FOR IMMEDIATE RELEASE

BAXTER LAUNCHES ZOSYN PREMIX IN US

- *Supports Baxter's ongoing efforts to expand its anti-infective portfolio to increase access to essential medications and advance patient care*
- *Frozen premix formulation helps support patient safety, simplify medication preparation, and improve operational efficiencies*

DEERFIELD, Ill., APRIL 4, 2023 — Baxter International Inc. (NYSE:BAX), a global leader in sterile medication production and delivery, today announced the U.S. launch of **ZOSYN** (piperacillin and tazobactam) Injection. **Zosyn** premix is indicated for the treatment of multiple infections caused by susceptible bacteria and is available in Baxter's proprietary single-dose **Galaxy** containers. Please see Indications, Important Risk Information and link to full Prescribing Information below.

"**Zosyn** premix is an important addition to Baxter's portfolio of valuable anti-infective medications that help treat some of the most pressing healthcare needs facing patients today," said Alok Sonig, executive vice president and group president, Pharmaceuticals, at Baxter. "We are thrilled to provide an additional frozen premix option that can help support patient safety and offer added convenience for healthcare providers."

The use of premixes, or ready-to-use formats of standard doses of commonly prescribed drugs, may offer operational efficiencies for healthcare providers. Compounding a drug for patient use is a multi-step, manual process that requires oversight by pharmacy staff. A ready-to-use product like **Zosyn** premix can simplify the preparation process and help improve patient safety by reducing the chance of contamination and avoiding potential dosing errors that may occur when medications are compounded.

Baxter will sell **Zosyn** premix in 2.25 g in 50 mL, 3.375 g in 50 mL, and 4.5 g in 100mL presentations. Like other medications in Baxter's premix portfolio, **Zosyn** premix uses Baxter's proprietary **Galaxy** container technology. **Galaxy** is a non-PVC and non-DEHP system that enables premixed medications to have a longer shelf life.

About Baxter Pharmaceuticals

Baxter provides a wide range of valuable medications including difficult-to-manufacture oncology drugs and standard-dose, ready-to-use premixed injectable anti-infectives, analgesics and critical care medications. Baxter has rapidly expanded its pharmaceuticals portfolio through recent acquisitions, strategic partnerships and internal development programs that will help increase access to essential medications and advance pharmacy efficiency and patient care. Baxter is also the first and only company to offer all three of the most commonly used modern inhaled anesthetics for general anesthesia.

About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For more than 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on Twitter, LinkedIn and Facebook.

ZOSYN (piperacillin and tazobactam) Injection

2.25 g/50 mL, 3.375 g/50 mL, 4.5 g/ 100 mL

Indications and Important Risk Information

Indications

Zosyn is a combination of piperacillin, a penicillin-class antibacterial and tazobactam, a beta-lactamase inhibitor, indicated for the treatment of:

- Intra-abdominal infections in adult and pediatric patients 2 months of age and older
- Nosocomial pneumonia in adult and pediatric patients 2 months of age and older
- Skin and skin structure infections in adults
- Female pelvic infections in adults
- Community-acquired pneumonia in adults

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Zosyn and other antibacterial drugs, Zosyn should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria.

Important Risk Information

Contraindications

Zosyn is contraindicated in patients with a history of allergic reactions to any of the penicillins, cephalosporins, or beta-lactamase inhibitors.

