



Antegren: Hype Or Hyperdrug

Biogen's much-ballyhooed MS fighter is getting positive signals from the FDA

MULTIPLE SCLEROSIS sufferers have not benefited from a new type of drug for more than a decade. That may change by Nov. 26, when the Food & Drug Administration is expected to decide whether to approve Antegren, a dramatically different treatment for the chronic disease. The drug was co-developed by Biogen Idec Inc. of Cambridge, Mass., and Ireland's Elan Pharmaceuticals Inc.

Expectations are running high for Antegren, particularly on Wall St. Biogen Idec's stock is up 57% since January, to about \$57 in mid-October, while Elan has soared from \$5 to \$24. Although most of the gains came early in the year, glowing analysts' reports in recent weeks have also fueled rumors that Biogen might buy its partner. Morgan Stanley sees annual sales surpassing \$2 billion by 2008, while market researchers Decision Resources Inc. says Antegren "will radically alter the multiple sclerosis market."

Will Antegren live up to the hype?

Plenty of biotech drugs have generated outside expectations only to fizzle. And Antegren faces challenges, not least whether insurers will pay the drug's projected \$20,000 annual cost, nearly double that of current treatments.

What's more, doctors don't know if the drug works better than existing treatments. In an unusual move, Biogen and Elan decided not to release data from two large clinical trials until after the FDA rules. Although the drug did show promising results in a mid-stage trial, that study lasted only six months and involved a small number of patients. "We don't know anything about the long-term safety of the drug, or how it compares with existing therapies," cautions Stephen C. Reingold, research head of the National Multiple Sclerosis Society.

The FDA has sent positive signals,

ADELMAN So far, Biogen's research head says, the FDA likes what it sees

though, granting Antegren a rapid review last May after looking at one-year results from the Phase III clinical trials, designed to run two years. Biogen says it wants to hold off releasing that interim data so as not to prejudice the final outcomes of the trials, due to end early next year. But Dr. Burt A. Adelman, head of research and development for Biogen, says the FDA typically doesn't like to base approvals on interim data. "They said these results were very striking."

MISSING EVIDENCE

ANTEGREN ALSO seems promising because it is the first drug designed to block the out-of-control immune cells that cause MS. These cells attack the coating that surrounds and protects nerve fibers. Over time, nerve cells are destroyed, and patients experience symptoms ranging from fatigue and blurred vision to poor muscle control and speech impairment. A patient can go weeks, months, or years without a relapse, but about 50% of sufferers end up progressing to permanent disability.

The most common treatments, led by Biogen's own Avonex, are based on interferon, an inflammation-fighting protein a patient self-injects with a needle daily or weekly. The interferons fight inflammation and reduce relapses, but they haven't been very effective in delaying progres-

sion of the disease, and they can cause debilitating flulike symptoms. By contrast, Antegren, a targeted antibody that blocks immune cells from reaching the nerve fibers, appears to have few serious side effects. It is given intravenously just once a month. Data from the mid-stage trial indicated that Antegren reduces inflammation and relapses better than interferon.

But so far no evidence exists that Antegren can

slow the progression of MS. That's what doctors want, says Dr. John R. Richert, head of the immunology department at Georgetown University Medical Center in Washington: "The most important information is whether it [delays] disability progression. If it doesn't, I don't really care what it does to [inflammation] or the relapse rate." Given the side effects of interferon, however, patients may beg to differ. ■

—By Catherine Arnst in New York

THE STAT

\$2
BILLION

Projected Antegren sales by 2008, 30% of the multiple sclerosis drug market

Data: Morgan Stanley