

CMS Establishes Unique J-Code for Eagle Pharmaceuticals' PEMFEXY[™] (Pemetrexed for Injection)

July 9, 2020

--Exclusive launch February 1, 2022 --

-- Approval for 500mg multiple-dose vial from U.S. Food and Drug Administration (FDA) granted June 18, 2020 --

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)--

Eagle Pharmaceuticals, Inc. ("Eagle" or the "Company") (NASDAQ: EGRX) today announced that the Centers for Medicare & Medicaid Services (CMS) has established a unique, product-specific billing code for PEMFEXY[™] (pemetrexed for injection). This new Healthcare Common Procedure Coding System [HCPCS] code, or J-code, is J9304 (Injection, pemetrexed (PEMFEXY), 10 mg). The J-code will become effective on October 1, 2020.

The new HCPCS code provides coding clarity to outpatient facilities and physicians who will administer PEMFEXY, facilitating access for patients and reimbursement from Medicare, Medicaid and commercial insurance.

In February 2020, Eagle received final approval of its New Drug Application (NDA) from FDA for PEMFEXY[™], a branded alternative to ALIMT[®], following settlement of patent litigation with Eli Lilly and Company. The Company is entitled to initial market entry (equivalent to approximately a three-week supply of current ALIMTA[®] utilization) on February 1, 2022, and a subsequent uncapped entry on April 1, 2022.

The Company also received a supplement approval from FDA for a 500mg multiple-dose vial of PEMFEXY on June 18, 2020.

About PEMFEXY

PEMFEXY[™] is a pemetrexed injection ready-to-dilute formulation for locally advanced or metastatic nonsquamous non-small cell lung cancer in combination with cisplatin; locally advanced or metastatic nonsquamous non-small cell lung cancer whose disease has not progressed after four cycles of platinum-based first-line chemotherapy, as maintenance treatment; locally advanced or metastatic nonsquamous non-small cell lung cancer after prior chemotherapy as a single agent; and malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery in combination with cisplatin.

About Eagle Pharmaceuticals, Inc.

Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. Eagle is committed to developing innovative medicines that result in meaningful improvements in patients' lives. Eagle's commercialized products include RYANODEX[®], BENDEKA[®], BELRAPZO[®], and its oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on Eagle's website at www.eagleus.com.

Eagle's Forward-Looking Statements

This press release contains forward-looking information within the meaning of the Private Securities Litigation Reform Act of 1995 including, but not limited to, statements regarding the timeline for effectiveness of the Company's J-code for PEMFEXY; the timing of the Company's PEMFEXY launch, if ever; and the ability of the J-code for PEMFEXY to facilitate access for patients and insurers. Forward-looking statements in this press release should be evaluated together with the many risks and uncertainties that affect the Company's business, particularly those identified in the "Risk Factors" section of the Company's Annual Report on Form 10-K for the year ended December 31, 2019 filed with the Securities and Exchange Commission on March 2, 2020 and its other subsequent filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

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