Endo and Premier, Inc. Collaborate to Address Pitocin® (oxytocin injection, USP) Shortage

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Strategic effort aims to bring stable, quality supply to providers and enhanced pricing predictability for critical labor and delivery drug

CHARLOTTE, N.C. and DUBLIN, July 17, 2023 /PRNewswire/ -- Endo International plc (OTC: ENDPQ) and Premier, Inc. (NASDAQ: PINC) announced today that Endo's Par Sterile Products business will supply Pitocin® (oxytocin injection, USP) vials through Premier's ProvideGx® and PremierProRx® programs.

Pitocin® is used to induce labor in pregnant women. The product is on the World Health Organization's essential medications list and has a history of supply disruptions, which can result in potential health risks to mothers and babies, as well as costly delays in hospital labor and delivery wards. The partnership involves a multifaceted approach seeking to provide stable product supply through adequate safety stock on a long-term basis.

"We're pleased to offer Pitocin® injection through the robust and highly reliable ProvideGx® and PremierProRx® supply channels," said Scott Sims, Senior Vice President and General Manager, Injectable Solutions & Generics at Endo. "As a long-standing collaborator with Premier, we're proud to join the organization in helping to address drug shortages and serving as a reliable supplier of this labor and delivery product."

"This initiative with Endo is yet another step forward to help eliminate drug shortages for our healthcare provider members, create increased market competition and promote more predictable, long-term prices," said Michael J. Alkire, President and CEO of Premier. "Both ProvideGx® and the PremierProRx® private label program are building a more diversified pharmaceutical market designed to create sustainable supply of a drug vital for maternal care and health in the U.S."

Guided by health systems with more than 1,600 hospitals across the nation, Premier's ProvideGx® and PremierProRx® programs create long-term committed buying contracts with participating manufacturers—creating a steady demand signal and guaranteed buyer base in exchange for increasing production of generics in shortage, maintaining safety stocks or diversifying supply sources. These programs offer members access to more than 150 drugs that are or have been recently designated as shortage drugs, and have successfully helped resolve 14 drug shortages, resulting in their official delisting from the U.S. Food & Drug Administration's shortage list.

With a stable supply of Pitocin®, Premier can continue efforts aimed at addressing factors that impact maternal and infant health outcomes, including the PINC AI™ Perinatal Improvement Collaborative that brings together more than 220 health systems in all 50 states using performance improvement tools and standardized data to measure outcomes and help identify the drivers of maternal mortality and morbidity.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS
Antepartum use of Pitocin is contraindicated in any of the following circumstances:

1. Where there is significant cephalopelvic disproportion;
2. In unfavorable fetal positions or presentations, such as transverse lies, which are undeliverable without conversion prior to delivery;
3. In obstetrical emergencies where the benefit-to-risk ratio for either the fetus or the mother favors surgical intervention;
4. In fetal distress where delivery is not imminent;
5. Where adequate uterine activity fails to achieve satisfactory progress;
6. Where the uterus is already hyperactive or hypertonic;
7. In cases where vaginal delivery is contraindicated, such as invasive cervical carcinoma, active herpes genitalis, total placenta previa, vasa previa, and cord presentation or prolapse of the cord;

8. In patients with hypersensitivity to the drug.

WARNINGS
Pitocin, when given for induction of labor or augmentation of uterine activity, should be administered only by the intravenous route and with adequate medical supervision in a hospital.

PRECAUTIONS

1. All patients receiving intravenous oxytocin must be under continuous observation by trained personnel who have a thorough knowledge of the drug and are qualified to identify complications. Electronic fetal monitoring provides the best means for early detection of overdosage.
2. When properly administered, oxytocin should stimulate uterine contractions comparable to those seen in normal labor. Overstimulation of the uterus by improper administration can be hazardous to both mother and fetus. Even with proper administration and adequate supervision, hypertonic contractions can occur in patients whose uteri are hypersensitive to oxytocin. This fact must be considered by the physician in exercising his judgment regarding patient selection.
3. Oxytocin should not be administered in the following conditions: fetal distress, hydramnios, partial placenta previa, prematurity, borderline cephalopelvic disproportion, and any condition in which there is a predisposition for uterine rupture, such as previous major surgery on the cervix or uterus including cesarean section, overdistention of the uterus, grand multiparity, or past history of uterine sepsis or of traumatic delivery. The decision can be made only by carefully weighing the potential benefits which oxytocin can provide in a given case against rare but definite potential for the drug to produce hypertonicity or tetanic spasm.
4. Maternal deaths due to hypertensive episodes, subarachnoid hemorrhage, rupture of the uterus, and fetal deaths due to various causes have been reported associated with the use of parenteral oxytocic drugs for induction of labor or for augmentation in the first and second stages of labor.
5. Oxytocin has been shown to have an intrinsic antidiuretic effect, acting to increase water reabsorption from the glomerular filtrate. Consideration should, therefore, be given to the possibility of water intoxication, particularly when oxytocin is administered continuously by infusion and the patient is receiving fluids by mouth.
6. When oxytocin is used for induction or reinforcement of already existent labor, patients should be carefully selected. Pelvic adequacy must be considered and maternal and fetal conditions evaluated before use of the drug.

ADVERSE REACTIONS
The following adverse reactions have been reported in the mother:
Anaphylactic reaction, postpartum hemorrhage, cardiac arrhythmia, fatal afibrinogenemia, nausea, vomiting, premature ventricular contractions, pelvic hematoma, subarachnoid hemorrhage, hypertensive episodes, and rupture of the uterus.
The following adverse reactions have been reported in the fetus or neonate:
Due to induced uterine motility: Bradycardia, premature ventricular contractions and other arrhythmias, permanent CNS or brain damage, fetal death, and neonatal seizures have been reported with the use of Pitocin.
Due to use of oxytocin in the mother: Low Apgar scores at five minutes, neonatal jaundice, and neonatal retinal hemorrhage.

