Eagle Pharmaceuticals Completes Acquisition of Acacia Pharma Group plc, Expanding Acute Care Footprint

June 9, 2022

- Adds two U.S. Food and Drug Administration ("FDA") approved new chemical entities with strong patent protection
- BARHEMSYS® (amisulpride for injection) and BYFAVO® (remimazolam for injection) join Eagle portfolio, with an estimated combined $3.1 billion per year[1] addressable market and projected annual peak sales of $275[2] million in the U.S.
- Expected to be earnings accretive by 2024

WOODCLIFF LAKE, N.J., June 09, 2022 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced it has completed the acquisition of the entire issued share capital of Acacia Pharma Group plc ("Acacia Pharma") (EURONEXT: ACPH) by way of a scheme of arrangement under Part 26 of the United Kingdom's Companies Act 2006 (the "Transaction").

"The closing of this transaction is a great achievement for Eagle both strategically and financially. The addition of the two products expands our presence in the acute care space, and we believe that our highly capable hospital-based salesforce will have great success commercializing these assets. We believe BARHEMSYS and BYFAVO represent two compelling opportunities, as both address significant unmet clinical needs," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"With the recent launches of vasopressin and PEMFEXY™ and the completion of this transaction, Eagle has gone from three commercial products to eight within a year, with a ninth on the horizon if the new drug application submitted for landiolol last month is approved. The acquisition of Acacia Pharma should not only help improve the care of patients undergoing medical treatments but also solidify our leadership position in the hospital and oncology space and bring long-term value to our shareholders," concluded Tarriff.

Key Highlights

- Strong synergistic fit with Eagle's infrastructure and current and planned portfolio of hospital products;
- Two commercially compelling FDA-approved products:
  - BARHEMSYS® is the first and only antiemetic approved by the FDA for rescue treatment of postoperative nausea and vomiting ("PONV") despite prophylaxis [3]. Eagle currently calls on healthcare providers and institutions representing over 70% of the expected BARHEMSYS addressable market opportunity;
  - BARHEMSYS is also approved for the treatment of PONV in patients who have not received prophylaxis and for the prevention of PONV. The total estimated annual U.S. addressable market for prophylaxis and rescue is $2.7 billion[4];
  - BYFAVO® is indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less, with an estimated total addressable market in procedural sedation of more than $0.4 billion per year in the U.S.[5]
- Opportunity to realize the full potential of BARHEMSYS and BYFAVO by leveraging Eagle's longstanding relationships and highly experienced, hospital-based salesforce;
- The addition of diversified but complementary revenue streams, accelerating Eagle's growth and strengthening its advantage in acute care; and
- Expected to be earnings accretive in 2024.

Product Descriptions BARHEMSYS® (amisulpride for injection)[6] is the first and only FDA-approved product for PONV rescue after failed prophylaxis. It is a selective dopamine D_2 /D_3 antagonist with a broad, differentiated label. PONV is a common complication of surgery, occurring in approximately 30% of all surgical patients and 80% of high-risk patients. PONV is associated with the use of anesthetic gases and opioid painkillers and is particularly common following gynecological, abdominal, breast, eye, and ear operations, especially those lasting an hour or more. PONV can delay hospital discharge; result in re-admission after in-patient procedures; and lead to day-case patients being admitted to the hospital, all of which can result in significantly increased healthcare costs. By reducing these risks, BARHEMSYS® offers the potential for significant economic savings to hospitals and ambulatory centers. There are approximately 70 million invasive surgical procedures where patients receive antiemetic prophylaxis annually in the U.S. Approximately 10 million of these patients per year require PONV rescue treatment. BARHEMSYS is the only drug with an FDA-approved indication to treat patients who have failed PONV prophylaxis. It has an established safety profile and efficacy demonstrated in multiple well-controlled clinical studies. BARHEMSYS® is nonsedating, a common complaint of standard antiemetic agents. Patients experiencing PONV who were treated in a pivotal clinical trial and failed prophylaxis were treated with BARHEMSYS. These patients were observed to have shorter post-anesthesia care (PACU) and hospital stays then patients who were not. Please see Important Safety Information for BARHEMSYS, below.

