FDA's Hold on NGF Inhibitors Won't End Soon

BY MARY ELLEN SCHNEIDER

FROM A RHEUMATOLOGY MEETING SPONSORED BY NEW YORK UNIVERSITY

NEW YORK – Researchers will likely have to wait for months before they find out if they can continue studies on the use of nerve growth factor inhibitors in treating osteoarthritis pain, said Dr. Nancy E. Lane, Endowed Professor of Medicine and Rheumatology at the University of California, Davis, in Sacramento.

Over the past year, the Food and Drug Administration has put on clinical hold nearly all programs for nerve growth factor inhibitor (anti-NGF) development, particularly those related to treating knee pain in osteoarthritis. The agency requested that pharmaceutical manufacturers halt their trials because of reports that study subjects taking the drugs had developed rapidly progressive hip and knee osteoarthritis requiring total joint replacement. A few of those patients also were reported to have had osteonecrosis. The fate of those studies could be determined later this year, when the FDA meets with the pharmaceutical companies involved in developing NGF inhibitors to discuss the issue, she said.

Dr. Lane, who was an investigator for Pfizer's anti-NGF drug tanezumab, said the drug makers developing these compounds have been studying the possible causes of the adverse effects. The question remains whether the disease progression was due to reduced pain and increased activity, or if the inhibition of NGF compromised blood flow to the bone, resulting in osteonecrosis, she said. Regardless of whether the anti-NGF trials continue, Dr. Lane said understanding the NGF receptor TrkA and how to inhibit it may "bear fruit in the long term." ■