



Akorn Receives FDA Approval for Loteprednol Etabonate Ophthalmic Gel, 0.5%

LAKE FOREST, Ill., Feb. 11, 2021 /PRNewswire/ -- Akorn Operating Company LLC (Akorn), a leading specialty pharmaceutical company, announced that it received approval of its Abbreviated New Drug Application (ANDA) from the U.S. Food and Drug Administration (FDA) for Loteprednol Etabonate Ophthalmic Gel, 0.5%.

Douglas Boothe, Akorn's President and Chief Executive Officer, stated, "We are excited to launch yet another first-to-market generic of a complex ophthalmic. This approval comes in just over 12 months from submission to the FDA and is the result of strong collaboration among Akorn's research and development, operations, quality, and regulatory teams."

According to IQVIA, U.S. sales of Loteprednol Etabonate Ophthalmic Gel, 0.5% were approximately \$35 million for the twelve months ended December 2020.

Loteprednol Etabonate Ophthalmic Gel, 0.5% is indicated for the treatment of post-operative inflammation and pain following ocular surgery.

About Akorn

Akorn develops, manufactures and markets specialty pharmaceuticals, including prescription, consumer health and animal health products. As an industry leader in branded and generic products in alternate dosage forms such as ophthalmics, injectables, oral liquids, otics, topicals, inhalants and nasal sprays, we focus each day on our mission to improve lives, through the quality, availability and affordability of our products. Additional information is available on Akorn's website at www.akorn.com.

Cautionary Note Regarding Forward-Looking Statements

This press release includes statements that may constitute "forward-looking statements," including those regarding the Company's long-term business plan and outlook. A number of important factors could cause actual results of the Company and its subsidiaries to differ materially from those indicated by such forward-looking statements and readers should not place undue reliance on the Company's forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this release. The Company undertakes no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

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