Eagle Pharmaceuticals Agrees to Terms to Acquire Acacia Pharma Group plc

March 28, 2022

- Expects to add two U.S. Food and Drug Administration ("FDA")-approved, new chemical entities ("NCEs") with patent life into 2031 and expand acute care footprint
- Commercialized assets, BARHEMSYS® (amisulpride for injection) and BYFAVO® (remimazolam for injection), represent a strong strategic fit with Eagle's specialized hospital-based salesforce
- Addressable market for the two products combined is estimated to be $3.1 billion per year[1]
- Anticipates significant financial synergies from the proposed transaction
- Company to hold investor conference call to discuss proposed transaction on Thursday, March 31, 2022, at 8:30am ET

WOODCLIFF LAKE, N.J., March 28, 2022 (GLOBE NEWSWIRE) -- Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") today announced it has reached agreement on the terms of a transfer of the entire issued and to be issued share capital of Acacia Pharma Group plc ("Acacia Pharma") (EURONEXT: ACPH) to Eagle by way of a scheme of arrangement under Part 26 of the United Kingdom's Companies Act 2006 (the "Scheme").

The terms of the proposed transaction value Acacia Pharma's existing issued and to be issued share capital at approximately €94,700,000, or the equivalent of €0.90 per share. Each shareholder of Acacia Pharma would receive, as consideration for each share of Acacia Pharma held by such shareholder, €0.68 in cash and 0.0049 shares of common stock of Eagle. The terms of the proposed transaction also provide for Eagle to guarantee approximately €25.0 million of debt within the Acacia Pharma group. In connection with the proposed transaction, (i) the Company and Acacia Pharma entered into a co-operation agreement (the "Cooperation Agreement") on March 27, 2022 and (ii) certain shareholders and directors owning shares in the capital of Acacia delivered to the Company and Acacia deeds of irrevocable undertaking.

The proposed transaction has been approved by the boards of directors of both companies and is expected to close in late Q2 2022, subject to approval by Acacia Pharma's shareholders and the sanction of the High Court of England and Wales and customary closing conditions for transactions of this type. There is no assurance that the proposed transaction will be consummated on the proposed terms or timing or at all.

The proposed transaction is expected to provide Eagle with two currently marketed, acute care, hospital products with the potential to disrupt the marketplace:

- BARHEMSYS® is the first and only antiemetic approved by the FDA for rescue treatment of postoperative nausea and vomiting (PONV) despite prophylaxis. 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, and
- 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.[2]

"We are delighted to announce that we have agreed to terms for the proposed acquisition of Acacia Pharma. This will be a very important acquisition for us, both financially and strategically. In recent years, the pharmaceutical industry has witnessed slower uptake of new products and longer ramp periods. In the face of further challenges brought about by the COVID-19 pandemic, many smaller underfunded companies experienced significant hurdles launching products. We therefore believe that Eagle is well suited to drive uptake of these two new products, building from Acacia Pharma's established foundation since its launch, through our experienced and specialized hospital-based sales organization with minimal additional infrastructure," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"We have been extremely disciplined in managing our balance sheet over the years, and we believe that the proposed acquisition is a wise use of the cash we have generated. With these two products, together with landiolol, which is on track for an NDA submission to the FDA in May of this year, Eagle will potentially have three NCEs going into their launch phase. We believe these efforts will strengthen our leadership position in the hospital and oncology space and establish a strong foundation for sustainable long-term growth and bring value to our shareholders," concluded Tarriff.

"We believe that BARHEMSYS and BYFAVO address unmet clinical needs and are nearing usage inflection points, with strong formulary acceptance, and that with our longstanding relationships in the hospital space, we can accelerate uptake and capture the commercial potential of these assets. In doing so, we strive to impact and improve the care of patients undergoing medical treatments such as surgery and invasive procedures. Additionally, their value to anesthesia providers, who are key users, is important, facilitating precision medicine for patients. We see our sales infrastructure as a strategic asset, and as we add to our commercial product portfolio going forward, we plan to expand the size of our salesforce over the next two years," stated Michael Moran, Executive Vice President and Chief Commercial Officer of Eagle Pharmaceuticals.

Proposed Transaction Rationale

- Opportunity for Eagle's highly skilled hospital-based salesforce to integrate and promote BYFAVO and BARHEMSYS and to leverage longstanding relationships to realize the full potential of these assets.
- Anticipated strong synergistic fit with Eagle's current and expanding portfolio of hospital products and other expected cost synergies.
- Attractive opportunity to accelerate Eagle's existing growth strategy and further its advantage in acute care.
- Commercial stage, NCE products with long patent duration through 2031 would add complementary and diversified revenue streams to Eagle.
- Eagle's strong financial position enables it to invest in this opportunity for potential significant value creation.
- Compelling commercial opportunity in both FDA-approved products:
    - BARHEMSYS is the first and only antiemetic approved for rescue treatment of PONV despite prophylaxis and offers the potential for savings to hospitals and ambulatory centers.
    - BYFAVO addresses an unmet need in procedural sedation by offering a fast-acting agent with a favorable safety profile versus other current treatments.
- Expected to be earnings accretive in 2024.

Product Descriptions and Potential Commercial Opportunity

BARHEMSYS® (amisulpride for injection)[3] is the first and only FDA-approved product for PONV rescue after failed prophylaxis[4]. 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. Approximately 70 million invasive surgical 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 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)[5] 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.

