



Akorn Receives FDA Approval for Fluticasone Propionate Nasal Spray USP, 50 mcg per spray (OTC)

April 18, 2019

LAKE FOREST, Ill., April 18, 2019 (GLOBE NEWSWIRE) -- Akorn, Inc. (Nasdaq: AKRX), a leading specialty generic pharmaceutical company, today announced that it received a new Abbreviated New Drug Application (ANDA) approval from the U.S. Food and Drug Administration (FDA) for Fluticasone Propionate Nasal Spray USP, 50 mcg per spray (OTC).

Douglas Boothe, Akorn's President and Chief Executive Officer, stated, "We are excited to add to our Fluticasone franchise and look forward to expanding into the over-the-counter (OTC) market. Among other private label possibilities, we have a supply agreement in place for Fluticare® through Innovus Pharmaceuticals, Inc. (OTCQB Venture Market: INNV)."

Fluticasone propionate nasal spray USP, 50 mcg per spray is indicated for the temporary relief of hay fever and other upper respiratory allergies in adult and pediatric patients 4 years of age and older.

Fluticare® is a registered trademark of Innovus Pharmaceuticals, Inc.

About Akorn

Akorn, Inc. is a specialty generic pharmaceutical company engaged in the development, manufacture and marketing of multisource and branded pharmaceuticals. Akorn has manufacturing facilities located in Decatur, Illinois; Somerset, New Jersey; Amityville, New York; Hettlingen, Switzerland and Paonta Sahib, India that manufacture ophthalmic, injectable and specialty sterile and non-sterile pharmaceuticals. 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 expectations and other statements regarding Akorn's expansion into the OTC market and other goals and plans. When used in this document, the words "will," "expect," "continue," "scheduled," "plans," "intend," and similar expressions are generally intended to identify forward-looking statements. These statements are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. A number of important factors could cause actual results of Akorn and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to: (i) the effect of the Delaware court's recent decision against Akorn on Akorn's ability to retain and hire key personnel, its ability to maintain relationships with its customers, suppliers and others with whom it does business, or its operating results and business generally, (ii) the risk that ongoing or future litigation related to the court's decision may result in significant costs of defense, indemnification and/or liability, (iii) the outcome of the investigation conducted by Akorn with the assistance of outside consultants, into alleged breaches of FDA data integrity requirements relating to product development at Akorn and any actions taken by Akorn, third parties or the FDA as a result of such investigations, (iv) the difficulty of predicting the timing or outcome of product development efforts, including FDA and other regulatory agency approvals and actions, if any, (v) the timing and success of product launches, (vi) difficulties or delays in manufacturing, and (vii) such other risks and uncertainties outlined in the risk factors detailed in Part I, Item 1A, "Risk Factors," of Akorn's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (as filed with the Securities and Exchange Commission ("SEC") on March 1, 2019), and other risk factors identified from time to time in our filings with the SEC. Readers should carefully review these risk factors, and should not place undue reliance on our forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this report. Akorn 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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