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New 'biologic' drug may help severe asthma

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(HealthDay)—A "biologic" drug in development to treat severe asthma reduces the rate of serious attacks by about two-thirds compared to a placebo drug, according to preliminary research findings.

If approved, the drug, tezepelumab, could join a group of costly medications that appear to offer relief when nothing else curbs respiratory distress.

"A new era has begun in which many new drugs are being developed for patients with severe asthma," said Dr. Elisabeth Bel, a professor of respiratory medicine at the University of Amsterdam in the Netherlands.

"Similar to what has happened for rheumatoid arthritis, I expect that in a few years effective treatments will be available for almost all patients with severe asthma," said Bel, author of a commentary accompanying the new study.

The new research was funded by the drug's developers, Amgen and MedImmune, a subsidiary of AstraZeneca.

Asthma is a chronic lung disease. Bel said an estimated 15 percent of asthma patients can't control the disease with current inhaled medications.

"They have severe disease with persistent airway inflammation, which causes continuous symptoms of breathlessness and exercise intolerance," Bel said. This also puts them at risk of severe attacks for which they have to be hospitalized, she added.

Tezepelumab, an injectable drug, is a monoclonal antibody—a term that refers to how it's made.

Drugs in this category help many patients with severe asthma, but not all of them, Bel said. That's because the disease comes in different types, she explained.

The new study represents the second of three phases of research required

before a drug can be approved in the United States. Researchers wanted to understand tezepelumab's effects on asthma patients who'd suffered at least one asthma attack that required hospitalization within the past year, or two attacks that forced physicians to increase their medication level.

The 584 study patients with severe asthma were nonsmokers, aged 18 to 75, who used asthma inhalers. They were randomly divided into low-dose, medium-dose or high-dose groups, or assigned to take a sham ("placebo") drug.

The researchers found that those on the drug had 61 percent to 71 percent fewer asthma attacks that required a hospital visit or change in medication dose than those who took a placebo.

Study co-author Dr. Rene van der Merwe said, "Tezepelumab also demonstrated improvements in lung function at all doses, in asthma control at the two higher doses, and in quality of life across all treatment groups relative to placebo." She's a researcher with MedImmune.

The study "did not reveal any unexpected safety concerns," said van der Merwe. Between 62 percent and 66 percent of the patients in the various groups reported side effects, and between 9 percent and 12 percent reported serious side effects.

The researchers reported two cases of serious side effects—stroke and pneumonia in one patient, and Guillain-Barre syndrome in another. The patient with stroke and pneumonia died.

Bel said patients with severe asthma suffer greatly. "They have very poor quality of life and have much difficulty in functioning and cannot go to work," she said.

"Many of them have to take oral corticosteroids—prednisone—on a

daily basis and suffer from the serious side effects. And these patients are at risk of severe asthma attacks, admission to the intensive care unit and death," she added.

In her commentary, she writes that "tezepelumab appears to be the broadest and most promising biologic for the treatment of persistent uncontrolled asthma to date."

The drug blocks a molecule that's key to the development of swelling in the airway, Bel said, "and is therefore effective in different subtypes of asthma."

As a result, "the chances that the drug will work in severe asthma patients are higher than with the existing monoclonals that are more selective for a specific subtype of patients," she said.

Van der Merwe said it's too early to estimate how much the drug may cost. A spokesperson for AstraZeneca also refused to discuss cost.

However, similar biologic asthma drugs cost $25,000 to $30,000 a year.

The study is published in the Sept. 7 issue of *The New England Journal of Medicine*.

More information: Elisabeth Bel, M.D., Ph.D., professor, respiratory medicine, University of Amsterdam, the Netherlands; Rene van der Merwe, MBChB, senior director, clinical development, respiratory and inflammation, MedImmune; Sept. 7, 2017, *New England Journal of Medicine*

For more about asthma, see the U.S. National Heart, Lung, and Blood Institute.