Revolutionary New Treatment for Sciatica Advances in the Clinic

Chronic and severe sciatica causes widespread disability, and represents a significant unmet medical need. Localized administration of etanercept, a unique anti-inflammatory therapeutic, represents a revolutionary new approach for reducing nerve root inflammation. This off-label treatment method, invented by a Los Angeles physician, Edward Tobinick MD, has increasing scientific support, including new data from randomized, placebo-controlled studies.

Los Angeles, California (PRWEB) October 27, 2009 -- Favorable new data from Japan regarding the efficacy of local administration of the unique anti-inflammatory therapeutic, etanercept, for treatment of sciatica was presented at the just concluded American College of Rheumatology Annual meeting in Philadelphia(1). Chemical inflammation of spinal nerve roots is a major factor in sciatic pain. Chronic and severe sciatica causes widespread disability, and represents a significant unmet medical need. The new data from Japan joins an increasing body of scientific evidence suggesting the efficacy of localized administration of etanercept for this indication.

The Japanese study was conducted by Kume et. al. in Hiroshima, utilizing a form of local perispinal ("around the spine") administration called caudal epidural injection. Local perispinal and epidural administration of etanercept for treatment of sciatica was invented by Edward Tobinick MD, Director of the Institute for Neurological Research® (INR®), a private medical group, inc. in Los Angeles, nearly a decade ago(2). Dr. Tobinick published the first results of perispinal etanercept for sciatica and related forms of intervertebral disc-related pain in 2003, with further publications in 2004 and 2009(3,4,5). The new placebo-controlled data from Kume et. al. joins favorable published data from multiple academic centers around the world, including a recently concluded randomized, double-blind, placebo-controlled study conducted at Walter Reed Army Medical Center(6).

Etanercept works by neutralizing excess TNF, an immune molecule which initiates and amplifies the inflammatory response, and which also regulates communication between nerve cells. Etanercept is one of the top selling therapeutics in the world, with annual world-wide sales exceeding $6 billion. It is FDA-approved for treating psoriasis and several forms of arthritis. For these conditions it is used systemically. Local administration of etanercept for treating sciatica is a novel, patented(2), off-label(7) treatment method which has been used for intractable sciatica at the INR for more than eight years. Recent studies by UCSD researchers provide scientific support for the local methods of administration of etanercept for treating sciatica and neuropathic pain which Dr. Tobinick invented, and cite his original publications(8,9).The Walter Reed Army Medical Center is currently conducting a head-to-head, randomized, double-blind, placebo-controlled study of epidural etanercept vs. epidural corticosteroids.

Chronic, severe sciatica, and related forms of disc-related pain, such as intractable back and neck pain, cause severe disability and economic harm. Improved forms of treatment are urgently needed. Local administration of etanercept could provide a much needed new treatment option for this patient population if these results are confirmed by additional studies, and may have the potential to reduce healthcare expenditures and reduce disability.

References

1. Kume, K., et al., The efficacy and safety of caudal epidural injection with the TNF-antagonist, adalimumab

2. U.S. patents 6015557;6419944;6537549;6982089; and additional pending patents.


7. Off-label use of drugs by physicians is legal and a widespread practice, which may contribute to patient care and to the discovery of new uses of existing drugs. Drug manufacturers, however, are not permitted to promote off-label uses to the public. For example, Amgen and Wyeth, the U.S. manufacturers of etanercept, have been sued for alleged off-label promotion of Enbrel®, their brand of etanercept(U.S. District Court for Massachusetts, Civil Action No. 06-10972WGY). Allergan has recently initiated a lawsuit against the FDA seeking to invalidate the FDA's prohibition on truthful off-label promotion by pharmaceutical manufacturers.


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