DRUG INTERACTIONS
Severe hypertension has been reported when oxytocin was given three to four hours following prophylactic administration of a vasoconstrictor in conjunction with caudal block anesthesia.
Cyclopropane anesthesia may modify oxytocin's cardiovascular effects, so as to produce unexpected results such as hypotension. Maternal sinus bradycardia with abnormal atrioventricular rhythms has also been noted when oxytocin was used concomitantly with cyclopropane anesthesia.

INDICATIONS AND USAGE

IMPORTANT NOTICE
Elective induction of labor is defined as the initiation of labor in a pregnant individual who has no medical indications for induction. Since the available data are inadequate to evaluate the benefits-to-risks considerations, Pitocin is not indicated for elective induction of labor.

Antepartum: Pitocin is indicated for the initiation or improvement of uterine contractions, where this is desirable and considered suitable for reasons of fetal or maternal concern, in order to achieve vaginal delivery.
It is indicated for (1) induction of labor in patients with a medical indication for the initiation of labor, such as Rh problems, maternal diabetes, preeclampsia at or near term, when delivery is in the best interests of mother and fetus or when membranes are prematurely ruptured and delivery is indicated; (2) stimulation or reinforcement of labor, as in selected cases of uterine inertia; (3) as adjunctive therapy in the management of incomplete or inevitable abortion. In the first trimester, curettage is generally considered primary therapy. In second trimester abortion, oxytocin infusion will often be successful in emptying the uterus. Other means of therapy, however, may be required in such cases.
Postpartum: Pitocin is indicated to produce uterine contractions during the third stage of labor and to control postpartum bleeding or hemorrhage.

Please click for full Prescribing Information.

About Endo
Endo (OTC: ENDPQ) is a specialty pharmaceutical company committed to helping everyone we serve live their best life through the delivery of quality, life-enhancing therapies. Our decades of proven success come from passionate team members around the globe collaborating to bring treatments forward. Together, we boldly transform insights into treatments benefiting those who need them, when they need them. Learn more at www.endo.com or connect with us on LinkedIn.

About Premier, Inc.

Premier, Inc. (NASDAQ: PINC) is a leading healthcare improvement company, uniting an alliance of more than 4,400 U.S. hospitals and health systems and approximately 250,000 other providers to transform healthcare. With integrated data and analytics, collaboratives, supply chain solutions, and consulting and other services, Premier enables better care and outcomes at a lower cost. Premier plays a critical role in the rapidly evolving healthcare industry, collaborating with members to co-develop long-term innovations that reinvent and improve the way care is delivered to patients nationwide. Headquartered in Charlotte, N.C., Premier is passionate about transforming American healthcare. Please visit Premier's news and investor sites on www.premierinc.com; as well as Twitter, Facebook, LinkedIn, YouTube, Instagram and Premier's blog for more information about the company.

Cautionary Note Regarding Forward-Looking Statements

Certain information in this press release may be considered "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and any applicable Canadian securities legislation including, but not limited to, the statements by Messrs. Sims and Alkire, any statements relating to product supply, reliability, availability or pricing, and any statements that refer to expected, estimated or anticipated future results or that do not relate solely to historical facts. Statements including words or phrases such as "believe," "expect," "anticipate," "intend," "estimate," "plan," "will," "may," "look forward," "intend," "guidance," "future," "potential" or similar expressions are forward-looking statements. All forward-looking statements in this communication reflect Endo's (the "Company's") current views as of the date of this communication about its plans, intentions, expectations, strategies and prospects, which are based on the information currently available to it and on assumptions it has made. Actual results may differ materially and adversely from current expectations based on a number of factors, including, among other things, the outcome of the Company's contingency planning and restructuring activities; the timing, impact or results of any pending or future litigation, investigations, proceedings or claims, including opioid, tax and antitrust related matters; any actual or contingent liabilities; settlement discussions or negotiations; the Company's liquidity, financial performance, cash position and operations; the risks and uncertainties associated with chapter 11 proceedings; the time, terms and ability to confirm a sale of the Company's businesses under Section 363 of the U.S. Bankruptcy Code; the risk that the Company's chapter 11 cases may be converted to cases under chapter 7 of the Bankruptcy Code; the adequacy of the capital resources of the Company's businesses and the difficulty in forecasting the liquidity requirements of the operations of the Company's businesses; the unpredictability of the Company's financial results; the Company's ability to discharge claims in chapter 11 proceedings; negotiations with the holders of the Company's indebtedness and its trade creditors and other significant creditors; the risks and uncertainties with performing under the terms of the restructuring support agreement and any other arrangement with lenders or creditors while in chapter 11 proceedings; the performance, including the approval, introduction, and consumer and physician acceptance of new products and the continuing acceptance of currently marketed products; and the Company's ability to obtain and successfully manufacture, maintain and distribute a sufficient supply of products to meet market demand in a timely manner. The Company expressly disclaims any intent or obligation to update these forward-looking statements, except as required to do so by law.

Additional information concerning risk factors, including those referenced above, can be found in press releases issued by the Company, as well as the Company's public periodic filings with the U.S. Securities and Exchange Commission and with securities regulators in Canada, including the discussion under the heading "Risk Factors" in the Company's most recent Annual Report on Form 10-K and any subsequent Quarterly Reports on Form 10-Q or other filings with the U.S. Securities and Exchange Commission.

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