

## Eagle Pharmaceuticals' Vasopressin ANDA Accepted for Filing by the FDA

April 16, 2018

Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or "the Company") today announced that it has submitted and the U.S. Food and Drug Administration (FDA) has accepted for filing its abbreviated new drug application (ANDA) for vasopressin injection, 1ml. This product is the generic version of Endo International plc's original Vasostrict <sup>®</sup> formulation, which is indicated to increase blood pressure in adults with vasodilatory shock (e.g., post-cardiotomy or sepsis) who remain hypotensive despite fluids and catecholamines. Vasostrict had approximately \$400 million in brand sales in 2017.

"We are pleased that the FDA has accepted our vasopressin injection formulation for filing. We look forward to the FDA's decision and intend to work closely with them through the review process," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

## 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 <a href="https://www.eagleus.com">www.eagleus.com</a>.

## **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 such as "will," "may,", "believe," "intends," "anticipate(s)," "plan," "enables," "potentially," "entitles," and similar expressions are intended to identify forward-looking statements. These statements include statements regarding future events including, but not limited to: the impact, if any, of Eagle's success in gaining timely FDA approval of the vasopressin product; the timing and level of success of a future launch of the vasopressin product; difficulties or delays in manufacturing; the availability and pricing of third party sourced products and materials; successful compliance with FDA and other governmental regulations applicable to manufacturing facilities, products and/or businesses; the commercial success of Eagle's commercial portfolio, including vasopressin once launched; the ability of Eagle to deliver sustained shareholder value over time; and other factors that are discussed in Eagle's Annual Report on Form 10-K for the year ended December 31, 2017, as filed with the U.S. Securities and Exchange Commission (SEC) on February 26, 2018, and its other filings with the U.S. Securities and Exchange Commission (SEC). 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 whether Eagle's management and/or board of directors will be effective in managing Eagle's business and future growth, as well as the other risks described in Eagle's filings with the SEC. 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.

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