Warnings and Precautions

- **Hypersensitivity Adverse Reactions:** Serious and occasionally fatal hypersensitivity (anaphylactic/anaphylactoid) reactions (including shock) have been reported in patients receiving therapy with **Zosyn**. These reactions are more likely to occur in individuals with a history of penicillin, cephalosporin, or carbapenem hypersensitivity or a history of sensitivity to multiple allergens. If an allergic reaction occurs, **Zosyn** should be discontinued and appropriate therapy instituted.
- **Severe Cutaneous Adverse Reactions:** **Zosyn** may cause severe cutaneous adverse reactions, such as Stevens-Johnson syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, and acute generalized exanthematous pustulosis. If patients develop a skin rash they should be monitored closely and **Zosyn** discontinued if lesions progress.
- **Hemophagocytic Lymphohistiocytosis (HLH):** Cases of HLH have been reported in pediatric and adult patients treated with **Zosyn**. Signs and symptoms of HLH may include fever, rash, lymphadenopathy, hepatosplenomegaly and cytopenia. If HLH is suspected, discontinue **Zosyn** immediately and institute appropriate management.
- **Hematologic Adverse Reactions:** Bleeding manifestations have occurred in some patients receiving beta-lactam drugs, including piperacillin. These reactions have sometimes been associated with abnormalities of coagulation tests such as clotting time, platelet aggregation and prothrombin time, and are more likely to occur in patients with renal failure. If bleeding manifestations occur, **Zosyn** should be discontinued and appropriate therapy instituted. The leukopenia/neutropenia associated with **Zosyn** administration appears to be reversible and most frequently associated with prolonged administration.
  Periodic assessment of hematopoietic function should be performed, especially with prolonged therapy, i.e., ≥ 21 days.
- **Central Nervous System Adverse Reactions:** As with other penicillins, **Zosyn** may cause neuromuscular excitability or seizures. Patients receiving higher doses, especially patients with renal impairment may be at greater risk for central nervous system adverse reactions. Closely monitor patients with renal impairment or seizure disorders for signs and symptoms of neuromuscular excitability or seizures.
- **Nephrotoxicity in Critically Ill Patients:** The use of **Zosyn** was found to be an independent risk factor for renal failure and was associated with delayed recovery of renal function as compared to other beta-lactam antibacterial drugs in critically ill patients. Alternative treatment options should be considered in the critically ill population. If alternative treatment options are inadequate or unavailable, monitor renal function during treatment with **Zosyn**.
- ***Clostridioides difficile*-associated diarrhea (CDAD):** CDAD has been reported with use of nearly all antibacterial agents, including **Zosyn**, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drug use. Careful medical history is necessary since CDAD has been reported to occur over two months after the administration of antibacterial agents.
If CDAD is suspected or confirmed, ongoing antibacterial drug use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibacterial treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

- **Adverse Reactions:** The most common adverse reactions (incidence >5%) are diarrhea, constipation, nausea, headache, and insomnia.
- **Renal Impairment:** In patients with creatinine clearance ≤ 40 mL/min and dialysis patients (hemodialysis and CAPD), the intravenous dose of **Zosyn** should be reduced to the degree of renal function impairment.
- **Drug Interactions:**
    - **Zosyn** administration can significantly reduce tobramycin concentrations in hemodialysis patients. Monitor tobramycin concentrations in these patients.
    - Probenecid prolongs the half-lives of piperacillin and tazobactam and should not be co-administered with **Zosyn** unless the benefit outweighs the risk.
    - Co-administration of **Zosyn** with vancomycin may increase the incidence of acute kidney injury. Monitor kidney function in patients receiving **Zosyn** and vancomycin.
    - Monitor coagulation parameters in patients receiving **Zosyn** and heparin or oral anticoagulants.
    - **Zosyn** may prolong the neuromuscular blockade of vecuronium and other non-depolarizing neuromuscular blockers. Monitor for adverse reactions related to neuromuscular blockade.

Please click here for accompanying full Prescribing Information for **Zosyn**.

*This release includes forward-looking statements concerning the launch of **Zosyn** premix and Baxter's proprietary **Galaxy** container technology, including potential benefits associated with the use of **Zosyn** and **Galaxy** containers. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: demand for and market acceptance for new and existing products; product development risks; inability to create additional production capacity in a timely manner or the occurrence of other manufacturing or supply difficulties (including as a result of natural disasters, public health crises and epidemics/pandemics, regulatory actions or otherwise); satisfaction of regulatory and other requirements; actions of regulatory bodies and other governmental authorities; product quality, manufacturing or supply, or patient safety issues; changes in law and regulations; and other risks identified in Baxter's most recent filing on Form 10-K and Form 10-Q and other SEC filings, all of which are available on Baxter's website. Baxter does not undertake to update its forward-looking statements.*

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