PIRAMAL CRITICAL CARE ANNOUNCES THE U.S. LAUNCH OF MITIGO™

Bethlehem, PA, USA (March 11, 2019) – Piramal Critical Care, a global leader in anesthesia, pain management, and intrathecal therapy, today announced the launch of MITIGO™ (Morphine Sulfate Injection, USP – Preservative-free) in 10 mg/mL and 25 mg/mL concentrations in the US market.

Piramal Critical Care will continue to work with wholesalers, hospitals, interventional pain doctors, and pain management centers across the country to ensure availability of MITIGO™ for patients with intractable chronic pain.

Peter DeYoung, Chief Executive Officer, Piramal Critical Care said: "Piramal Critical Care has established itself as the leader in U.S. intrathecal therapy with Gablofen® which we have successfully integrated post its acquisition from Mallinckrodt. We are pleased to support intrathecal therapy for pain management with FDA approval and our launch of MITIGO™. We continue to expand our leadership in intrathecal therapy through this launch, as well as in inhaled anesthesia and the injectable anesthesia and pain management drugs that we acquired from Janssen. We stay committed to executing on our strategy to expand our portfolio, address patient and customer needs, and deliver high quality critical care solutions to the market."

About MITIGO™

MITIGO™ (Morphine Sulfate Injection, USP – Preservative-free) is an opioid agonist, for use in continuous microinfusion devices indicated only for intrathecal or epidural infusion for the management of intractable chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Available in 200 mg/20 mL (10 mg/mL) and 500 mg/20 mL (25 mg/mL) preservative-free amber glass vials.

About Piramal Critical Care

Piramal Critical Care, a business unit of Piramal Enterprises Limited, is a global leader in anesthesia, pain management, and intrathecal therapy. Piramal Critical Care maintains a wide presence across the US, Europe, and more than 100 countries. Our product portfolio includes inhalation anesthetics, injectable pain and anesthesia drugs, injectable drugs for myxedema coma, intrathecal therapy for spasticity management, and plasma volume expanders. Piramal Critical Care has strong manufacturing and process development capabilities with state-of-the-art manufacturing facilities in Bethlehem, PA, United States and Telangana, India, which are inspected by US FDA, UK MHRA and other regulators, and partners with leading pharmaceutical development and manufacturing organizations around the world.

About Piramal Enterprises

Piramal Enterprises Limited (PEL) is one of India's large diversified companies, with a presence in Financial Services, Pharmaceuticals and Healthcare Insights & Analytics. PEL's consolidated revenues were over US$1.6 billion in FY2018, with ~46% of revenues generated from outside India.

In Pharma, through an end-to-end manufacturing capabilities across 13 global facilities and a large global distribution network to over 100 countries, PEL sells a portfolio of niche differentiated pharma products and provides an entire pool of pharma services (including in the areas of injectable, HPAPI etc.). The Company is also strengthening its presence in the Consumer Product segment in India. PEL's Healthcare Insights & Analytics business is the premier provider of healthcare analytics, data & insight products and services to the world's leading pharma, biotech and medical technology companies and enables them to take informed business decisions.

In Financial Services, Piramal Capital & Housing Finance Ltd is registered as a housing finance company with National Housing Bank (NHB) and engaged in various financial services businesses. It provides both wholesale and retail funding opportunities across sectors including real estate, infrastructure, SMEs etc. PCHFL through its group companies provides customized strategies for institutional and retail investors such as Mumbai Redevelopment Fund and Apartment Fund focused (through Piramal Fund Management) and strategic partnerships with leading global pension funds such as CPPIB, APG and Ivanhoe Cambridge. The division also has a Distressed Asset Investing platform with Bain Capital Credit – India Resurgence Fund that will invest in equity and/or debt in assets across sectors (other than real estate) to drive restructuring with active participation in turnaround. PEL also has long term equity investments worth ~US$1 billion in Shriram Group, a leading financial conglomerate in India.

PEL is listed on the BSE Limited and the National Stock Exchange of India Limited in India.

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Gablofen® (baclofen injection) INDICATIONS AND USAGE

Gablofen® (baclofen injection) is a gamma-aminobutyric acid (GABA) ergic agonist indicated for use in the management of severe spasticity of cerebral or spinal origin in adult and pediatric patients' age 4 years and above.

Gablofen should be reserved for patients unresponsive to oral baclofen therapy, or those who experience intolerable central nervous system side effects at effective doses.

Patients should first respond to a screening dose of intrathecal baclofen prior to consideration for long term infusion via an implantable pump.

Spasticity due to traumatic brain injury: wait at least one year after injury before considering Gablofen therapy.