BYFAVO® (remimazolam for injection)[7] is a rapid onset/offset procedural sedative with an established safety and efficacy profile. Additional benefits

include predictability and a readily available reversal agent. Please see Important Safety Information, including boxed warning, below. BYFAVO has a compelling commercial opportunity, addressing a clear unmet need. There has been no innovation in the sedation space for over 20 years. Customers seek a fast onset, titratability, and rapid recovery for quick discharge, and shorter procedure times allow for increased procedural volumes. BYFAVO has a broad label and potential health economic benefits and may enable shorter procedure times and greater patient throughput. It is indicated for procedural sedation in adults in procedures lasting 30 minutes or less and has a substantial clinical data package demonstrating efficacy and safety in colonoscopies and bronchoscopies, including the most challenging patients.

Advisors

Cooley (UK) LLP acted as legal advisor and William Blair & Company, L.L.C. acted as exclusive financial advisor to Eagle Pharmaceuticals in connection with the transaction. Locust Walk served as a transaction advisor to Eagle Pharmaceuticals. NautaDutilh BV acted as legal advisor to Eagle Pharmaceuticals in connection with Belgian law.

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 vasopressin injection, PEMFEXY™, RYANODEX®, BENDEKA®, BELRAPZO®, TREAKISYM (Japan), 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.

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," "could," "should," "may," "remain," "potential," "prepare," "expected," "believe," "plan," "near future," "belief," "guidance," "estimate," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements regarding future events such as: statements regarding expectations with respect to whether and when the Acacia acquisition may be earnings accretive; expectations with respect to synergies; expectations that the acquisition of Acacia Pharma will help improve the care of patients undergoing medical treatments, solidify the Company's leadership position in the hospital and oncology space and bring long-term value to the Company's shareholders; the estimated addressable market size and estimated sales figures for BARHEMSYS, BYFAVO and other products or product candidates; the Company's marketing, product development, partnering and growth strategy, including relating to the commercialization of BARHEMSYS and BYFAVO and the Company's ability to expand the application of BARHEMSYS and BYFAVO; the timing, scope or likelihood and timing of regulatory filings and approvals from the FDA for the Company's product candidates, including landiolol; the ability of BARHEMSYS, BYFAVO, landiolol and other products and product candidates to address unmet clinical needs; the potential market opportunity for the Company's products or product candidates, including for BARHEMSYS, BYFAVO and landiolol; expectations regarding expansion of the Company's product portfolio, including potential acquisitions; the ability of the Company's executive team to execute on the Company's strategy and build stockholder value; the ability of Eagle's hospital-based sales force to commercialize BARHEMSYS and BYFAVO; expectations regarding the Company's future growth; and the ability of the Company's product candidates 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 risk that the anticipated benefits of the Company's recently completed transaction with Acacia Pharma are not realized; the impacts of the COVID-19 pandemic and geopolitical events such as the conflict in Ukraine, including disruption or impact in the sales of the Company's marketed products, interruptions or other adverse effects to clinical trials, delays in regulatory review, manufacturing and supply chain interruptions, adverse effects on healthcare systems, disruption in the operations of the Company's third party partners and disruption of the global economy, and the overall impact of the COVID-19 pandemic or other events on the Company's business, financial condition and results of operations; whether the Company will incur unforeseen expenses or liabilities or other market factors; whether the Company will successfully implement its development plan for its product candidates; delay in or failure to obtain regulatory approval of the Company's or its partners' product candidates; whether the Company can successfully market and commercialize its products or product candidates; the success of the Company's relationships with its partners; the availability and pricing of third party sourced products and materials; the outcome of litigation involving any of its products or that may have an impact on any of the Company's products; successful compliance with the FDA and other governmental regulations applicable to product approvals, manufacturing facilities, products and/or businesses; general economic conditions, including the potential adverse effects of public health issues, including the COVID-19 pandemic and geopolitical events, on economic activity and the performance of the financial markets generally; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; competition from other pharmaceutical and biotechnology companies and the potential for competition from generic entrants into the market; the risks inherent in the early stages of drug development and in conducting clinical trials; and factors in addition to the foregoing that may impact the Company's financial projects and guidance, including among other things, any potential business development transactions, acquisitions, restructurings or legal settlements, in addition to any unanticipated factors, that may cause the Company's actual results and outcomes to materially differ from its projections and guidance; and those risks and uncertainties identified in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission (the "SEC") on March 8, 2022 and its other subsequent filings with the SEC, including the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, which the Company filed with the SEC on May 9, 2022. Readers are cautioned not to place undue reliance on these forward-looking statements. 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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Important Safety Information for BARHEMSYS® (amisulpride) Injection

Contraindication

BARHEMSYS is contraindicated in patients with known hypersensitivity to amisulpride.

