**FDA Approves First Biologic Treatment for Sepsis**

22.11.2001 - FDA today approved the first biologic treatment for the most serious forms of sepsis, a life-threatening illness caused by severe infection. The new treatment is a genetically engineered version of a naturally occurring human protein, Activated Protein C, which interferes with some of the body's harmful responses to severe infection, including the formation of blood clots that can lead to organ failure and death. Eli Lilly and Co., Indianapolis, Ind., will market the product as Xigris.

"Xigris is a new treatment that helps to save the lives of patients with the most severe forms of sepsis" said FDA's Acting Principal Deputy Commissioner Bernard A. Schwetz, D.V.M., Ph.D. "While not everyone will benefit from this treatment, we believe the approval of Xigris is an important advance for the treatment of this often deadly disease."

Of about 750,000 people who get sepsis in the U.S. each year, an estimated 30% will die from it, despite treatment with intravenous antibiotics and supportive care. Patients with severe sepsis often experience failures of various systems in the body, including the circulatory system, as well as kidney failure, bleeding, and clotting.

Xigris was approved by FDA for the treatment of adult patients with severe sepsis who have an especially high risk of dying from sepsis, as measured by a scoring system based on their general health and the severity of their illness.

In a placebo-controlled, multi-center, randomized clinical trial of nearly 1700 patients, the overall mortality rate was reduced by 6% (from 31% to 25%) during the 28 day study period of the trial. Although treatment with Xigris did not lower mortality rates in patients in the study who were less severely ill, among patients at higher risk of dying, the group for whom Xigris is now indicated, mortality was reduced 13 percent (from 44% to 31%).

Because Activated Protein C interferes with blood clotting, the most serious side effect associated with Xigris therapy is bleeding, including bleeding that causes stroke. During the period of time when the drug was infused (continuously over four days), serious bleeding episodes occurred in 2.4% of patients treated with Xigris compared to 1% of patients in the placebo group. Patients at high risk of bleeding were excluded from the trial, as were severely ill patients with pre-existing conditions not related to sepsis that made them likely to die within the study period.

Xigris is contraindicated -- should not be used -- for patients who have active internal bleeding, or who are more likely to bleed because of certain medical conditions including recent strokes, recent head or spinal surgery or severe head trauma.

Because sepsis is a life-threatening condition and because treatment with Xigris comes with potentially serious risks, the benefits and risks of treatment with
Xigris must be carefully weighed for each individual patient.