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Program Overview
Learning Objectives
 Upon successful completion of this educational program, the reader should be able to:
 1. Discuss the results of this study
 2. Review the relevance and significance of the study in the broader context of clinical care

Disclosures
Michael Smith and **Robert Jasmer, MD; Associate Clinical Professor of Medicine, University of California, San Francisco**, have disclosed that they have no relevant financial relationships or conflicts of interest with commercial interests related directly or indirectly to this educational activity.

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ACAAI: New Anti-Inflammatory Molecule Safe

By Michael Smith, North American Correspondent, MedPage Today
 Published: November 09, 2009
 Reviewed by **Robert Jasmer, MD**; Associate Clinical Professor of Medicine, University of California, San Francisco.

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MIAMI BEACH -- In its first clinical test, a novel anti-inflammatory molecule targeting asthma and other conditions appears to be safe, even at relatively high doses, a researcher said here.

The safety profile for the compound, dubbed FX125L, "couldn't be better," said Philippe Wiesel, MD, of Funxional Therapeutics of Cambridge, England.

"There was no safety signal at all," Wiesel said after his oral presentation at the annual meeting of the American College of Allergy, Asthma & Immunology.

The compound is a broad-spectrum chemokine receptor inhibitor, taken orally, that targets a single receptor whose identity is still under wraps, Wiesel said.

But he said the receptor is only expressed on a subset of leukocytes and only when inflammation is occurring, which should lead to very precise effects.

Both in the laboratory and in animal studies, the drug blocked the migration of inflammatory cells, he said.

In the first safety and pharmacokinetic test of the drug in healthy volunteers -- a randomized, placebo-controlled dose-ranging study -- there were likewise no surprises, Wiesel said.

With doses ranging from 0.03 to 3,000 milligrams, there were no serious adverse events, withdrawals, or dose-limiting toxicities, he said. Sixteen of the 66 volunteers reported a total of 30 adverse events, 18 of them in the active arm.

The most common event was headache, Wiesel said, followed by dizziness and nausea. Only three moderately severe events were reported and there were no significant changes in laboratory parameters.

Perhaps most important, Wiesel said, is that adverse events were not dose-dependent.

The half-life of the drug is about 25 hours, which lends itself to daily dosing, he said. Between 60.4% and 77.9% of the drug was excreted unchanged, he added.

The manufacturers are currently planning a series of Phase 1 studies that will test the drug in various diseases, including asthma, rheumatoid arthritis, and diabetic neuropathy.

"It's hard to know what home the product will find on the market," Wiesel said.

As an anti-inflammatory, the drug may well have benefits for asthma, according to Gailen Marshall, MD, PhD, of the University of Mississippi Medical Center in Jackson, Miss. Marshall, editor-in-chief of *Annals of Allergy, Asthma, and Immunology*, who was not involved in the research.

But because FX125L is an oral medication, it has systemic effects that create risks, as do the widely used steroids, he said.

"People are still looking for the anti-inflammatory that is a steroid equivalent but spares the side effects of steroids," Marshall said.

It's too early to say if this compound had that property, he said, but since it has a novel method of action, it might be useful in combination with other anti-inflammatories.

Marshall said the early presentation -- after just the first clinical tests -- was part of a policy aimed at keeping doctors aware of the drug pipeline. "We try to get new molecules out where our practitioners can hear about them sooner rather than later," he said.

Action Points

- Note that this novel molecule is hoped to have powerful anti-inflammatory effects, without some of the side effects seen with steroids.
- Caution that this report concerns the first use of the molecule in humans and more research is needed.
- Note that this study was published as an abstract and presented at a conference. These data and conclusions should be considered preliminary until published in a peer-reviewed journal.

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The study was supported by Funxional Therapeutics. Wiesel reported financial links with the company.

Marshall had no disclosures.

Primary source: Annals of Allergy, Asthma, and Immunology

Source reference:

Wiesel P, et al "First clinical experience with FX125L, an anti-inflammatory oral small molecule with an entirely novel mechanism of action" *Ann Allergy Asthma Immunol* 2009; 103(5): Supp 2; Abstract 5.

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