IMPORTANT RISK INFORMATION

WARNING: DO NOT DISCONTINUE ABRUPTLY

See full prescribing information for complete boxed warning

Abrupt discontinuation of intrathecal baclofen, regardless of the cause, has resulted in sequelae that include high fever, altered mental status, exaggerated rebound spasticity, and muscle rigidity, that in rare cases has advanced to rhabdomyolysis, multiple organ-system failure and death.

Prevention of abrupt discontinuation of intrathecal baclofen requires careful attention to programming and monitoring of the infusion system, refill scheduling and procedures, and pump alarms. Patients and caregivers should be advised of the importance of keeping scheduled refill visits and should be educated on the early symptoms of baclofen withdrawal. Special attention should be given to patients at apparent risk (e.g. spinal cord injuries at T-6 or above, communication difficulties, history of withdrawal symptoms from oral or intrathecal baclofen). Consult the technical manual of the implantable infusion system for additional post-implant clinician and patient information.

CONTRAINDICATIONS

Hypersensitivity to baclofen.

Do not use Gablofen for intravenous, intramuscular, subcutaneous or epidural administration.

WARNINGS AND PRECAUTIONS

Risk of life-threatening overdose during pump refills. Use extreme caution when filling the Medtronic SynchroMed® II Programmable Pump which is equipped with an injection port that allows direct access to the intrathecal catheter. Direct injection into the catheter through the catheter access port may cause a life-threatening overdose.

Use only with Medtronic SynchroMed® II Programmable Pump (or other pumps labeled for intrathecal administration of Gablofen (baclofen injection)).

Potential for contamination due to non-sterile external surface of prefilled syringe. Although the drug solution and pathway in the Gablofen prefilled syringes are sterile, the external surface of the prefilled syringes (all strengths, including the 50 mcg/mL strength) are non-sterile and have the potential to lead to contamination and consequent adverse reactions. The use of Gablofen prefilled syringe in an aseptic setting (e.g., operating room) to fill sterile intrathecal pumps prior to implantation in patients is not recommended, unless the external surface of the prefilled syringe is treated to ensure sterility. Gablofen supplied in vials may be used with conventional aseptic technique to fill intrathecal pumps prior to implantation.

Resuscitative equipment and trained staff must be available during screening dose, dose titration, and refills due to the potential life-threatening CNS depression, cardiovascular collapse, and/or respiratory failure.

Overdose may cause drowsiness, lightheadedness, dizziness, somnolence, respiratory depression, seizures, rostral progression of hypotonia and loss of consciousness progressing to coma.

Use with caution in patients with psychotic disorders, schizophrenia or confusional states as it may exacerbate condition(s).

Fatalities have been reported with intrathecal baclofen use.

Caution should be used in patients with a history of autonomic dysreflexia.

Presence of infection may increase the risk of surgical complication and complicate dosing of Gablofen.

May cause drowsiness: use caution in operation of automobiles, dangerous machinery and activity that may be hazardous by decreased alertness. Other CNS depressants and alcohol may add to this effect.

Potential development of intrathecal mass formation. Clinicians should monitor for signs and symptoms of new neurologic symptoms including the use of imaging diagnostic modalities.

Oral baclofen use has been associated with a dose-related increase in incidence of ovarian cysts.

ADVERSE REACTIONS

SERIOUS ADVERSE REACTIONS

Sudden withdrawal of Gablofen can result in serious complications that include high fever, confusion, muscle stiffness, multiple organ-system failure, and death. Inform patients that early symptoms of Gablofen withdrawal may include increased spasticity, itching, and tingling of extremities. If Gablofen withdrawal or a pump malfunction is suspected, patients should be brought immediately to a hospital for assessment and treatment.

Gablofen overdose may occur suddenly or insidiously, and symptoms may include confusion, drowsiness, lightheadedness, dizziness, slow or shallow breathing, seizures, loss of muscle tone, loss of consciousness, and coma.

Other serious adverse events may include: potential development of intrathecal mass formation, drainage, infection, meningitis, unmanageable trunk control, CSF leakage, coma and death.

COMMON ADVERSE REACTIONS

The most common adverse reactions in patients with spasticity of spinal origin were hypotonia (25.3%), somnolence (20.9%), dizziness, nausea/vomiting, hypotension, headache, and convulsions.

The most common adverse reactions in patients with spasticity of cerebral origin were hypotonia (34.7%), somnolence (18.7%), headache (10.7%), agitation, constipation, leukocytosis, chills, and urinary retention.