QT Prolongation

BARHEMSYS causes dose- and concentration-dependent prolongation of the QT interval. The recommended dosage is 5 mg or 10 mg as a single intravenous (IV) dose infused over 1 to 2 minutes.

Avoid BARHEMSYS in patients with congenital long QT syndrome and in patients taking droperidol.

Electrocardiogram (ECG) monitoring is recommended in patients with pre-existing arrhythmias/cardiac conduction disorders, electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, and in patients taking other medicinal products (e.g., ondansetron) or with other medical conditions known to prolong the QT interval.

Adverse Reactions

Common adverse reactions reported in ≥ 2% of adult patients who received BARHEMSYS 5 mg (n=748) and at a higher rate than placebo (n=741) in clinical trials for the prevention of PONV were: chills (4% vs. 3%), hypokalemia (4% vs. 2%), procedural hypotension (3% vs. 2%), and abdominal distention (2% vs. 1%).

Serum prolactin concentrations were measured in one prophylaxis study where 5% (9/176) of BARHEMSYS-treated patients had increased blood prolactin reported as an adverse reaction compared with 1% (1/166) of placebo-treated patients.

The most common adverse reaction, reported in ≥ 2% of adult patients who received BARHEMSYS 10 mg (n=418) and at a higher rate than placebo (n=416), in clinical trials for the treatment of PONV was infusion site pain (6% vs. 4%).

Use in Specific Populations

Lactation

Amisulpride is present in human milk. There are no reports of adverse effects on the breastfed child and no information on the effects of amisulpride on milk production.

BARHEMSYS may result in an increase in serum prolactin levels, which may lead to a reversible increase in maternal milk production. In a clinical trial, serum prolactin concentrations in females (n=112) increased from a mean of 10 ng/mL at baseline to 32 ng/mL after BARHEMSYS treatment and from 10 ng/mL to 19 ng/mL in males (n=61). No clinical consequences due to elevated prolactin levels were reported.

To minimize exposure to a breastfed infant, lactating women may consider interrupting breastfeeding and pumping and discarding breast milk for 48 hours after receiving a dose of BARHEMSYS.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established.

Geriatric Use

No overall differences in safety or effectiveness were observed between these patients and younger patients, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out.

Renal Impairment

Avoid BARHEMSYS in patients with severe renal impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73 m2). The pharmacokinetics of amisulpride in patients with severe renal impairment have not been adequately studied in clinical trials. Amisulpride is known to be substantially excreted by the kidneys, and patients with severe renal impairment may have increased systemic exposure and an increased risk of adverse reactions.

No dosage adjustment is necessary in patients with mild to moderate renal impairment

(eGFR ≥ 30 mL/min/1.73 m2).

Drug Interactions

- BARHEMSYS causes dose- and concentration-dependent QT prolongation. To avoid potential additive effects, avoid use of BARHEMSYS in patients taking droperidol.
- ECG monitoring is recommended in patients taking other drugs known to prolong the QT interval (e.g., ondansetron).
- Reciprocal antagonism of effects occurs between dopamine agonists (e.g., levodopa) and BARHEMSYS. Avoid using levodopa with BARHEMSYS.

Important Safety Information **for BYFAVO™ (remimazolam) Injection**

Indications

BYFAVO is a benzodiazepine indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.

Important Safety Information

WARNING: PERSONNEL AND EQUIPMENT FOR MONITORING AND RESUSCITATION AND RISKS FROM CONCOMITANT USE WITH OPIOID ANALGESICS

Personnel and Equipment for Monitoring and Resuscitation

- **Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO.**
- **Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation.**
- **BYFAVO has been associated with hypoxia, bradycardia, and hypotension. Continuously monitor vital signs during sedation and during the recovery period.**
- **Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO.**

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics

Concomitant use of benzodiazepines, including BYFAVO, and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of intravenous BYFAVO can be accentuated by concomitantly administered CNS depressant medications, including other benzodiazepines and propofol. Continuously monitor patients for respiratory depression and depth of sedation.

Contraindication

BYFAVO is contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products containing dextran 40.

