Eagle Pharmaceuticals, Inc. Expands Licensing Agreement for BENDEKA™ with Teva Pharmaceuticals International GmbH

April 15, 2019

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)--Eagle Pharmaceuticals, Inc. (“Eagle” or the “Company”) (Nasdaq: EGRX) today announced that it has expanded its existing BENDEKA™ (bendamustine hydrochloride) licensing agreement with Teva Pharmaceuticals International GmbH (“Teva”). Under the terms of the revised licensing agreement, beginning on October 1, 2019, Eagle’s royalty payment will increase from 25% to 30% of BENDEKA net U.S. sales, provided that BENDEKA’s orphan drug exclusivity has not been rescinded, withdrawn or waived by such date. The royalty rate will increase by one percentage point on each anniversary of October 1, 2019 until it reaches 32%, and it will remain at 32% thereafter.

The revised agreement, effective April 13, 2019, also extends the U.S. BENDEKA royalty term until it is no longer sold in the United States. The previous U.S. royalty term was set to expire in 2025. The extended term recognizes the strength of the bendamustine patents with expiries through 2033, and the value of the product beyond the original ten-year period. As part of the agreement restructuring, Eagle will continue to manufacture BENDEKA for the U.S. market for so long as it is sold in the United States and has agreed to assume a portion of the BENDEKA-related patent litigation expenses.

“We are very pleased to deepen our relationship with Teva by extending and expanding our licensing agreement for BENDEKA. This agreement recognizes the long-term value of the product, which is supported by orphan drug exclusivity through December 7, 2022 and an extensive patent portfolio through 2033. Teva has been a strong commercial partner, and we look forward to exploring additional areas of cooperation,” stated Scott Tarriff, Chief Executive Officer of Eagle.

BENDEKA was granted orphan drug designation by the U.S. Food and Drug Administration (FDA) and is approved for the treatment of patients with chronic lymphocytic leukemia (CLL) and for the treatment of patients with indolent B-cell non-Hodgkin lymphoma (NHL) that has progressed during or within six months of treatment with rituximab or a rituximab-containing regimen.

About Eagle Pharmaceuticals, Inc.

Eagle is a specialty pharmaceutical company focused on developing and commercializing injectable products that address the shortcomings, as identified by physicians, pharmacists and other stakeholders, of existing commercially successful injectable products. Eagle’s strategy is to utilize the FDA's 505(b)(2) regulatory pathway. Additional information is available on the Company’s website at www.eagleus.com.

Forward-Looking Statements

This press release contains forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities laws. Forward-looking statements are statements that are not historical facts. Words and phrases such as “will,” “expected,” “we believe,” “committed,” “plan,” “promise,” “may,” “enables,” “potential,” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events, including: the performance of our marketed products, including BENDEKA; statements regarding the collaboration between Eagle and Teva; statements regarding royalty payments that Teva may be obligated to make in connection with the revised licensing agreement; the ability to maintain BENDEKA’s orphan drug exclusivity; success of Eagle’s commercial relationship with Teva and the parties’ ability to work effectively together; whether Eagle and Teva will successfully perform their respective obligations under the revised licensing agreement and any other agreements in effect between Eagle and Teva; the outcome of any litigation involving BENDEKA or any litigation that may have an impact on BENDEKA or on our relationship with Teva; and the strength and enforceability of our intellectual property rights with respect to BENDEKA. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond Eagle’s control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Such risks include, but are not limited to: the risk that the benefits of the revised license agreement described above are not realized; the continued willingness of Teva to collaborate with Eagle; the risk that the conditions necessary for the increased royalty payments to take effect will not be realized; the outcome of ongoing or future litigation; the risk that Eagle’s orphan drug exclusivity for BENDEKA may be rescinded, withdrawn or waived prior to the expiration of such orphan drug exclusivity; Eagle’s ability to protect its intellectual property; dependence on third parties; other risks inherent to drug development and commercialization; and other risks described in Eagle’s filings with the U.S. Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements that speak only as of the date hereof, and we do not undertake any obligation to revise and disseminate forward-looking statements to reflect events or circumstances after the date hereof, or to reflect the occurrence of or non-occurrence of any events.

Investor Relations for Eagle Pharmaceuticals, Inc.:
Lisa M. Wilson
In-Site Communications, Inc.
T: 212-452-2793
E: lwilson@insitecony.com