

Emerging Company Profile

Amira: Beyond Singulair

By Andy Heller
Staff Writer

Based on the work of CSO Peppi Prasit, Amira Pharmaceuticals Inc. is developing compounds to treat inflammation, including one that inhibits multiple targets in the leukotriene pathway to treat asthma. Prasit believes the compound, AM-103, will expand the patient population now covered by asthma drug Singulair montelukast from Merck & Co. Inc.

AM-103 inhibits cysteinyl leukotriene receptor 1 (CysLT1), CysLT2 and leukotriene B4 type 1 receptor (BLT1) in the leukotriene pathway. Singulair targets only CysLT1 but "is highly effective in a subset of asthmatics," according to Prasit. Thus the company believes its molecule should cover a bigger population than Singulair.

Amira, which discovered the oral small molecule in house, expects to file an IND by the end of the first quarter of 2007 and to start a Phase I biomarker study by next June.

Prasit knows a bit about Singulair, as he was executive director of medicinal chemistry at MRK (Whitehouse Station, N.J.) and led the optimization of the drug until 2005, when the company asked its San Diego employees to move to the East Coast.

He founded Amira in July 2005, along with former MRK employees John Hutchinson and Jilly Evans, as well as acting CMO Mark Moran from Versant Ventures, armed with \$9 million from the

Amira Pharmaceuticals Inc.

San Diego, Calif.
Technology: NA
Disease focus: Inflammation and dermatology
Clinical status: Preclinical
Founded: 2005 by Peppi Prasit, John Hutchinson, Jilly Evans and Mark Moran
University collaborators: None
Corporate partners: Roche
Number of employees: 28
Funds raised: \$14 million
Investors: Avalon Ventures; Versant Venture; and Prospect Venture Partners
CEO: None
Patents: None issued

first tranche of a series A round co-led by Versant, Avalon and Prospect Ventures.

Prasit says proof of concept for AM-103 lies not in comparisons with Singulair but with another asthma drug, Zyflo, an immediate-release formulation of zileuton marketed by Critical Therapeutics Inc. (CRTX, Lexington, Mass.).

Zyflo acts on 5-lipoxygenase, upstream of AM-103 and Singulair, essentially blocking all of the receptors that AM-103 is targeting. However, Zyflo has some liver toxicity issues, according to Prasit, and is

dosed four times a day at 600 mg per dose. Prasit hopes that AM-103 will be dosed once or twice a day for a total of 100 mg.

According to Prasit, 1-10 mg/kg AM-103 demonstrated statistically superior efficacy compared with 10-100 mg/kg Zyflo in several respiratory inflammatory rat models. In addition, AM-103 at 250 mg/kg/day for four days showed no liver toxicity in mice, while the same dose of Zyflo showed an increase in liver weight, which Prasit said is one symptom of toxicity.

Singulair posted six-month sales of \$1.8 billion. Zyflo posted \$2.8 million in sales in the same period.

Prasit sees the Phase I biomarker data for AM-103 as an inflection point, which the company expects late in the third quarter of next year. The study is intended to allow Amira to preselect patients for trials who are likely to be responders. The company is looking at biomarkers for leukotriene B4 (LTB4), C-reactive protein (CRP), leukotriene E4 (LTE4) and others.

Amira (San Diego, Calif.) plans to take AM-103 up to Phase IIa testing before out-licensing it. The company has had discussions with six undisclosed pharma companies concerning a possible partnership.

Amira will begin Phase I testing of AM-102 for an undisclosed dermatological indication in December. The topical compound was one of two that Amira has an option to license under a January deal

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with Roche (SWX:ROCZ, Basel, Switzerland).

The deal included R618, a tumor necrosis factor (TNF) alpha converting enzyme inhibitor in Phase I testing to treat rheumatoid arthritis (RA) and irritable bowel disease (IBD), and R1628, a p38 mitogen-activated protein (MAP) kinase inhibitor in Phase I testing to treat RA (see *BioCentury*, Jan. 16).

Prasit said the company will decide if it wants to exercise the option for AM-102 based on the Phase I data, which it expects at the end of the first quarter next year. If Amira exercises its option, ROCZ would receive a "significant" percentage of Amira's stock and could receive up to \$20 million in milestones, plus royalties.

Under that same deal, ROCZ will screen its compound repository against three targets provided by Amira, which will then optimize resulting leads. The pharma company will have opt-in rights on two of the three programs. If ROCZ exercises both options, Amira could receive up to \$287 million in milestones, plus royalties.

In addition to the \$14 million Amira already has raised, the company expects to raise \$5 million from the current investors in the first quarter of next year for the third tranche of the series A. The company raised \$5 million in the second tranche last month.