



Teligent, Inc. Announces FDA Approval of Fluocinonide Cream USP, 0.1%

April 4, 2019

BUENA, N.J., April 04, 2019 (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 Cream USP, 0.1%. This is Teligent's fourth approval of 2019, and its thirty-sixth approval from its internally-developed pipeline of topical generic pharmaceutical medicines.

Based on recent IQVIA data from February 2019, the total addressable market for this product is approximately \$17.3 million.

"Teligent continues to deliver on the promise of our pipeline with this latest approval," commented Jason Grenfell-Gardner, President and CEO of the Company. "This was a first review cycle approval and was received ten months from filing. The filing contained paragraph IV certifications, however no action for infringement was brought against Teligent within the statutory 45-day period and therefore we plan to launch this product in the third quarter of 2019."

Mr. Grenfell-Gardner continued, "We now have forty 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.

Contact:

Damian Finio
Teligent, Inc.
856-336-9117
www.teligent.com

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.



Source: Teligent, Inc.