FDA Panel: Qutenza Pain Patch for Neuropathy Not Ready for Approval

February 10, 2012

A U.S. Food and Drug Administration advisory committee voted unanimously against recommending the approval of a novel patch applied to the soles of the feet to remedy pain associated with neuropathy in people living with HIV. Though the patch is commercially available for the treatment of shingles-related neuropathy pain, the FDA's Anesthetic and Analgesic Drug Products Advisory Committee's review of two clinical trials of the Qutenza capsaicin patch involving HIV-positive volunteers did not find "substantial evidence of effectiveness."

Based on the data submitted by the drug's manufacturer, San Mateo, California–based NeurogesX, the advisory committee also concluded that the benefits of Qutenza patch applications did not necessary outweigh the risks of treatment and therefore it was not acceptable for an approval.

Though the FDA is not required to follow the guidance of its independent advisory committees, it usually does so. In a pre-advisory committee briefing document, released February 7, the agency's division of anesthesia, analgesia and addiction products expressed reservations about approving Qutenza. "It would not be in the best interest of these patients for us to approve a product for which substantial evidence of efficacy has not been demonstrated, or one for which the benefits do not clearly outweigh the risks," the document reads.

"We will continue to work closely with the FDA to address the advisory committee's comments as the Agency finalizes its review of our [application]," said Ronald Martell, president of NeurogesX, in a brief announcement released by the company. "We remain confident that Qutenza has the potential to address significant, unmet medical needs and to improve the quality of life for patients with HIV-[associated peripheral neuropathy]."

In light of the conflicting data from the two studies reviewed by the FDA, advisory committee members suggested that a third study be conducted to either confirm or refute Qutenza's efficacy. It is not clear whether NeurogesX can commit to such a study.

The FDA has until March 7, 2012, to determine whether or not to expand Qutenza's approved usages to include HIV-associated peripheral neuropathy. Though people suffering from HIV-associated peripheral neuropathy may still be able to access the patch "off label," many public and private health insurance plans require FDA approval supporting specific use of a drug in their coverage determinations.

The Qutenza patch—it contains 8 percent capsaicin, a high concentration of the chemical that gives chili peppers their pungency—was approved in the United States in November 2009 for the treatment of neuropathic pain associated with postherpetic neuralgia, and it has been approved in the European Union for the treatment of peripheral neuropathic pain in nondiabetic adults.

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