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SAFE, EFFECTIVE PILL FOR MS.
COULD RESULT FROM DALLAS RESEARCH

DALLAS -- A safe, effective oral medication to treat multiple sclerosis could be on the horizon.

Dr. Staley A. Brod, assistant professor of neurology at The University of Texas Southwestern Medical Center at Dallas, reports promising results from laboratory research on oral interferon-alpha.

"It's not a magic bullet, but it is the next step," he told the American Academy of Neurology annual meeting in New York this week.

An FDA advisory panel recently recommended approval of a similar drug, interferon-beta, which is given by injection. Both interferon-alpha and interferon-beta are known as Type-1 interferons.

"Giving a Type-1 interferon orally appears to be safe and even more effective than injected interferon-beta in animals with experimental autoimmune encephalitis, an animal model for MS," said Brod. "If you got some response from injected interferon-beta, you may get more response from oral interferon-alpha."

Brod's work with oral interferon-alpha as a potential treatment for MS breaks exciting new ground. "Drugs that we did not know would be effective <u>are</u> effective by mouth, and even more effective when given by mouth compared to injection," Brod said.

Interferon-alpha and -beta are cytokines, proteins produced by the immune system. Brod likens them to hormones, proteins produced by one cell that act on other cells at a distance.

MS is an auto-immune disease in which immune-system cells known as pathogenic T-cells may attack and destroy the myelin sheath -- a coating that insulates and protects the body's own nerve fibers. Lab and clinical studies have shown that Type-1 interferons reduce the immune response, and researchers reasoned that the controlling

(More)

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action of the Type-1 interferons could be helpful.

In three years of clinical trials in 11 medical centers, every-other-day injection of interferon-beta was found to reduce the frequency and severity of acute MS attacks.

But Brod's group is the first to try administering a cytokine orally.

"Cytokines are protein, and no one gave protein by mouth because everyone knows that protein gets digested," he said. "You eat a steak, and it gets digested. But you ingest interferon, and it doesn't -- at least not totally."

Not totally digested before it can act, as researchers before Brod assumed it would be, the orally administered interferon-alpha packs a bigger wallop than its injected cousin. That's because the immune response to proteins is suppressed naturally in the digestive system, to prevent protein consumed as food from provoking an immune system attack.

"Up to now, treatments for MS have been relatively toxic and haven't been administered until late in the progression of the disease," said Brod. "We think oral interferon-alpha will be safe enough to administer early, decrease relapses and hopefully prevent progression."

Since oral interferon-alpha has proven successful in research with mice and rats, Brod and his research group hope to begin human clinical trials at UT Southwestern later this year.

Brod's research has been supported in part by a grant from the National Multiple Sclerosis Society and by a Distinguished Young Researcher award from the UT Southwestern President's Research Council.

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