Other common adverse events may include hypoventilation, hypertonia, paresthesia, increased salivation, back pain, pruritus, diarrhea, peripheral edema, asthenia, pain, confusion, speech disorder, amblyopia, accidental injury, and dry mouth.

USE IN SPECIFIC POPULATIONS

Pregnancy Category C. The effect of baclofen in labor and delivery is unknown.

Breastfeeding: Baclofen is excreted into breast milk at oral therapeutic doses.

Pediatric use: Safety and effectiveness in pediatric patients below the age of 4 years have not been established.

MITIGO™ INDICATIONS AND USAGE

MITIGO (Morphine Sulfate Injection, USP – Preservative-free) is an opioid agonist for use in continuous microinfusion devices and indicated only for intrathecal or epidural infusion in the management of intractable chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Important Risk Information

WARNING: RISKS WITH NEURAXIAL ADMINISTRATION; LIFE-THREATENING RESPIRATORY DEPRESSION; RISK OF ADDICTION, ABUSE, AND MISUSE; NEONATAL OPIOID WITHDRAWAL SYNDROME; and RISKS FROM CONCOMITANT USE WITH BENZODIAZEPINES OR OTHER CNS DEPRESSANTS See full prescribing information for complete boxed warning.

Single-dose neuraxial administration may result in acute or delayed respiratory depression up to 24 hours. Because of the risk of severe adverse reactions when MITIGO is administered by the epidural or intrathecal route of administration, patients must be observed in a fully equipped and staffed environment for at least 24 hours after the initial dose.

Serious, life-threatening, or fatal respiratory depression may occur. Monitor closely, especially upon initiation or following a dose increase. Patients must be observed in a fully equipped and staffed environment for at least 24 hours after each test dose and, as indicated, for the first several days after surgery.

MITIGO exposes users to risks of addiction, abuse, and misuse, which can lead to overdose and death. Assess patient's risk before prescribing and monitor regularly for these behaviors and conditions.

Prolonged use of MITIGO during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated. If prolonged opioid use is required in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

Concomitant use of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death. Reserve concomitant prescribing for use in patients for whom alternative treatment options are inadequate; limit dosages and durations to the minimum required; and follow patients for signs and symptoms of respiratory depression and sedation.

CONTRAINDICATIONS

Significant respiratory depression

Acute or severe bronchial asthma in an unmonitored setting in absence of resuscitative equipment Concurrent use of monoamine oxidase inhibitors (MAOIs) or use of MAOIs within the last 14 days

Known or suspected gastrointestinal obstruction, including paralytic ileus

Hypersensitivity or intolerance to morphine Neuraxial administration of MITIGO is contraindicated in patients with: Infection at the injection microinfusion site, concomitant anticoagulant therapy, uncontrolled bleeding diathesis the presence of any other concomitant therapy or medical condition, which would render epidural or intrathecal administration of medication especially hazardous

WARNINGS AND PRECAUTIONS

Risk of Inflammatory Masses: Monitor patients receiving continuous infusion of MITIGO via indwelling intrathecal catheter for new signs or symptoms of neurologic impairment. Risk of Tolerance and Myoclonic Activity: Monitor patients for unusual acceleration of neuraxial morphine, which may cause myoclonic-like spasm of lower extremities. Detoxification may be required. Life-Threatening Respiratory Depression in Patients with Chronic Pulmonary Disease or in Elderly, Cachectic, or Debilitated Patients: Monitor closely, particularly during initiation and titration.

Adrenal Insufficiency: If diagnosed, treat with physiologic replacement of corticosteroids, and wean patient off of the opioid. Severe Hypotension: Monitor during dosage initiation and titration. Avoid use of MITIGO in patients with circulatory shock Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness: Monitor for sedation and respiratory depression. Avoid use of MITIGO in patients with impaired consciousness or coma.

ADVERSE REACTIONS

Most serious adverse reactions were respiratory depression, apnea, circulatory depression, respiratory arrest, shock, and cardiac arrest. Other common frequently observed adverse reactions include: sedation, lightheadedness, dizziness, nausea, vomiting, and constipation.

USE IN SPECIFIC POPULATIONS

Pregnancy: May cause fetal harm. Hepatic and Renal Impairment: May affect the metabolism and excretion of MITIGO.

Adverse Events, Product Monitoring, and Medical Inquiries, please call 888.525.8114 or email Global Medical Information at medical.information@piramal.com. You may also report this information to the FDA's MedWatch Reporting System by phone at 1.800.FDA.1088, by facsimile at 1.800.FDA.0178, or by mail using Form 3500 available at www.fda.gov/medwatch. For additional Important Risk Information, including boxed warning, see Full Prescribing Information.

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