Eagle Pharmaceuticals Announces Licensing Agreement with AOP Orphan for U.S. Commercial Rights to Landiolol, a Beta-1 Adrenergic Blocker

August 9, 2021

-- Eagle poised to facilitate regulatory pathway for approval in the U.S. based on existing data from Japanese and European studies, with no additional clinical work expected –

-- Anticipates filing new drug application ("NDA") in Q1 2022, with expected ten-month review, based on well-defined feedback from U.S. Food and Drug Administration provided during AOP Orphan's Type C meeting --

-- Landiolol, a leading hospital emergency use product, is approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias --

-- Eagle to support seeking the approval of Landiolol for the short-term reduction of ventricular rate in patients with supraventricular tachycardia, including atrial fibrillation and atrial flutter in the U.S. --

-- Studies of additional indications, including sepsis and other cardioprotective indications, have begun in Europe, with the potential to be pursued in the U.S. --

-- Enrollment of study of pediatric patients with supraventricular tachycardia is underway in Europe and will serve as the basis for initial pediatric study plans for a future FDA submission –

-- Company expects five years of new chemical entity exclusivity --

WOODCLIFF LAKE, N.J.--(BUSINESS WIRE)-- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced that it has entered into a licensing agreement with AOP Orphan Pharmaceuticals GmbH ("AOP Orphan"), a privately owned Austrian company devoted to the treatment of rare and special diseases, for the commercial rights to its product, Landiolol in the United States. Landiolol, a leading hospital emergency use product, is currently approved in Europe for the treatment of non-compensatory sinus tachycardia and tachycardic supraventricular arrhythmias. The Company will support the submission of a new drug application ("NDA") to the U.S. Food and Drug Administration ("FDA") seeking approval for Landiolol for the short-term reduction of ventricular rate in patients with supraventricular tachycardia ("SVT"), including atrial fibrillation and atrial flutter.

Landiolol is a short-acting, ultra-high selective beta-1 adrenoceptor blocker developed by AOP Orphan 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.

Under the terms of the agreement, Eagle will facilitate the U.S. regulatory pathway for the approval of Landiolol. In addition, Eagle will be responsible for the U.S. commercialization of the product upon approval. Landiolol, which has not previously been marketed in the U.S., is covered by several patents, and the Company anticipates five years of new chemical entity ("NCE") exclusivity.

Landiolol is already commercially available in Japan (Onoact®) and several European markets as RAPIBLOC®. A review of multiple clinical studies suggests that Landiolol is a useful option for the rapid short-term control of tachyarrhythmias (Syed YY. Landiolol: A Review in Tachyarrhythmias. Drugs. 2018 Mar;78(3):377-388. doi: 10.1007/s40265-018-0883-9. PMID: 29470800.). A Type C meeting was held with FDA in July 2020, at which time AOP Orphan proposed a submission strategy in which it would provide summaries of pre-existing safety and efficacy data and a meta-analysis of published randomized controlled trials. FDA tentatively agreed with this methodological approach and deemed data sets adequate to support a proposed NDA.

"This is an exciting near-term opportunity for Eagle, with the potential to file an NDA in the first quarter of next year. The clinical advantages of Landiolol are well recognized within the medical community, and we look forward to advancing this asset for FDA approval in the United States. Our deep understanding of the U.S. regulatory landscape, along with our established research and development infrastructure, will be valuable in accelerating the program. Once approved, we plan to leverage our current sales force and relationships in the critical care setting to promote the product. There is broad potential to expand the portfolio of future indications for Landiolol's use," stated Scott Tarriff, Chief Executive Officer of Eagle Pharmaceuticals.

"With this license agreement, we are solidifying our hospital and critical care product portfolio, as we look to capitalize on multiple near- and longer-term opportunities. As we have stated, executing on our growth strategy for Eagle beyond 2021 has been a priority. With the anticipated launch of vasopressin, the February 2022 launch of PEMFEXY, the recent launch of bendamustine in Japan, our current pipeline, and now the future potential Landiolol launch, we believe we have a firm foundation for sustained future growth," concluded Tarriff.

"The step into the American market forms the basis for further expansion of AOP Orphan. I am convinced that with an experienced partner like Eagle, we will succeed in making Landiolol available to patients in the U.S. as well," stated Georg Fischer, Chief Executive Officer of AOP Orphan.

The management of rapid heart rate (tachycardia) in critically ill patients can be quite complicated regardless of the underlying cause, which may include shock, arrhythmias, heart failure, and the postoperative setting. Beta blockers, also known as beta-adrenergic blocking agents, are a class of drugs that works by blocking the neurotransmitters norepinephrine and epinephrine from binding to receptors. These neurotransmitters contribute to the development of tachycardia. The β-1 receptor beta blockers are used frequently in critical care settings to manage tachycardia; however, the available β-1 beta blockers in the U.S. also can have the unwanted effects of decreasing the contractility, or muscle strength, of the heart, and of lowering blood pressure.

Landiolol has the potential to become a cornerstone therapy in the management of these patients. It is ultra short acting, with a rapid on and off effect that allows clinicians to balance heart rate control and blood pressure more precisely. In addition, it predominantly affects heart rate without much effect on cardiac contractility and blood pressure. The Company believes that clinicians will welcome Landiolol as a key therapeutic tool for the more precise management of tachycardia in the critical care setting.

There are additional clinical settings for which Landiolol has the potential to improve patient management. Enrollment is under way in Europe for a trial of Landiolol in patients with tachycardia and septic shock, and importantly, the product is also being studied in a pediatric population, for whom no beta-blocker drug products are approved in the U.S. for ventricular rate control. The U.S. FDA has tentatively agreed that this study could form the basis for initial pediatric study plan ("iPSP") for a future submission to FDA.

"We believe that we can expedite and prepare a compelling submission for approval of this important cardioprotective therapeutic," stated Judith Ng-Cashin, MD, Chief Medical Officer of Eagle Pharmaceuticals

Terms of the Agreement

The agreement is subject to regulatory clearance. Under the terms of the agreement, Eagle will make an upfront payment of $5 million, followed by additional payments upon regulatory approval(s) and based upon commercial sales. The agreement is subject to regulatory clearance.

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.

AOP Orphan Pharmaceuticals GmbH is an international pharmaceutical company with its registered office in Vienna and a focus on rare and special diseases. Over the past 25 years, the company has become an established provider of integrated therapy solutions from its headquarters in Vienna. 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 but also the doctors and care professionals treating them. In the third quarter of 2020, AOP Orphan took over Amomed and SciPharm, two European health care companies, continuing its consistent path of growth into a pan-European health care group specializing in rare and special diseases.

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, statements concerning potential regulatory approval of the licensing agreement between the Company and AOP Orphan; the timing of and AOP's ability to obtain any regulatory approval of Landiolol; the Company's ability to maintain regulatory approval of its products and product candidates, including Landiolol and vasopressin; 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 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 timing of commercial launch of vasopressin and PEMFEXY; anticipated future payments from the Company to AOP Orphan; and the ability of the Company's product candidates, including Landiolol, vasopressin and PEMFEXY, 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: delays in or failure to obtain regulatory approval of the license agreement with AOP Orphan; 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 and other governmental regulations applicable to product approvals; whether the Company will successfully implement its development plan for its product candidates; whether the Company can successfully market and commercialize its product candidates; the outcome of litigation involving any of its products or that may have an impact on any of its products; 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 Report on Form 10-Q for the quarter ended March 31, 2021, filed with the SEC on May 10, 2021, 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.

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