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Antibody treatment efficacious in psoriasis

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An experimental, biologic treatment, brodalumab, achieved 100 percent reduction in psoriasis symptoms in twice as many patients as a second, commonly used treatment, according to the results of a multicenter clinical trial led by Mount Sinai researchers and published online today in the *New England Journal of Medicine*.

The study drug, brodalumab, is a monoclonal antibody, akin to proteins built by the human immune system to recognize and block specific target molecules. A therapeutic antibody, brodalumab was designed to block the function of the immune signaling protein interleukin 17 (IL-17). If not blocked, IL-17 docks into specifically shaped proteins, IL-17 receptors, to pass on signals that contribute to abnormal, psoriatic inflammation.

"Brodalumab is the only IL-17 receptor antagonist in clinical development," said Mark Lebwohl, MD, Sol and Clara Kest Professor and Chairman of the Kimberly and Eric J. Waldman Department of Dermatology, Icahn School of Medicine at Mount Sinai. "Studies demonstrate that brodalumab binds to the IL-17 receptor, thus preventing IL-17 and its partner molecules or ligands from doing so, to counter inflammatory diseases. When it comes to complete clearing, our results are better than any previously published and confirm that targeting the IL-17 receptor is highly effective in the treatment of moderate to severe plaque psoriasis. Treatment was so effective that many patients did not have a dot of psoriasis left on their bodies."

Plaque psoriasis is a non-contagious chronic disease in which the

immune system causes skin cells to grow at an accelerated rate. Instead of being shed, skin cells pile up, causing painful, scaly patches that can crack and bleed on the scalp, knees, elbows, and lower back. The lifelong disease affects two to three percent of the global population and can have a significant negative impact on health-related quality of life.

The main measure of success in the newly published Phase III clinical studies was the degree of reduction in the Psoriasis Area Severity Index or (PASI), which scores psoriatic plaque redness, scaling and thickness of psoriatic skin lesions and the extent of the body involved. Treatment efficacy is often measured by the reduction of PASI from the baseline (i.e., a 100 percent reduction is known as PASI 100).

After 12 weeks, 44 percent of patients randomized to receive the greater 210-mg every-other-week dosage of brodalumab in one study had achieved PASI 100, compared with 22 percent of patients treated with ustekinumab (Stelara), a treatment that blocks related inflammatory signaling chemicals or cytokines (IL-12 and IL-23). In the second study, 37 percent of patients randomized to receive the greater 210-mg every-other-week dosage of brodalumab achieved PASI 100, compared with 19 percent of patients treated with Stelara. Also, with the greater dosage of brodalumab, 86 percent of patients achieved PASI 75, a 75 percent reduction in symptoms.

Stelara is already approved the U.S. Food and Drug Administration (FDA) and is widely used for the treatment of psoriasis. The results of the current studies will be relevant when the FDA considers the application for brodalumab.

During the past two decades, new data on the physiopathology of psoriasis has opened the doors to novel therapeutic treatments such as Il-17 inhibitors, a new class of drugs in clinical studies for the treatment of the disease. Earlier systemic therapies and medications used to treat

the disease were not as targeted at blocking the IL-17 receptor and therefore affected larger portions of the immune system.

Overall, the frequencies of the most common adverse events in the new studies were similar between brodalumab treatment and placebo. These events were generally mild to moderate and included upper respiratory tract infection, headache, joint pain, low white blood cell count, inflammation of the mucous membranes, and yeast infection. In addition, two patients of the 3,712 (0.05%) enrolled in the published clinical studies committed suicide (one brodalumab patient in the 52-week controlled period and one in the open-label extension of the present studies during which all patients received brodalumab). Independent of therapy, psoriasis patients are at increased risks for depression, anxiety, and suicidal ideation. No causality between brodalumab and these events has been established.

Provided by The Mount Sinai Hospital

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