
Amgen Gets Cell Lines For Testing

Analyst: Roche's EPO Drug Near Match With Aranesp

By Randall Osborne

West Coast Editor

At least in the view of one analyst, court papers filed late last week in the erythropoietin battle between against Amgen Inc. and would-be competitor F. Hoffmann-La Roche Ltd. confirm what many have long believed - that the pharma giant's product candidate called Mircera amounts to pegylated EPO similar enough to Amgen's Aranesp that it's unlikely to win the judicial go-ahead for marketing.

"If the market fully digests this development, we believe [Amgen's] shares could trade up sharply," wrote Bear, Stearns analyst Mark Schoenebaum. The mainstream media reacted excitedly, but Amgen's stock (NASDAQ:AMGN), rose only $1.60 Monday, or 2.2 percent, to close at $75.85.

Patent attorney John ***Iwanicki*** of Banner & Witcoff Ltd. in Boston cautioned against making decisions outside the courtroom, where the conflict continues.

"Amgen wanted Roche's cell lines so they could test them and see what the heck they were making, and they were granted that this morning," ***Iwanicki*** said Monday. "They'll probably do some testing to determine how it operates in the human." ***Iwanicki***'s firm is not involved in the current dispute, but did represent Amgen in an EPO skirmish in the early 1990s with Genetics Institute Inc., of Cambridge, Mass. (See *BioWorld Today*, Aug. 19, 1991.)

In the sharply worded Monday ruling, U.S. District Court Judge William Young in Massachusetts told Roche that "this whole business of filing allegedly confidential documents [with regard to] discovery motions is proving a massive waste of time," and granted Amgen's motion for the cell lines.

Amgen's EPO is Aranesp, the second generation of Epogen (epoetin alfa), both involved in Amgen's lawsuit against Basel, Switzerland-based Roche, which wants to introduce in the U.S. its competing red-blood cell booster, called continuous erythropoiesis receptor activator (CERA), now branded Mircera.

Roche's European EPO product, NeoRecormon (epoetin beta), already is blocked here by Amgen's six patents. Roche has claimed its product for patients with kidney-disease acts differently in the body. (See *BioWorld Today*, Nov. 10, 2005, and Oct. 25, 2006.)

Christopher Raymond with Robert Baird & Co. in New York pointed out in his report that the court paperwork reveals Roche's product is not modified beyond pegylation, nor is it partially chemically synthesized in a way that could differentiate the product from Amgen's.

"We see Amgen as gaining an incremental advantage in this matter," Raymond wrote.

Last month, Brett Holley at CIBC World Markets in New York predicted a "reasonable probability" that Amgen would block Mircera from the market, and even in the worst-case scenario of Roche's launch followed by a price war, Amgen's earnings per share would be "only be marginally reduced."

As far back as October, Joel Sendek at Lazard Capital Markets in New York forecast that Amgen's patent estate would prevent U.S. entry of Roche's anemia drug candidate, especially with a judge he described as "Amgen friendly" hearing the case. "Latest [Mircera] data appear equivalent to EPO and Aranesp at best," Sendek wrote.

And it was three years before the Sendek report that Eric Schmidt, an analyst with Cowen and Co. in New York, called "reports of Aranesp's demise grossly exaggerated," adding that Mircera most likely infringed on intellectual property held by Amgen, which has been "thoroughly tested."

Still, the patents are due to be tested again in the Roche dispute, scheduled for trial in September in the same court where Amgen scored a victory over Cambridge, Mass.-based Transkaryotic Therapies Inc. and Hoechst Marion Roussel Inc. (now Aventis Pharma AG, of Frankfurt, Germany) in a battle over their Dynepo (epoetin delta), a gene-activated EPO that TKT was developing for the U.S. market. (See *BioWorld Today*, Oct. 19, 2004.)

Iwanicki told *BioWorld Today* that "very strong case law encourages folks to design around existing patent claims," as Roche may have tried to do. "It might be the case that you simply can't design around [Amgen's claims], because they are so broad."

Many investors are focusing on Amgen's other efforts, such as the potential $725 million deal at the start of the year with South San Francisco-based Cytokinetics Inc. for small molecules that activate cardiac muscle contractility. Amgen paid $42 million in cash up front, and made a $33 million investment in Cytokinetics, taking an option to participate in future development and commercialization of the program's lead candidate, CK-1827452. (See *BioWorld Today*, Jan. 3, 2006.)

Aranesp itself is undergoing Phase III tests for congestive heart failure. The trials carry "a reasonable probability of success," Holley wrote in a research report earlier this month. He cited the firm's robust pipeline, which represents a "promise not fully reflected" in the stock price.

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