HIV Neuropathy Pain Patch Reaches for FDA Approval

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An application supporting approval for a skin patch containing the chili pepper–derived chemical capsaicin to manage HIV-associated neuropathy pain has been submitted to the U.S. Food and Drug Administration, according to a news release from NeurogesX, a pharmaceutical company based in San Mateo, California.

The patch, called Qutenza, is already approved by the FDA for managing nerve pain associated with shingles outbreaks, and it is also available in Europe for the treatment of pain related to diabetic neuropathy.

Chili peppers and mustards have been used for centuries in topical balms to treat chronic pain. Only during the past few decades, however, have scientists figured out how capsaicin—the chemical that gives chilies their pungency—works as an analgesic: It depletes a neurochemical called substance P responsible for transmitting pain.

NeurogesX has spent several years testing capsaicin in skin patches to treat a variety of chronic pain conditions. Qutenza is a skin patch made up of a gel containing 8 percent capsaicin.

The application submitted to the FDA calls for Qutenza to be applied for 30 minutes in a single application to help manage the pain stemming from HIV-associated peripheral neuropathy.

Data in support of NeurogesX's application included the pooled results from two clinical trials, originally presented in March at the annual meeting of the American Academy of Pain Management. Analyzed together, both studies showed that Qutenza relieved HIV-related neuropathy pain by about a third.

The studies compared 239 people who received a single application of Qutenza with 99 people who received a single application of a control patch containing only 0.04 percent capsaicin.

The researchers found that those receiving Qutenza had a 27 percent decrease in their neuropathy pain compared with a 15.7 percent decrease in those who received the control patch. The improvement was highly statistically significant, meaning that the difference between Qutenza and the control was too large to have occurred by chance.

What’s more, when the researchers looked at those who received a higher degree of pain relief—a 30 percent or more reduction in pain scores—36 percent of those on Qutenza saw this higher level of relief compared with 22 percent on the active control.

According to NeurogesX president and CEO Anthony DiTonno, who is quoted in the news release, an approval “would be particularly meaningful as the treatment of [HIV-associated peripheral neuropathy] represents a significant unmet medical need in the HIV community. Currently, no FDA approved drugs are available to treat this complication.”
