory disease

**SAN DIEGO, February 4, 2008** -- Amira Pharmaceuticals and GlaxoSmithKline today announced they have entered into a worldwide exclusive agreement to develop, manufacture and commercialize FLAP (5-Lipoxygenase Activating Protein) inhibitors for the treatment of respiratory and cardiovascular disease.

Under the terms of the agreement GSK will be granted an exclusive, worldwide license to develop, manufacture and commercialize Amira's FLAP inhibitors, including AM103 and other compounds within the current development program. In the event that all potential development and regulatory milestones are successfully achieved, Amira could receive up to US \$425 million in upfront and milestone payments. In addition, Amira will be entitled to receive tiered royalty payments based on worldwide net sales and commercial sales milestones.

Initial development activities will focus on candidate compound AM103, for the treatment of asthma. Positive data, from a phase I study completed in November 2007, show AM103 has the potential as a once-daily, oral, non-steroidal asthma treatment. In this study the compound was also well-tolerated.

Peppi Prasit, Chief Scientific Officer and Co-Founder Amira said: "To have identified such a positive drug candidate and progressed to the completion of phase I clinical trials just two years after the company was founded is a tremendous achievement for the team at Amira. We are delighted that GlaxoSmithKline will be taking this asset into full development. With their experience and expertise in this area we hope that AM103 will become the first FLAP inhibitor available to patients worldwide to treat symptoms of asthma and possibly other inflammatory diseases."

"This is a momentous day in the young life of Amira," said Bob Baltera, Chief Executive Officer, Amira. "This deal validates the abilities and expertise in Amira to expedite the delivery of novel medicines. We are particularly pleased to have partnered with GSK, one of the leading pharmaceutical companies in the world, and a company that has a strong heritage in the treatment of respiratory diseases."

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## **About respiratory diseases**

The prevalence of asthma is increasing globally and despite the success of inhaled beta-agonist and corticosteroid therapy there is still a significant need for alternative therapies. Although other therapies are available that target the leukotriene pathway, a FLAP inhibitor has the potential to inhibit a broad spectrum of leukotrienes. FLAP inhibitors are also being investigated for use in other respiratory indications, including rhinitis, as well as having potential for the treatment of other inflammatory and cardiovascular diseases.

The global non-steroidal market for the treatment of asthma and rhinitis is currently worth in excess of US \$4 billion; prescriptions for the treatment of rhinitis contribute 15% to total worldwide sales of non-steroidals. A FLAP inhibitor with improved efficacy and equal or improved safety and tolerability to existing leukotriene receptor antagonists, in both asthma and rhinitis, would likely capture a significant portion of this market.

## **About the agreement**

Commenting on the agreement, Dave Allen, SVP Respiratory Centre of Excellence in Drug Discovery, GlaxoSmithKline said: "The role of anti-leukotriene agents has been well validated in the treatment of respiratory diseases. We are very excited at entering into this global agreement with Amira to deliver novel therapies to patients based on this mechanism."

In addition Moncef Slaoui, Chairman R&D, GSK said: "As leaders in the development, manufacture and marketing of medicines for respiratory diseases GSK is pleased to be introducing this treatment to our product pipeline. We believe AM103, a novel FLAP inhibitor, has the potential to offer patients a convenient and effective alternative treatment for respiratory diseases including asthma and rhinitis."

## **About FLAP Inhibitors**

FLAP (5-lipoxygenase activating protein) 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 production of leukotrienes 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 GlaxoSmithKline**

GlaxoSmithKline is one of the world's leading research-based pharmaceutical and healthcare companies. GlaxoSmithKline is committed to improving the quality of human life by enabling people to do more, feel better and live longer. For company information visit [www.gsk.com](http://www.gsk.com).

## **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).

## **GlaxoSmithKline Forward-Looking Statements**

Under the safe harbor provisions of the US Private Securities Litigation Reform Act of 1995, the company cautions investors that any forward-looking statements or projections made by the company, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect the Group's operations are described under 'Risk Factors' in the Business and Prospects in the company's Annual Report on Form 20-F for 2006.

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