



GENTA'S GENASENSE CANCER DRUG

Will it be resurrected?

Genta (GNTA) initiated submission of a New Drug Application (NDA) with the FDA for accelerated marketing approval of Genasense™ (oblimersen sodium) injection in **combination with fludarabine plus cyclophosphamide** for the treatment of patients with **chronic lymphocytic leukemia** (CLL) who have previously received fludarabine.

Taking advantage of Genasense Fast Track status, Genta began submitting the NDA on a "rolling" basis as specific sections are completed. Genta has already submitted the initial section, anticipating that the NDA will be **completed within 6 months**.

Genasense has also received designation as an Orphan Drug in CLL, which provides for a period of marketing exclusivity, tax benefits, and exemption from certain fees at the time of NDA submission. Accelerated approval will require the developing firm to conduct a confirmatory study. Genta plans to discuss the design of that study with FDA.

In other news, Genta has filed a formal Letter of Intent with the **European Medicines agency** (EMA) as the initial step for submission of a Marketing Authorization Application (MAA) for Genasense™ for use with dacarbazine (DTIC) for the treatment of patients with **metastatic melanoma** who have not previously received chemotherapy.

Has the drug been resurrected and so has the condemned firm?

When Genasense failed to get enough votes to pass a previous FDA test, most observers and newsletters condemned the drug and the whole antisense technology. Many believed and stated that Genta itself will soon be on its way out of the biotech industry's door. Now it seems that the past setback had less impact on the drug than it had on the firm's scientists. This impact was positive though. It came as an added experience that led the Genta to find the right path for rescuing a drug that was described by one member of the FDA panel as a great drug that can find its way to the market. So the drug has not fallen. What has really fallen was Genta's stock price based on the negative, well intended, but probably, premature, speculation.

What happened since the setback that made the drug reaches another NDA for accelerated approval?
Is there a chance for approval and why, if any?

To know the answer to these questions go back to the Prohost Newsletter May issue page 6 (The Sky's the limit) and examine the reasons behind the increased enthusiasm to the novel biological treatments. Also read the separate comments on Genta's news, which will be posted on the web in the next couple of hours.

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