



### Resolvix, Swinging for the Fence in First Human Study, Passes Test with Drug for Dry Eye

Luke Timmerman 8/24/09

**RESOLVYX PHARMACEUTICALS**, the company that develops derivatives from omega-3 fish oils into new drugs, is announcing today that the first therapy from this class passed its first clinical trial, helping alleviate symptoms for patients with chronic dry eye.

This was a big hurdle for Bedford, MA-based Resolvix to clear, partly because the company set the initial bar unusually high. Most initial clinical trials enroll only a dozen or so patients, assess safety at a number of low doses, then start thinking about effectiveness. But Resolvix cut to the chase. It is reporting today that its proprietary eye drop was able to achieve a statistically significant reduction in the dryness, stinging, burning, and grittiness sensations in a trial of 232 patients who were randomly assigned to get the drug or a placebo. There were no serious side effects.

This is certainly a big step for Resolvix, because it provides some validation to the company's claim that its class of compounds, called resolvins, can have potent anti-inflammatory effects. Resolvix plans to develop oral pill formulas that can be used broadly in common inflammatory diseases like asthma or inflammatory bowel disease. While dry eye doesn't sound nearly as serious as those conditions, it is one of the most common eye conditions treated by doctors, and is estimated to affect 25 million to 30 million people in the U.S..

"There is an urgent need for new treatment options in dry eye and the results of this Phase 2 study are as strong as any I have seen," said Stephen Pflugfelder, an expert in dry eye at Baylor College of Medicine, in a company statement. "Based both on these clinical results and on its unique mode of action, I am confident that RX-10045 can be an important new treatment."

Full details haven't yet been presented in a peer-reviewed journal, although the results are expected to be presented at the Association for Research in Vision and Ophthalmology

meeting next year, the company says.

For the biostatistical sticklers out there, don't worry, I had a chance to comb through the details with Resolvix's chief operating officer James Nichols. But for those who just want the gist, here goes: Resolvix can't go quite so far as to say this was an absolute grand slam, but the results are certainly good enough to go ahead with final stage clinical trials, estimated to begin in the first half of 2010. It's also enticing enough that Resolvix will now hit the fundraising trail to seek another round from investors, and discuss partnership possibilities with big drugmakers, Nichols says.

So what about the details has gotten Resolvix so excited? The trial looked at patients with moderate dry eye problems, who got either a plain liquid solution eye drop, or one of three different doses of the experimental compound from Resolvix, called RX-10045. They took eye drops twice a day, for 28 days.

Patients who got high doses of the Resolvix drug did better than those who got lower doses, the company said. Improvements were seen as quickly as one week, according to the main measurement of symptoms, which were reported in diaries kept by the patients. Resolvix was also able to show that its drug was better than a placebo in a scientific measurement of how patients corneas appeared in a dry environment, although that difference didn't reach the point of statistical significance. (One reason it may have fallen short, Nichols says: People in the placebo group also improved, because they had some liquid squirted into their eyes, like those in the drug group.)

"This is our first in man study, it's the first study for this drug and the class," Nichols says. "We saw a rapid and dose-dependent symptom control, which to our minds is unprecedented."

Only one competing pharmaceutical is approved by the FDA—Allergan's cyclosporine ophthalmic emulsion (Restasis), Nichols says. That drug takes as long as three months to control dry eye symptoms, according to published literature he cited. Another drug in development from Durham, NC-based Inspire Pharmaceuticals, diquafosol tetrasodium (Prolacria), has shown promise on improving the scientific signs of the disease, but not as much improvement against the symptoms patients care about, Nichols says.

"We think we stack up fairly well," he says.

Some big decisions about what to do next will now have to be made at Resolvix, and someone new will be calling the shots. Paul Rubin stepped down recently as CEO, and the company is initiating a search for a new CEO, Nichols says. Whoever gets that job will be in an unusual position, at a venture-backed biotech company heading soon to the ultimate proving ground in biotech—Phase 3 clinical trials.

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