

New Drug Under Review For Fighting Severe Sepsis—The “Grim Reaper Of The ICU” Ⓜ

(NAPS)—When a 19-year-old student called her college health center complaining of flu-like symptoms, no one could have predicted that nearly 24 hours later she would be in the emergency room, weak and disoriented, with kidney and lung failure, large purple blotches over her body, and bloated beyond recognition. Although she received adequate antibiotics to treat the underlying infection that started this cascade towards death, her condition continued to worsen, and the otherwise healthy young woman was diagnosed with severe sepsis—a deadly condition for which there was no specific treatment.

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Sepsis strikes hard and takes lives quickly. It begins with a bacterial, viral, or fungal infection. The body's normal reaction to fight the infection goes into overdrive, setting off a cascade of events that can lead to abnormal inflammation and clotting in the blood vessels, causing multiple organs to fail and ultimately resulting in death. Every year, sepsis strikes nearly 750,000 Americans, at least 225,000 of whom die. And its incidence is on the rise. Yet despite these staggering statistics, little is really known about why it affects the people it does.

Typically, doctors treat these patients with antibiotics to fight the underlying infection, and provide supportive care, such as mechanical ventilation and kidney dialysis, to help keep them alive as their organs fail. But none of these measures specifically treats sepsis. That is why this syndrome

remains the leading killer in non-coronary intensive care units, taking more lives than stroke, breast cancer, and lung cancer combined.

“Sepsis is the grim reaper of the ICU—three of every ten people die within a month using the current standard of care,” said Gordon Bernard, M.D., Associate Director of the Division of Allergy, Pulmonary and Critical Care Medicine, Vanderbilt University Medical Center. “Without an available therapy to specifically treat sepsis, many patients have little hope for a fighting chance of survival.”

The Relentless Search for a Treatment

Since 1979, the number of people with sepsis has increased more than 91 percent. But medical research has failed in this time to produce an answer to address this growing problem. More than twenty experimental drugs have been examined in clinical trials involving nearly 20,000 patients—none of which has proven to effectively reduce the large number of deaths associated with severe sepsis (sepsis with organ failure).

During the last twenty years, Eli Lilly and Company has been hard at work trying to solve the sepsis crisis. Its research has led to a new experimental compound known as Xigris™ (drotrecogin alfa [activated]). One of the most complex biotech products ever commercially produced, Xigris is a recombinant form of the body's own Activated Protein C.

Lilly is seeking regulatory approval for Xigris in the United States and other countries.

“If Xigris is approved, it will be the first treatment specifically indicated for severe sepsis, finally offering thousands of patients a chance to fight this horrifying killer,” Dr. Bernard said.