FDA hosts next act in drug feud

B-MS vested in cancer killer

By THERESA AGOVINO
Associated Press

NEW YORK — In an industry better known for sterile lab coats and meticulous science, a messy, soured billion-dollar deal over a potentially promising new cancer drug is playing out more like daytime television.

Representatives of the feuding principals — drug giant Bristol-Myers Squibb Co. and biotech company ImClone Systems Inc. — were meeting yesterday with FDA administrators to discuss the fate of Erbitux, a colorectal cancer drug.

The FDA set off the drama in December by refusing to accept ImClone's application to review the drug.

An avalanche of shareholder lawsuits ensued, alleging that ImClone misled investors, whose shares have lost 75 percent of their value since late November. Three federal investigations were launched — by the Justice Department, the Securities and Exchange Commission and lawmakers — and a very public duel arose between the two companies vested in Erbitux.

Bristol-Myers, which has its drug research center in Lawrence, N.J., and is among the region's largest employers, had paid $1 billion in September for 19.9 percent of ImClone on the strength of what it knew — or thought it knew — about the drug's promise.

Ahead of yesterday's meeting, executives scoured patient records for additional data to shore up the application — hoping to get it back on track.

But few believe ImClone's small, unconventional trial can be salvaged. Neither the FDA, Bristol-Meyers nor ImClone would comment on yesterday's meeting.

Analysts say ImClone will either have to conduct a new trial or use data from studies being conducted by Germany's Merck KGaA, which bought the European rights to Erbitux.

In the meantime, no one expects Bristol-Myers and ImClone to be chummy again.

After the December fireworks, Bristol-Myers tried to restructure the companies' deal. It wanted to temporarily remove the biotech firm's top management, eliminate $800 million in future payments — and get a bigger share of Erbitux profits.

ImClone refused. Bristol-Myers said it would examine its options after the FDA meeting. Insiders, meanwhile, say Bristol-Myers chairman Peter Dolan and ImClone chief executive Samuel Waksal haven't spoken in weeks.

The two companies were an odd match from the start.

Bristol-Myers has its headquarters on posh Park Avenue, ImClone in funky SoHo.

Dolan is a suburban father of three who married his high school sweetheart. Waksal has partied with Mick Jagger, started a restaurant with Mariel Hemingway and dates celebrities. He has accepted loans from ImClone, been sued for not paying bills and had troubles with the Internal Revenue Service.

Waksal's brother Harlan, ImClone's chief operating officer, was convicted of cocaine possession after police found cocaine in his carry-on bag in Fort Lauderdale International Airport in 1981.

The ruling was eventually thrown out, Harlan served no time and the case wasn't retried.

Analysts say Erbitux's launch would probably be delayed until 2004 — if the Merck trial data were used. If another trial is required, Erbitux probably wouldn't hit the market until 2005.

Experts don't expect Bristol-Myers to abandon ship. It has already written off $735 million of its investment and will only look foolish if it severs ties to ImClone and Erbi-

See IMCLONE, C2

IMCLONE

Continued from Page C1

tux succeeds.

"I don't think Bristol will walk away," said Michael Wood, an analyst at Lehman Brothers. "It is not going to cost them anything to wait it out."

Banc of America Securities Analyst Len Yaffe thinks ImClone needs Bristol-Myers' expertise in the cancer market to sell Erbitux, especially since competing products are expected in the next few years.

No matter what the outcome, the imbroglio has disheartened thousands of cancer patients while casting unfavorable attention on the biotech industry just as its boosters herald a new era of smarter drugs made possible by the deciphering of the human genome.

Erbitux had been widely hailed as a major advance in the fight against cancer because it targets diseased cells while leaving healthy ones alone. Doctors believe it could be useful in fighting several different types of cancer.

Erbitux was given a priority review at the FDA, a fast track reserved for breakthrough therapies.

Some analysts thought such a high-profile drug would almost ensure very close contact between the FDA and ImClone during the trial process so they were surprised by the rejection.

Clearly, there was miscommunication along the way.

Erbitux was tested in patients with advanced colon cancer who had not responded to a chemotherapy drug called irinotecan. The patients were given Erbitux along with irinotecan and, the company reported, tumors shrank in 27 of 120 patients, or 22.5 percent.

ImClone has said the FDA's main concern was that the company's application was missing the documentation to prove that the patients in the trial really had failed to respond to irinotecan alone. If irinotecan had been working in those patients, then the tumor shrinkage in the clinical trial might have been due to irinotecan.

The FDA, in its rejection of ImClone's application, raised several other issues. For example, the agency said that for 15 of the patients whose tumors reportedly shrank, two radiologists who reviewed the data differed in their conclusions.

"The FDA can say contradictory things and there is nothing a company can do," said Jim McCamant, a consulting analyst at Moors & Cabot, a San Francisco-based brokerage firm.

Others insist the FDA is just an easy target when promising drugs either fail to live up to expectations or are delayed because of corporate errors.

The New York Times contributed to this report.