Eagle Pharmaceuticals on Track to Support Submission of New Drug Application in Second Quarter 2022 for Landiolol, a Beta-1 Adrenergic Blocker

January 31, 2022

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) (“Eagle” or the “Company”) today announced that AOP Orphan Pharmaceuticals GmbH, Member of the AOP Health Group, (“AOP Health”), with whom it entered into a licensing agreement in August 2021, has engaged with the U.S. Food and Drug Administration (“FDA”) to obtain alignment on the content and format of the pre-clinical and clinical data required to support a new drug application (“NDA”) seeking approval of Landiolol, a novel therapeutic, for the short-term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter.

In August 2021, Eagle entered into a licensing agreement with AOP Health, a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to Landiolol in the United States.

“We are pleased to be advancing Landiolol along the regulatory pathway. Landiolol is an important hospital emergency use product, with the potential to become a market leader in this drug class, and would complement our critical care portfolio. Landiolol has never been marketed in the United States, has robust patent protection, and we anticipate five years of new chemical entity exclusivity upon approval. Based on the FDA’s responses to AOP Health’s communications, we remain on track to support the NDA next quarter,” stated Scott Tarriff, President and Chief Executive Officer of Eagle.

Landiolol is a short-acting, ultra-high selective beta-1 adrenoceptor blocker developed by AOP Health that has a selective effect on heart rate over cardiac contractility. Landiolol is available in two forms (20 mg/2ml concentrate, 300 mg powder) and is designed for use in emergency, cardiac critical care, operating room, and intensive care settings. It is registered in several European countries for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. The drug uses a proprietary dosing algorithm to facilitate the administration.

Landiolol is already commercially available in Japan (Onoact®) and several European markets as RAPIBLOC®.

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.

About AOP Health

The brand **AOP Health** incorporates several companies: The international Healthcare Group is the European pioneer for integrated therapies for rare diseases and in critical care. Over the past 25 years, the company has become an established provider of integrated therapy solutions from its headquarters in Vienna, its subsidiaries and representative offices throughout Europe and the Middle East, as well as through partners worldwide. This development has been made possible by a continually high level of investment in research and development on the one hand and a highly consistent and pragmatic orientation towards the needs of all our stakeholders on the other - especially the patients and their families as well as also the doctors and care professionals treating them. More information at www.aop-health.com

Forward-Looking Statements

This press release contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities law. Forward-looking statements are statements that are not historical facts. Words and phrases such as “anticipated,” “forward,” “will,” “would,” “may,” “remain,” “potential,” “prepare,” “expected,” “believe,” “plan,” “near future,” “belief,” “guidance,” and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, the timing of and AOP Orphan’s ability to obtain any regulatory approval of Landiolol; the anticipated benefits of Landiolol and its potential acceptance by clinicians; the timing, progress and results of additional trials of Landiolol and the ability of such trial results to support regulatory filings and approvals; anticipated actions by the FDA; the Company’s ability to support the commercial launch of Landiolol in the United States, if approved; the expected duration of new chemical entity exclusivity; the potential market opportunity for Landiolol; and the ability of the Company’s product candidates, including Landiolol, to deliver value to stockholders. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company’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 and uncertainties include, but are not limited to: the impacts of the ongoing COVID-19 pandemic, including interruptions or other adverse effects on clinical trials and delays in regulatory review or further disruption or delay of any pending or future litigation; delay in or failure to obtain regulatory approval of the Company's product candidates and successful compliance with FDA, European Medicines Agency and other governmental regulations applicable to product approvals; whether the Company can successfully market and commercialize its product candidates; the success of the Company's relationships with its partners; the outcome of litigation involving any of its products or that may have an impact on any of its products; general economic conditions, including the potential adverse effects of public health issues, including the COVID-19 pandemic, on economic activity; the strength and enforceability of the Company’s intellectual property rights or the rights of third parties; the risks inherent in drug development and in conducting clinical trials; and those risks and uncertainties identified in the “Risk Factors” section of the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission (the “SEC”) on March 5, 2021, as updated by the Company’s Quarterly Reports on Form 10-Q for the quarters ended March 31, 2021, June 30, 2021 and September 30, 2021 filed with the SEC on May 10, 2021, August 9, 2021 and November 9, 2021, respectively, and its other subsequent filings with the SEC. 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.

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

Source: Eagle Pharmaceuticals, Inc.