Teligent, Inc. Announces FDA Request for Further Data on Complex Drug

December 23, 2019

BUENA, N.J., Dec. 23, 2019 (GLOBE NEWSWIRE) -- Teligent, Inc. (NASDAQ: TLGT), a New Jersey-based specialty generic pharmaceutical company, today announced its development partner has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) for its abbreviated new drug application (ANDA) for its first complex drug indicated for an orphan disease population. In the letter, the FDA requested further information and raw data to support the ANDA.

"This latest response from the FDA is unexpected given the time and opportunity that the FDA had to request the information during the ANDA's active review. Our development partner has assured us that they have the available data and the ability to respond to the FDA's request expeditiously. We and our development partner will be in active communication with the FDA to ensure that this delay of a critical drug for patients is as short as possible," commented Jason Grenfell-Gardner. President and CEO of the Company.

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.

Source: Teligent, Inc.