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Amira Inks $425M FLAP Inhibitor Deal with GSK

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Three months after reporting positive Phase I data with lead compound AM103, Amira Pharmaceuticals Inc. licensed the drug and the rest of its 5-lipoxygenase activating protein (FLAP) inhibitor program for respiratory and cardiovascular disease to GlaxoSmithKline plc.

The deal could bring Amira $425 million in up-front fees and development milestone payments, as well as tiered royalties and additional milestone payments tied to sales.

Bob Baltera, CEO of San Diego-based Amira, declined to further break down the structure of the deal but said the money will provide Amira with two to four years worth of nondilutive funding.

In exchange, GSK gets exclusive, worldwide rights to develop and commercialize AM103, a Phase I back-up compound known as AM803, and two additional back-up compounds yet to be chosen.

AM103 is slated for development as a once-daily asthma drug, although the compound also may be applicable in allergic rhinitis, chronic obstructive pulmonary disease and cardiovascular inflammation. Data from a Phase I trial completed in November showed the drug to be 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, and pharmacodynamic data indicated a statistically significant, dose-dependent reduction of leukotrienes LTB4 and LTE4.

Within the crowded asthma market, AM103 is perhaps most similar to the 5-lipoxygenase inhibitor Zyflo (zileuton tablets, Critical Therapeutics Inc.), at least mechanistically speaking. Zyflo sales generated about $3.9 million in the third quarter of 2007, up more than 66 percent over the third quarter of 2006 but still representing just a tiny slice of the $4 billion asthma pie. But with the marketing muscle of GSK behind it, Baltera noted that AM103 could be positioned to compete with Merck and Co. Inc.'s blockbuster Singulair (montelukast sodium), a drug several members of Amira's scientific team had a hand in developing. AM103 works upstream from Singulair, potentially allowing it to hit more leukotriene receptors and help a broader patient population.

GSK's respiratory expertise – gained through management of products like the asthma and chronic obstructive pulmonary disease drug Advair (fluticasone and salmeterol) – was a primary reason Amira chose the big pharma for its partner, Baltera said. After 18 months of discussions, Amira had a number of options that "basically were a wash" as far as financial terms, but GSK's experience in treating respiratory disease "made the decision an easy one," he said.

Amira held on to a few undisclosed niche indications for which it could discover and develop new FLAP inhibitors, but Baltera said the "lion's share" of the FLAP program will be transitioned to GSK.

Despite off-loading its lead program, Amira has plenty of projects to keep it busy. In early 2006, the company signed a deal with F. Hoffmann-La Roche Ltd. for screening against three targets, with Roche holding an option to compounds hitting two of the targets, and Amira retaining rights to compounds hitting the third. Amira also picked up an option to license two Phase I programs from Roche. Baltera said both aspects of the Roche deal are "making progress" and the company should have more to say later this year or early next year. (See *BioWorld Today*, Jan. 12, 2006.)

Internally, Amira's scientific team has moved on from FLAP and is "making progress with another target in the respiratory field," Baltera said. With the money from the GSK deal, Amira also will evaluate opportunities to in-license compounds of interest. ■