



Evolus Announces Progress with DWP-450 Regulatory Submissions

May 16, 2018

FDA Issues Favorable EIR Letter Related to Manufacturing Facility

Evolus Receives FDA Complete Response Letter with Comments Isolated to CMC Items

Conference Call Scheduled for 8:30am ET / 5:30am PT

IRVINE, Calif., May 16, 2018 (GLOBE NEWSWIRE) -- Evolus, Inc. (NASDAQ:EOLS) ("Evolus"), a lifestyle aesthetics company focused on delivering advanced aesthetic procedures and treatments to physicians and consumers, today announced updates related to the regulatory progress of its pending Biologics License Application ("BLA") for DWP-450 (prabotulinumtoxinA) to the U.S. Food and Drug Administration ("FDA").

The FDA issued an Establishment Inspection Report ("EIR") to Daewoong Pharmaceutical Co. Ltd. ("Daewoong") confirming the favorable completion of its pre-approval inspection of Daewoong's manufacturing facility in South Korea which was purpose built for production of DWP-450.

The DWP-450 manufacturing facility is fully validated by Daewoong under current good manufacturing practice ("cGMP") requirements, and has capacity expected to meet anticipated product demand. Evolus plans to utilize the Daewoong facility to support commercial production following the anticipated approval of DWP-450.

Additionally, the FDA has issued a Complete Response Letter ("CRL") to Evolus related to its BLA for DWP-450 for the treatment of glabellar lines, also known as frown lines, in adult patients.

In the CRL, deficiencies cited by the FDA were isolated to items related to Chemistry, Manufacturing, and Controls ("CMC") processes. No deficiencies were related to clinical or non-clinical matters. Evolus expects to respond with a complete submission to FDA within 90 days.

Mr. Moatazedi, President and Chief Executive Officer of Evolus, commented, "The successful completion of the FDA inspection of the manufacturing facility and issuance of the EIR represents a key operational milestone and entirely concludes the pre-approval inspection process by the FDA."

Mr. Moatazedi continued, "We are pleased with the progress we continue to make with the FDA, and this CRL confirms our confidence in our clinical submission. Deficiencies cited within the CRL are isolated to CMC matters and we expect to respond comprehensively within 90 days. Overall, we view these updates as positive, which together give us the line of sight necessary to build our commercial infrastructure. We look forward to working closely with the FDA and remain committed to bringing DWP-450 to market by spring 2019."

Mr. Moatazedi concluded, "We appreciate our continued relationship with Daewoong and the work of our entire team as we continue to advance our BLA submission towards expected approval."

Company to Host Conference Call

Evolus will host a conference call related to these regulatory updates today, Wednesday, May 16, 2018, at 8:30 a.m. ET/ 5:30 a.m. PT. A question and answer session will follow management remarks.

The dial-in numbers are (866) 916-2317 for domestic callers and (703) 925-2662 for international callers. The conference ID is 6479037.

A replay of the call will be available following its completion through May 23, 2018 at 8:30 p.m. PT/11:30 p.m. ET. To access the replay, dial (855) 859-2056 for domestic callers and (404) 537-3406 for international callers and use the replay conference ID 6479037.

A live audio webcast of the call will be available on the Investor Relations page of the Evolus, Inc. website, investors.evolus.com. A replay of the webcast will be archived on Evolus' website for 30 days following the completion of the call.

About the Pre-Approval Inspection

The FDA conducts inspections of establishments that manufacture, process, pack, or hold FDA-regulated products before approving products and/or after products are on the market, to determine the establishment's compliance with laws administered by FDA. If objectionable conditions are observed, the FDA provides the owner of the establishment with a document, called an FDA Form 483. If no enforcement action is contemplated, or after enforcement action is concluded, the FDA provides inspected establishments with a final inspection report, called an Establishment Inspection Report (EIR).

About PrabotulinumtoxinA

PrabotulinumtoxinA is a 900 kilodalton ("kDa") purified botulinum toxin type A complex. The product candidate's BLA is currently under review by the FDA. The product candidate's Marketing Authorization Application is currently also under review by the European Medicines Agency (EMA). The FDA application is for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adults. The EMA application is for temporary improvement in the appearance of moderate to severe vertical lines between the eyebrows seen at maximum frown (glabellar lines), when the severity has an important psychological impact in adult patients.

About Evolus, Inc.

Evolus is a lifestyle aesthetics company dedicated to bringing advanced aesthetic procedures and treatments to physicians and consumers. Evolus focuses on the self-pay aesthetic market and its lead product candidate DWP-450 (prabotulinumtoxinA neuromodulator), an injectable 900 kDa purified botulinum toxin type A complex.

Forward-Looking Statements

Statements made in this press release that relate to future plans, events, prospects or performance are forward-looking statements as defined under the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, are statements that could be deemed forward-looking statements, including statements containing the words "planned," "expect," "believes," "strategy," "opportunity," "anticipates," "outlook," "designed," and similar words. Examples of forward looking statements include expectations that Daewoong's facility will meet anticipated product demand, Evolus' expectation to make a complete submission to the FDA within 90 days, and Evolus' intention to bring DWP-450 to market by spring 2019. While these forward-looking statements are based on the current expectations and beliefs of management, such forward-looking statements are subject to a number of risks, uncertainties, assumptions and other factors that could cause actual results to differ materially from the expectations expressed in this press release, including whether Daewoong can continue to comply with cGMP requirements at its manufacturing facility; whether the FDA was to re-inspect the manufacturing facility; our ability to conduct any activities required by the CRL in a timely manner in order to completely respond to the items raised in the CRL issued by the FDA; uncertainties inherent in the drug development process including the regulatory approval process and the FDA's review and comments on any regulatory submission; and the risks and uncertainties disclosed in Evolus' periodic filings with the Securities and Exchange Commission, including factors described in the section entitled "Risk Factors" in its Annual Report on Form 10-K for the year ended December 31, 2017 and its Quarterly Report on Form 10-Q for the Quarter ended March 31, 2018, as filed with the Securities and Exchange Commission on March 29, 2018 and May 10, 2018, respectively, all of which are available online at www.sec.gov. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Except as required by law, Evolus undertakes no obligation to update or revise any forward-looking statements to reflect new information, changed circumstances or unanticipated events.

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