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Serono Purchases Rights To Experimental MS Drug

By Carey SargentDow Jones Newswires

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GENEVA -- Serono SA, Europe's biggest biotechnology company, said it has bought from Ivax Corp. rights to an experimental drug to treat multiple sclerosis, with the aim of developing the first multiple-sclerosis treatment that can be taken orally.

Currently, MS drugs have to be injected, because the active protein in them is destroyed in the digestive system.

Under the terms of the deal, Serono will make a series of undisclosed milestone payments to the U.S. company and get royalties on sales of the product, Cladribine, if it makes it to market.

"Formulating Cladribine for oral use looks less daunting than doing it with other compounds; there's nothing about the drug to suggest it can't be administered orally," said Leon Bushara, Serono's head of business development.

Still, the project is risky. The drug's development is in the early stages, and there is no sign that oral formulations of MS drugs work. Also, an injectable version of the drug has made an abortive bid for approval by the U.S. Food and Drug Administration before.

The drug previously won FDA approval for use against hairy-cell leukemia in 1993 and is still on the market as Leustatin. The company developing the drug at the time, Ortho Biotech, a division of Johnson & Johnson **JNJ 0.69% ▲**, also asked the FDA for permission to market the injectable version for use against MS, but withdrew the application.

Mr. Bushara said J&J dropped the project because of the need for more data

concerned about the drug's history. "On the contrary, we've reviewed that data extensively, and that's one of the reasons we think the drug is so promising," he said.

Serono's Rebif for multiple sclerosis posted sales of \$380 million in 2001, while Biogen Inc.'s Avonex, another MS treatment, had sales of \$972 million.

Separately, the FDA slapped Biogen on the wrist for making "misleading claims" about Avonex. The claims, made in brochures and ads intended for doctors, boast that Avonex has the highest rate of satisfaction among patients. But the statement is based on tables that "misrepresent the results of the survey," according to an FDA letter to the company dated Oct. 24.

Biogen said it is talking with the agency about the issue.

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