Collegium Announces Authorized Generic Agreement with Hikma Pharmaceuticals USA Inc. for Nucynta® and Nucynta® ER

April 29, 2024

STOUGHTON, Mass., April 29, 2024 (GLOBE NEWSWIRE) -- Collegium Pharmaceutical, Inc. (Nasdaq: COLL), a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions, today announced it has entered into an authorized generic agreement with Hikma Pharmaceuticals USA Inc. (“Hikma”), pursuant to which Hikma will have the exclusive right to sell the authorized generic versions of Nucynta® and Nucynta® ER (“the Nucynta Franchise”) in the United States.

“Our agreement with Hikma bolsters the value of the Nucynta Franchise through 2025 and beyond,” said Joe Ciaffoni, President and Chief Executive Officer of Collegium. “Collegium is pleased to work with Hikma, an industry leader, to ensure that these important products continue to be manufactured to the highest quality standards and remain broadly and consistently accessible to appropriate patients.”

Under the terms of the agreement:

- Collegium will manufacture and supply Hikma with all authorized generic product for sale on an exclusive basis during the term of the agreement.
- Hikma will sell the authorized generic forms of the Nucynta Franchise in the United States, commencing 30 days prior to the anticipated loss of exclusivity for each product, or earlier under certain circumstances.
- Collegium will receive a meaningful share of net profits of the authorized generic products, that declines based on the number of generic entrants, if any.

About Collegium Pharmaceutical, Inc.

Collegium is a leading, diversified specialty pharmaceutical company committed to improving the lives of people living with serious medical conditions. Collegium’s headquarters are located in Stoughton, Massachusetts. For more information, please visit the Company’s website at www.collegiumpharma.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "forecasts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "should" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Examples of forward-looking statements contained in this press release include, among others, statements related to current and future market opportunities for our products and our assumptions related thereto, expectations (financial or otherwise) and intentions, and other statements that are not historical facts. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results, performance, or achievements to differ materially from the company's current expectations, including risks relating to, among others: unknown liabilities; risks related to future opportunities and plans for our products, including uncertainty of the expected financial performance of such products; our ability to commercialize and grow sales of our products; our ability to manage our relationships with licensors; the success of competing products that are or become available; our ability to maintain regulatory approval of our products, and any related restrictions, limitations, and/or warnings in the label of our products; the size of the markets for our products, and our ability to service those markets; our ability to obtain reimbursement and third-party payor contracts for our products; the rate and degree of market acceptance of our products; the costs of commercialization activities, including marketing, sales and distribution; changing market conditions for our products; the outcome of any patent infringement or other litigation that may be brought by or against us; the outcome of any governmental investigation related to our business; our ability to secure adequate supplies of active pharmaceutical ingredient for each of our products and manufacture adequate supplies of commercially saleable inventory; our ability to obtain funding for our operations and business development; regulatory developments in the U.S.; our expectations regarding our ability to obtain and maintain sufficient intellectual property protection for our products; our ability to comply with stringent U.S. and foreign government regulation in the manufacture of pharmaceutical products, including U.S. Drug Enforcement Agency, or DEA, compliance; our customer concentration; and the accuracy of our estimates regarding expenses, revenue, capital requirements and need for additional financing. These and other risks are described under the heading "Risk Factors" in our Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q and other filings with the SEC. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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