Teligent, Inc. Announces FDA Approval of Fluocinonide Gel, 0.05%

June 20, 2018

BUENA, N.J., June 20, 2018 (GLOBE NEWSWIRE) -- Teligent, Inc. (NASDAQ:TLGT), a New Jersey-based specialty generic pharmaceutical company, today announced it has received approval of the Company's abbreviated new drug application (ANDA) from the U.S. Food and Drug Administration (FDA) of Fluocinonide Gel, 0.05%. This is Teligent's sixth approval for 2018, and its twenty-fifth approval from its internally-developed pipeline of topical generic pharmaceutical medicines.

Based on recent IQVIA data from April 2018, the total addressable market for this product is approximately $6.2 million.

"Fluocinonide Gel, 0.05% is Teligent's sixth FDA approval in 2018," commented Jason Grenfell-Gardner, President and CEO of the Company. "This is yet another demonstration of Teligent's ability to successfully develop products internally and to get those products successfully through the approval process. We are planning to launch this product in the third quarter of 2018."

Mr. Grenfell-Gardner continued, "We now have thirty topical generic pharmaceutical products in the US portfolio, in addition to our four US injectable products."

About Teligent, Inc.

Teligent is a specialty generic pharmaceutical company. Our mission is to be a leading player in the specialty generic prescription drug market. Learn more on our website www.teligent.com.

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Forward-Looking Statements

This press release includes certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, plans, objectives, expectations and intentions, and other statements contained in this press release that are not historical facts and statements identified by words such as "plan," "believe," "continue," "should" or words of similar meaning. Factors that could cause actual results to differ materially from these expectations include, but are not limited to: our inability to meet current or future regulatory requirements in connection with existing or future ANDAs; our inability to achieve profitability; our failure to obtain FDA approvals as anticipated; our inability to execute and implement our business plan and strategy; the potential lack of market acceptance of our products; our inability to protect our intellectual property rights; changes in global political, economic, business, competitive, market and regulatory factors; and our inability to complete successfully future product acquisitions. These statements are based on our current beliefs or expectations and are inherently subject to various risks and uncertainties, including those set forth under the caption "Risk Factors" in Teligent, Inc.'s most recent Annual Report on Form 10-K, Quarterly Reports on Form 10-Q and other periodic reports we file with the Securities and Exchange Commission. Teligent, Inc. does not undertake any obligation to update any forward-looking statements contained in this document as a result of new information, future events or otherwise, except as required by law.

Primary Logo

Source: Teligent, Inc.