FOR IMMEDIATE RELEASE

BAXTER SECURES FDA APPROVAL OF CLINOLIPID (LIPID INJECTABLE EMULSION) NEONATAL AND PEDIATRIC INDICATION

- *Clinolipid provides calories and essential fatty acids for parenteral nutrition*
- *Expanded indication demonstrates Baxter's continued commitment to meeting the diverse nutritional needs of patients, from preterm neonates to adults*

DEERFIELD, Ill., MAY 13, 2024 – Baxter International Inc. (NYSE:BAX), a global leader in nutrition therapy, today announced U.S. FDA approval of an expanded indication for **Clinolipid** (Lipid Injectable Emulsion) to be used in pediatric patients, including preterm and term neonates. **Clinolipid** is Baxter's proprietary mixed oil lipid emulsion that is used to provide calories and essential fatty acids in parenteral (intravenous) nutrition (PN) when oral or enteral nutrition is not possible, insufficient or contraindicated. **Clinolipid** has been available in the U.S. for adults since 2019 and is now available for use in all ages.

"Improving patient outcomes inspires our work every day, and we are proud to continue to address the unique nutritional needs of neonatal and pediatric patients through innovative products and therapies," said Cecilia Soriano, president of Baxter's global Infusion Therapies and Technologies division. "Expanding access to **Clinolipid** for this critical and vulnerable patient population offers clinicians versatility in choosing the product that best meets their patients' needs when it matters most."

A Mixed Lipid Emulsion with Unique Characteristics

Parenteral nutrition plays an important role in helping treat and reduce the risk of malnutrition. In the U.S., it's estimated that about 40 percent of patients who receive PN as an intravenous source of nourishment are under the age of 18.[1,2] Intravenous lipid emulsions (ILEs) are used to provide calories and essential fatty acids for patients who cannot intake a sufficient source of nutrition orally or enterally. Over the last several years, clinical practice has shifted away from using 100 percent soybean oil lipid emulsions – which was the standard of care for decades – to mixed lipid emulsions. Baxter's **Clinolipid** contains the lowest amount of soybean oil (20 percent) and highest amount of olive oil (80 percent) of any mixed ILE available in the U.S. today.[3,4] With more than 150 million doses worldwide,[5] **Clinolipid** has been shown to be a safe and effective source of

energy and essential fatty acids needed for growth and development in neonatal and pediatric patients.[3] Specifically, **Clinolipid**:

- Is rich in omega-9 oleic acid, the most prevalent fatty acid in human breast milk;[6]
- Minimizes the decline in post-natal arachidonic acid levels;[7]
- Is supported by extensive PN admixture stability.[8,9]

Clinolipid is available to order in the U.S. today. Click here to learn more about Baxter's clinical nutrition portfolio.

About Baxter's Global Clinical Nutrition Business

Baxter's broad portfolio of clinical nutrition products includes metabolic monitors, automated nutrition compounders and parenteral nutrition solutions. These tools and solutions help enable clinicians to measure accurately, mix with control and nourish effectively. Our innovative and accessible clinical nutrition products and services are used extensively across a wide array of acute and alternate care settings.

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 X/Twitter, LinkedIn and Facebook.

Indication

CLINOLIPID injection is indicated in adults and pediatric patients, including term and preterm neonates as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

Important Risk Information

- The use of CLINOLIPID injection is contraindicated in patients with the following:

- Known hypersensitivity to egg, soybean, peanut, or any of the active or inactive ingredients.
- Severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglycerides >1,000 mg/dL).

- **Clinical Decompensation with Rapid Infusion of Intravenous Lipid Emulsion in Neonates and Infants** Acute respiratory distress, metabolic acidosis, and death after rapid infusion of intravenous lipid emulsions have been reported. Carefully monitor the infant's ability to eliminate the infused lipids from the circulation (e.g., measure serum triglycerides and/or plasma free fatty acid levels). If signs of poor clearance of lipids from the circulation occur, stop the infusion and initiate a medical evaluation.

- **Parenteral Nutrition-Associated Liver Disease (PNALD):** Increased risk in patients who receive parenteral nutrition for greater than 2 weeks, especially preterm neonates. Monitor liver tests: if abnormalities occur, consider discontinuation or dosage reduction.

- **Hypersensitivity Reactions:** Monitor for signs or symptoms. Discontinue infusion if reactions occur.

- **Risk of Infections, Fat Overload Syndrome, Refeeding Syndrome, Hypertriglyceridemia, and Essential Fatty Acid Deficiency (EFAD):** Monitor for signs and symptoms; monitor laboratory parameters.
  - Ensure aseptic techniques are used for catheter placement, catheter maintenance, and preparation and administration of CLINOLIPID.
  - If signs or symptoms of fat overload syndrome occur, stop CLINOLIPID.
  - To prevent complications from Refeeding Syndrome, closely monitor severely malnourished patients and slowly increase their nutrient intake.
  - Measure serum triglycerides before the start of infusion and regularly throughout treatment. If triglyceride levels are above 400 mg/dL in adults, stop the CLINOLIPID infusion and monitor serum triglyceride levels to avoid clinical consequences of hypertriglyceridemia.
  - Laboratory testing using the triene to tetraene ratio may not be adequate to diagnose EFAD, and assessment of individual fatty acid levels may be needed.

- **Aluminum Toxicity:** Increased risk in patients with renal impairment, including preterm neonates. CLINOLIPID injection contains no more than 25 mcg/L of aluminum.

- Most common (≥5%) adverse drug reactions from clinical trials in adults were nausea and vomiting, hyperlipidemia, hyperglycemia, hypoproteinemia, and abnormal liver function tests.

- Most common (≥5%) adverse reactions from clinical trials in pediatric patients were hyperbilirubinemia, patent ductus arteriosus, anemia, gastroesophageal reflux disease, bradycardia, feeding intolerance, neonatal intraventricular hemorrhage, increased alkaline phosphatase, atrial septal defect, hyponatremia, sepsis, and infantile apnea.

- The anticoagulant activity of coumarin derivatives, including warfarin, may be counteracted.

Please see accompanying full Prescribing Information for CLINOLIPID.

This release includes forward-looking statements concerning potential benefits associated with ***Clinolipid****. 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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[1] Agency for Healthcare Quality and Research. HCUP NIS data on parenteral nutrition use. 2016. https://hcupnet.ahrq.gov/#setup. Accessed June 23, 2019.

[2] Kraft M et al. Parenteral Nutrition Prescribing and Order Review Safety Study: The Need for Pharmacist Intervention. Nutr Clin Pract. 2021;36:480–488.

[3] CLINOLIPID 20% (Lipid Injectable Emulsion) for intravenous use PI, 4/2024.

[4] SMOFLIPID® (lipid injectable emulsion), for intravenous use PI, 6/2023.

[5] Internal Baxter Data on File

[6] Miliku K, Duan QL, Moraes TJ, et al. Human milk fatty acid composition is associated with dietary, genetic, sociodemographic, and environmental factors in the CHILD Cohort Study. Am J Clin Nutr. 2019;110(6):1370-1383. doi:10.1093/ajcn/nqz229.

[7] Baxter Internal Data on File

[8] Baxter Internal Data on File

[9] Baxter Internal Data on File

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