Personnel and Equipment for Monitoring and Resuscitation

Clinically notable hypoxia, bradycardia, and hypotension were observed in Phase 3 studies of BYFAVO. Continuously monitor vital signs during sedation and through the recovery period. Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO. Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation. Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO. Consider the potential for worsened cardiorespiratory depression prior to using BYFAVO concomitantly with other drugs that have the same potential (e.g., opioid analgesics or other sedative-hypnotics). Administer supplemental oxygen to sedated patients through the recovery period. A benzodiazepine reversal agent (flumazenil) should be immediately available during administration of BYFAVO.

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics

Concomitant use of BYFAVO and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of IV BYFAVO can be accentuated when administered with other CNS depressant medications (eg, other benzodiazepines and propofol). Titrate the dose of BYFAVO when administered with opioid analgesics and sedative-hypnotics to the desired clinical response. Continuously monitor sedated patients for hypotension, airway obstruction, hypoventilation, apnea, and oxygen desaturation. These cardiorespiratory effects may be more likely to occur in patients with obstructive sleep apnea, the elderly, and ASA-PS class III or IV patients.

Hypersensitivity Reactions

BYFAVO contains dextran 40, which can cause hypersensitivity reactions, including rash, urticaria, pruritus, and anaphylaxis. BYFAVO is contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products containing dextran 40.

Neonatal Sedation

Use of benzodiazepines during the later stages of pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) in the neonate. Observe newborns for signs of sedation and manage accordingly.

Pediatric Neurotoxicity

Published animal studies demonstrate that anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity increase neuronal apoptosis in the developing brain and result in long-term cognitive deficits when used for longer than 3 hours. The clinical significance of this is not clear. However, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life but may extend out to approximately 3 years of age in humans.

Anesthetic and sedation drugs are a necessary part of the care of children needing surgery, other procedures, or tests that cannot be delayed, and no specific medications have been shown to be safer than any other. Decisions regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.

Adverse Reactions

The most common adverse reactions reported in >10% of patients (N=630) receiving BYFAVO 5-30 mg (total dose) and undergoing colonoscopy (two studies) or bronchoscopy (one study) were: hypotension, hypertension, diastolic hypertension, systolic hypertension, hypoxia, and diastolic hypotension.

Use in Specific Populations

Pregnancy

There are no data on the specific effects of BYFAVO on pregnancy. Benzodiazepines cross the placenta and may produce respiratory depression and sedation in neonates. Monitor neonates exposed to benzodiazepines during pregnancy and labor for signs of sedation and respiratory depression.

Lactation

Monitor infants exposed to BYFAVO through breast milk for sedation, respiratory depression, and feeding problems. A lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk during treatment and for 5 hours after BYFAVO administration.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. BYFAVO should not be used in patients less than 18 years of age.

Geriatric Use

No overall differences in safety or effectiveness were observed between these subjects and younger subjects. However, there is a potential for greater sensitivity (eg, faster onset, oversedation, confusion) in some older individuals. Administer supplemental doses of BYFAVO slowly to achieve the level of sedation required and monitor all patients closely for cardiorespiratory complications.

Hepatic Impairment

In patients with severe hepatic impairment, the dose of BYFAVO should be carefully titrated to effect. Depending on the overall status of the patient, lower frequency of supplemental doses may be needed to achieve the level of sedation required for the procedure. All patients should be monitored for sedation-related cardiorespiratory complications.

Abuse and Dependence

BYFAVO is a federally controlled substance (CIV) because it contains remimazolam which has the potential for abuse and physical dependence.

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[1]Assumes a number of doses per patient at a WAC price of $85 per 10mg dose for the prophylaxis and rescue addressable market. These estimates are the result of market research performed by or for Eagle Pharmaceuticals.

[2] Estimate is based on market research performed by or for Eagle Pharmaceuticals.

[3] FDA labels for other recommended treatments do not include treatment after failed prophylaxis.

[4] Based on the number of doses per patient at a WAC price of $85 per 10mg dose.

[5] These estimates are the result of market research performed by or for Eagle Pharmaceuticals.

[6] https://bynder.acaciapharma.com/m/5d7c2cd0d58865f7/original/Barhemsys-Prescribing-Information.pdf

[7] https://bynder.acaciapharma.com/m/403e8c343b2922de/original/Byfavo-PI.pdf