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June 29th, 2011

Vancouver BC, Canada

Anticipated New Gout Medication Unlikely to Win FDA Approval

Gout sufferers awaiting the approval of Novartis' highly anticipated new gout medication Ilaris are likely in for disappointment. An FDA Advisory Committee recommended against approving the gout medication this week, citing concerns about the shortness of the clinical trials (12 weeks) and unanswered questions about possible long-term side effects.

Ilaris (generic name canakinumab) is an injectable anti-inflammatory drug currently approved to treat a rare inflammatory disorder. Ilaris injections exceeded researchers' expectations as a gouty arthritis pain reliever in two clinical trials, relieving pain more than an existing gout drug, the corticosteroid triamcinolone, and reducing the occurrence of flare ups.

"Our findings indicate that canakinumab 150 mg provides rapid and sustained pain relief in patients with acute gouty arthritis, and significantly reduces the risk of recurrent flares compared with triamcinolone acttonide," Swiss researchers enthused in a 2010 issue of *Arthritis & Rheumatism* after conducting Novartis supported research.

But the anti-inflammatory gout medication was also linked to twice as many potentially serious side effects than triamcinolone (7% compared to 3%). As well, serious infections developed in two study participants taking Ilaris, versus no infections in the group taking the older anti-inflammatory. The gout drug also elevated levels of uric acid and some forms of cholesterol. Ilaris was not tested in older patients or in people with renal failure.

The panel was not satisfied that the benefits of the proposed gout medication outweighed the risks. As Ilaris suppresses the immune system, the panel worried about the risk of infection in patients using it long term. Their decision was complicated by the fact that the effects of a single injection are long-lasting, making them more difficult to measure.

The FDA is not bound by panel recommendations, but usually makes their final decisions based on them. Nobody will be more disappointed than Novartis should the new gout medicine fail to win approval, as they have been anticipating huge sales from both gout and rheumatoid arthritis sufferers. Novartis estimated that 300,000 gout sufferers alone might make the switch from their current gout medications.

The manufacturer will now likely have to satisfy the FDA that the gout drug is safe for long-term use, possibly at a lower dose. "We continue to believe in the benefits of [Ilaris] for this painful and debilitating disease, and will work closely with the FDA to identify the right patient population who will benefit from this therapy," Novartis wrote in a press release, adding they "remain committed to addressing the needs of people with gouty arthritis."

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