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FDA panel recommends first lupus drug in 50 years

November 17 2010

An advisory panel for the US Food and Drug Administration recommended a new drug treatment Tuesday for lupus that if approved would be the first for the disease in over 50 years.

An FDA spokeswoman said the committee voted 13-2 in favor of Benlysta, an experimental drug therapy developed by pharmaceutical companies Human Genome Sciences and GlaxoSmithKline.

The full FDA must next consider whether to approve the drug for the market, likely in December. Typically, the agency follows the advisory panel's recommendations.

"It is possible that BENLYSTA could receive regulatory approval in the United States before the end of 2010," Human Genome Sciences said on its website, noting that the FDA was scheduled to take up the matter on December 9.

There have been no new treatments in the last several decades for lupus, a disease in which the body's immune system attacks its own organs and tissues and is most often seen in women of child-bearing age.

Symptoms can include fever, swollen joints, skin rashes and severe damage of the kidneys, lungs or central nervous system.

"We are pleased to share the exciting news that Benlysta has cleared a significant hurdle on its path to becoming the first FDA-approved

medication for lupus in 52 years," said Sandra Raymond, president of the Lupus Foundation of America.

"Each person with lupus is unique, and if Benlysta is approved, it would be a significant and necessary first step toward creating the full arsenal of treatments that lupus requires."

Of the 1.5 million people diagnosed with lupus in the United States, five percent have a life-threatening form of the disease that is resistant to standard treatment.

Five million people worldwide have the disease. Blacks and Asians tend to get a more severe form of lupus than whites.

According to FDA briefing documents made public on the agency's website ahead of the advisory panel meeting, the research to date has offered conflicting results regarding the drug's effects on African-Americans.

"The low numbers of black patients... and divergent results make it difficult to draw definitive conclusions about this subgroup," it said, adding that future studies would aim to "enroll greater numbers of black patients."

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