

FIRST LUPUS DRUG IN HALF CENTURY APPROVED



Today there is «cautions optimism» on new drugs for lupus.

For more than 50 years, the autoimmune disease **lupus** has confounded drug developers. But a new therapy finally broke through that barrier when the US Food and Drug Administration (FDA), the US Agency for drugs regulation, announced the approval of a new therapy for the treatment of systemic lupus erythematosus.

Lupus is a mysterious disease in which the immune system attacks healthy tissues. Nearly all lupus patients experience some degree of joint pain, and some will face serious

complications including kidney failure, heart problems and difficulty in breathing.

The approved therapy is an antibody that interferes with the immune system's assault by binding to and inhibiting a protein called the *B-lymphocyte stimulator* (BLyS). Blocking BLyS is thought to cause the immune system's antibody-producing B cells to self-destruct, thereby reducing the body's ability to attack its own tissues.

BLyS was discovered in the middle of the genomics revolution of the late 1990s. Some researchers see the success of the new drug as evidence that the often-criticized investments that many pharmaceutical companies made in genomics are beginning to pay off.

Drug developers had long struggled to conduct clinical trials in lupus patients. The disease is notoriously variable, with some patients experiencing only mild discomfort and other life-threatening complications. And lupus patients often take two or more drugs to control their disease. These other medications can mask the

effects of an experimental drug in a clinical trial.

In 2008, a trial of a drug, which binds both BLyS and a related protein, in patients with a severe form of lupus, was stopped as a result of an abnormally large number of infections in those taking the drug. Some say this effect may have been brought about by the combination of the experimental drugs with those already used by the patients that also suppressed the immune system.

Those failures have not stopped progress on other BLyS-targeting drugs in early clinical development, and some companies are pushing forward with therapies that target other proteins in the immune system.

[Adapted from «First lupus drug in half a century approved» by Heidi Ledford, *NatureNews* (March 10, 2011).]

Answer the following questions.

- What is lupus erythematosus?
- Why have researchers always struggled to conduct clinical trials in lupus patients?

