Teligent Announces First Injectable Filing From New Manufacturing Facility

October 28, 2019

BUENA, N.J., Oct. 28, 2019 (GLOBE NEWSWIRE) -- Teligent, Inc. (NASDAQ: TLGT), a New Jersey-based specialty generic pharmaceutical company, today announced that it has filed a prior approval supplement (PAS) for ranitidine hydrochloride injection. This is the planned first injectable product to be manufactured out of the newly completed expansion of its manufacturing site in Buena, NJ. As this is the first injectable filing related to the new expansion, the PAS review will be subject to a pre-approval inspection (PAI) of the manufacturing site by the FDA, which the Company expects to occur within four months of the date of the filing.

Since the FDA's announcement on September 13, 2019, alerting patients and health care professionals that certain ranitidine products may contain unsafe levels of the chemical NDMA, the Company has taken precautionary measure of performing additional tests and added necessary controls to confirm that its product is within FDA approved safe ranges for NDMA.

"This is a big step forward in terms of realizing our long-term business plan," said CEO Jason Grenfell-Gardner. "The filing of the PAS marks the culmination of years of cross functional effort, and I want to offer my sincere gratitude and congratulations to the employees of Teligent who have helped to make this possible. Teligent has put considerable resources into preparing for the PAI and we look forward to bringing our first internally manufactured injectable product to the market."

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.