

**REACHING THE FINISH LINE****IDENIX (IDIX)**

You know by now about Idenix ([IDIX-news](#)) and why we told you about it and what did we say. Time has come for this firm and its partner Novartis Pharmaceuticals to submit to the FDA seeking marketing approval for the 600 mg dose of telbivudine for the treatment of chronic hepatitis B. This NDA is the first marketing approval submission for **telbivudine**, an oral, once-daily **nucleoside analog**. Additional applications for marketing authorization in the European Union (EU) and key Asian markets are expected to be submitted by Novartis Pharma AG (an affiliate of Novartis Pharmaceuticals Corporation) in 1Q 2006.

As you also know, the drug's mode of action differ from the conventional treatments and is expected to do better on the virus. The NDA submission is primarily based on one-year data from the GLOBE study, the largest registration trial for a chronic hepatitis B treatment and the first global trial to include clinical sites and patients in mainland China. The GLOBE study is an ongoing two-year phase 3 clinical trial comparing telbivudine with a standard therapy, lamivudine, in 1,367 adults with chronic hepatitis B from 112 clinical centers in 20 countries worldwide.

READ MORE: [Idenix and Novartis Announce New Drug Application Submitted to the U.S. Food and Drug Administration for Telbivudine for the Treatment of Chronic Hepatitis B](#)

GENTA (GNTA)

Genta ([GNTA-news](#)) has completed a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) that seeks **approval of Genasense®** (oblimersen concentrate for solution for injection) **in combination with chemotherapy** for the treatment of patients with advanced malignant melanoma. Genasense

READ DETAILS: [Genta Completes Marketing Authorization Application to EMA for Approval of Genasense\(R\) plus Chemotherapy for Patients with Advanced Melanoma](#)

On December 29, Genta announced the completion of the filing of a New Drug Application (NDA) to the FDA for Genasense®. The application proposes the use of **Genasense plus fludarabine** and **cyclophosphamide** as treatment for patients with relapsed or refractory **chronic lymphocytic leukemia (CLL)**. The NDA was submitted pursuant to FDA's "Fast Track" and "Accelerated Approval" designations -- programs that are designed to expedite review of drugs that address important unmet medical needs.

Assuming this application is designated for Priority Review, an approval action would normally occur within six months from the filing date.

Genasense, inhibits production of Bcl-2, a protein that cancer cells produce to block the effects of chemotherapy-induced programmed cell death. It is a logical conclusion that when the amount of Bcl-2 in cancer cells is reduced, the chemotherapy will not meet the resistance that hinders its killing effect. Genasense developed programs to evaluate Genasense potential to help the anti-cancer treatments work on various forms of hematologic cancers and solid tumors. In addition, Genta has established a Cooperative Research and Development Agreement (CRADA) with the U.S. National Cancer Institute (NCI).

The Bcl-2 protein is found in high levels in most patients with **hematologic cancers** (such as leukemia, lymphoma, and myeloma), and solid tumors (such as melanoma and cancers of the lung, breast, colon and prostate). **High levels of Bcl-2 are believed to be a fundamental cause of the inherent resistance of cancer cells** to being killed by anticancer therapy.



Has Genta made the right choice of cancers and chemotherapies used to kill them this time? This is what we will be following on in the 2006 e-letters and Newsletters.

READ MORE: [Genta Files New Drug Application for FDA Approval of Genasense\(R\) Plus Chemotherapy for Patients with Advanced or Refractory Chronic Lymphocytic Leukemia](#)

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