Terms of the Proposed Transaction and Financing

The terms of the proposed transaction value Acacia Pharma's existing issued and to be issued share capital at approximately €94.7 million. The cash consideration payable by Eagle under the terms of the transaction would be approximately €71.6 million. The cash consideration payable by Eagle under the terms of the proposed transaction is expected to be financed by existing cash resources of Eagle. The remaining approximately €23.2 million consideration payable by Eagle is expected to be paid in shares of Eagle common stock. The terms of the proposed transaction also provide for Eagle to guarantee approximately €25.0 million of debt within the Acacia Pharma group

Conditions to Closing and Anticipated Timing

The Scheme is expected to become effective between the middle of May 2022 and June 30th, 2022, and is subject to closing conditions including, among other things, obtaining the requisite approval of Acacia Pharma's shareholders and the sanction of the High Court of England and Wales by June 30, 2022, which date may be extended by mutual agreement of the parties. There is no assurance that the proposed transaction will be consummated on the proposed terms or timing or at all.

Advisors

Cooley (UK) LLP is acting as legal advisor and William Blair & Company, L.L.C. is acting as exclusive financial advisor to Eagle Pharmaceuticals in connection with the proposed transaction. Locust Walk served as a transaction advisor to Eagle Pharmaceuticals. NautaDutilh BV is acting as legal advisor to Eagle Pharmaceuticals in connection with Belgian law. Sullivan & Cromwell LLP is acting as legal advisor and Greenhill & Co. International LLP and Jefferies International Limited are acting as co-financial advisors to Acacia Pharma in connection with the proposed transaction. Eubelius CVBA is acting as legal advisor to Acacia Pharma in connection with Belgian law and its listing on Euronext Brussels.

Conference Call

As previously announced, Eagle management will host an investor conference call to discuss the proposed transaction as follows:

Date:	Thursday, March 31, 2022
Time:	8:30am ET
Toll Free (U.S.):	800-909-7113
International:	203-518-9544
Webcast Live and Replay:	www.eagleus.com, under the “Investor + News” section

A replay of the conference call will be available for one week after the call's completion by dialing Toll Free Phone 800-839-5637 (US) or 402-220-2562 (International) and entering conference call ID Conference ID: EGRX0331. The webcast will be archived for 30 days at the aforementioned URL.

About Acacia Pharma

Acacia Pharma is a hospital pharmaceutical company focused on the development and commercialization of new products aimed at improving the care of patients undergoing significant treatments such as surgery, other invasive procedures, or cancer chemotherapy.

Acacia Pharma is a public company limited by shares, incorporated in England and is listed on the Euronext Brussels exchange under the ISIN code GB00BYWF9Y76 and ticker symbol ACPH.

Acacia Pharma has its U.S. headquarters in Indianapolis, IN and its R&D operations are centered in Cambridge, UK.

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.

Further Information

This announcement is for information purposes only and is not intended to and does not constitute, or form part of, an offer, invitation or the solicitation of an offer to purchase, otherwise acquire, subscribe for, sell or otherwise dispose of any securities, or the solicitation of any vote or approval in any jurisdiction, pursuant to the proposed transaction or otherwise, nor the announcement of a forthcoming solicitation of any offer to acquire or dispose of securities or of any vote or approval, nor shall there be any sale, issuance or transfer of securities of Acacia Pharma or Eagle in any jurisdiction. The information contained in this announcement should not be construed to constitute any form of advice or recommendation, including but not limited to investment, tax, legal or other advice, and should not be relied upon as the basis for any decision or action.

The proposed transaction will be implemented solely pursuant to the terms of a Scheme Document (the “Scheme Document”), which will contain the full terms and conditions of the proposed transaction, including details of how to vote in respect of the proposed transaction.

This announcement does not constitute a prospectus or a prospectus-equivalent document.

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 and phrases such as “anticipated,” “forward,” “will,” “would,” “may,” “remain,” “potential,” “prepare,” “expected,” “believe,” “plan,” “near future,” “belief,” “guidance,” “opportunity,” “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: the strategic fit of BARHEMSYS and BYFAVO with Eagle's specialized hospital-based salesforce; statements regarding the addressable market size and commercial potential for BARHEMSYS and BYFAVO and other products or product candidates; the expected structure, anticipated synergies, terms, timing and closing of the proposed transaction; Eagle’s marketing, product development, partnering and growth strategy, including relating to the commercialization of BARHEMSYS and BYFAVO, and the ability of Acacia Pharma’s technology and know-how to help Eagle achieve its strategy; the expectation that the addition of BARHEMSYS and BYFAVO will be accretive to Eagle, and the timing thereof; the expected sources of financing for the proposed transaction; the ability of Eagle to expand the application of the Acacia Pharma products; 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 and BYFAVO to address unmet clinical needs; the ability of BARHEMSYS to offer significant economic savings to hospitals and ambulatory centers; the ability of BYFAVO to offer potential health economic benefits and enable shorter procedure times and greater patient throughput; the ability of the proposed transaction to create shareholder value; and the ability of the Company’s executive team to execute on the Company’s strategy and build stockholder value. 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 transaction described above is not consummated or that the benefits of the transaction 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 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; the outcome of Acacia Pharma's shareholder vote, the High Court and other closing conditions; and factors in addition to the foregoing that may impact the Company's expectations, 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; 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, 2021, filed with the Securities and Exchange Commission (the "SEC") on March 8, 2022, and its other subsequent filings with the SEC. 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] These estimates are the result of market research performed by or for Eagle Pharmaceuticals.

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

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

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

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

EAGLE PHARMACEUTICALS

Source: Eagle Pharmaceuticals, Inc.