FDA News Release

FDA approves new medication for dry eye disease

For Immediate Release

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Release

The U.S. Food and Drug Administration approved Xiidra (lifitegrast ophthalmic solution) for the treatment of signs and symptoms of dry eye disease, on Monday, July 11, 2016. Xiidra is the first medication in a new class of drugs, called lymphocyte function-associated antigen 1 (LFA-1) antagonist, approved by the FDA for dry eye disease.

“Normal tear production is needed for clear vision and eye health,” said Edward Cox, M.D., director of the Office of Antimicrobial Products in the FDA’s Center for Drug Evaluation and Research. “This approval will provide a new treatment option for patients with dry eye disease.”

Dry eye disease includes a group of conditions in which the eye does not produce an adequate volume of tears or when the tears are not of the correct consistency. The chance of experiencing dry eye increases with age, affecting approximately five percent of the adult population age 30-40 and 10 to 15 percent of adults over age 65, and is more common among women. When severe and left untreated, this condition can lead to pain, ulcers or scars on the part of the eye called the cornea. Dry eye can make it more difficult to perform some activities, such as using a computer or reading for an extended period of time, and it can decrease tolerance for dry environments, such as the air inside an airplane.

The safety and efficacy of Xiidra was assessed in over a thousand patients, in four separate, randomized, controlled studies. These studies included patients 19–97 years of age, of which the majority were female (76 percent). Patients were randomized equally to receive either Xiidra eyedrops or placebo eyedrops, which were used twice a day for twelve weeks. The studies found that groups treated with Xiidra demonstrated more improvement in both the signs and the symptoms of eye dryness than the groups treated with placebo.

The most common side effects of Xiidra include eye irritation, discomfort or blurred vision and an unusual taste sensation (dysgeusia).

Dry eye disease does not routinely occur in children. Safety and efficacy in pediatric patients below the age of 17 years has not been studied.

Xiidra is manufactured by Shire US Inc., of Lexington, Massachusetts.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency is also responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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