PRESS RELEASE

Daiichi Sankyo, Inc. and Inspirion Delivery Sciences LLC Announce U.S. Licensing Agreement for MorphaBond™ Formulated with SentryBond™ Abuse-Deterrent Technology

Parsippany, NJ and Basking Ridge, NJ – (October 25, 2016) – Daiichi Sankyo, Inc. and Inspirion Delivery Sciences LLC (Inspirion) announced today that the companies have entered into a strategic collaboration agreement in the U.S. to commercialize FDA-approved MorphaBond™ (morphine sulfate) extended-release tablets, CII. The agreement also provides Daiichi Sankyo, Inc. with the rights to commercialize a separate investigational Inspirion compound in the U.S., if approved by the U.S. Food and Drug Administration (FDA). Both MorphaBond and the second product feature SentryBond™, a unique, patent-protected abuse-deterrent technology. MorphaBond (morphine sulfate) extended-release tablets, CII is an abuse-deterrent opioid indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate.

Under the terms of the agreement, which is pending Hart-Scott-Rodino clearance, Inspirion will receive an upfront payment, in addition to milestone payments and royalties. Daiichi Sankyo will lead the commercialization of the co-promotion with Inspirion for MorphaBond, and if approved, the second product.

MorphaBond is an abuse-deterrent formulation of extended release morphine using physical and chemical barriers, without the use of aversive agents or opioid antagonists. MorphaBond is formulated with inactive ingredients that make the tablet more difficult to adulterate for misuse and abuse while maintaining extended-release characteristics even if the tablet is subjected to physical manipulation and/or chemical extraction.

Relative to morphine sulfate extended-release tablets, these properties of MorphaBond increase resistance to cutting, crushing, or breaking using a variety of tools. When subjected to a liquid environment the manipulated MorphaBond formulation forms a viscous material that resists passage through a needle.

MorphaBond was developed in accordance with the FDA Guidance on Abuse-Deterrent Opioids.[i] MorphaBond has been tested in vitro using methods of manipulation that drug abusers commonly use for preparation of extended-release opioids for administration by various

routes, including oral consumption, intranasal insufflation, injection, and smoking. Overall, data from the Category 1 through Category 3 in vitro and in vivo studies suggest that MorphaBond has properties that are expected to reduce abuse or misuse via injection or insufflation; however, abuse by these routes is still possible.

“Our goal is to become a leader in the pain therapeutic area and to be known as a company that is focused on the needs of patients and committed to being part of the solution to prescription drug abuse,” says Ken Keller, President, Administrative and Commercial at Daiichi Sankyo, Inc. “MorphaBond is a valuable addition to the growing pain franchise at Daiichi Sankyo and will offer healthcare providers with a new option as part of a comprehensive approach to treating pain while fighting against the potential for abuse.”

“The FDA approval, this collaboration, and the joint commercialization of MorphaBond with Daiichi Sankyo are major milestones for Inspirion,” says Stefan Aigner, MD, CEO of Inspirion. “Daiichi Sankyo is a leader in the U.S. pharmaceutical market and has established a substantial presence in the opioid market. Inspirion is excited to be collaborating together on the launch of MorphaBond.”

"Opioids have been integral in the management of moderate to severe pain for decades. However, a national public health crisis of prescription opioid abuse has evolved in the U.S. The development of abuse-deterrent formulations of opioids in concert with other opioid risk mitigation methods is imperative,” said Joseph V. Pergolizzi Jr, MD, co-founder and Chief Operating Officer of NEMA Research, a Clinical Research Organization, and President of Naples Anesthesia and Pain Associates of Naples, Florida.

Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, physicians should reserve MorphaBond for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain. MorphaBond is not indicated as an as-needed (prn) analgesic.

MorphaBond should be prescribed only by healthcare professionals who are knowledgeable in the use of opioids for the management of chronic pain.

About SentryBond™

The SentryBond technology platform combines inactive excipients with active pharmaceutical ingredients in a tablet that is specifically designed to frustrate abuse via various methods of manipulation and routes of administration. When subjected to physical manipulation and/or attempts at chemical extraction, SentryBond is designed to maintain the intended release profile of extended-release products and to delay the release of immediate release products. Inspirion's technology imparts its abuse-deterrent characteristics via physical and chemical methods, without the use of antagonist or aversive agents. SentryBond technology is covered by an issued U.S. patent, with multiple U.S. and global patent applications pending.

About Inspirion Delivery Sciences LLC
Inspirion Delivery Sciences LLC is a privately held specialty pharmaceutical company that is dedicated to advancing solutions in the field of prescription drug abuse deterrence through continued innovation. Recognizing the serious unmet public health need to combat the escalating crisis of prescription opioid abuse and misuse, Inspirion began pioneering the development of novel abuse-deterrent technologies. For more information, visit the Company's website at www.inspiriondeliverysciences.com.

About Daiichi Sankyo
Daiichi Sankyo Group is dedicated to the creation and supply of innovative pharmaceutical products to address diversified, unmet medical needs of patients in both mature and emerging markets. With over 100 years of scientific expertise and a presence in more than 20 countries, Daiichi Sankyo and its 16,000 employees around the world draw upon a rich legacy of innovation and a robust pipeline of promising new medicines to help people. In addition to a strong portfolio of medicines for hypertension and thrombotic disorders, under the Group's 2025 Vision to become a "Global Pharma Innovator with a Competitive Advantage in Oncology," Daiichi Sankyo research and development is primarily focused on bringing forth novel therapies in oncology, including immuno-oncology, with additional focus on new horizon areas, such as pain management, neurodegenerative diseases, heart and kidney diseases, and other rare diseases. For more information, please visit: www.daiichisankyo.com. Daiichi Sankyo, Inc., headquartered in Parsippany, New Jersey, is a member of the Daiichi Sankyo Group. To learn more about Daiichi Sankyo, Inc., please visit www.dsi.com.

INDICATION AND IMPORTANT SAFETY INFORMATION

INDICATION

MORPHABOND™ (morphine sulfate) extended-release tablets, for oral use, CII is indicated for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Limitations of Use
Because of the risks of addiction, abuse, and misuse with opioids, even at recommended doses, and because of the greater risks of overdose and death with extended-release opioid formulations, reserve MORPHABOND for use in patients for whom alternative treatment options (e.g., non-opioid analgesics or immediate-release opioids) are ineffective, not tolerated, or would be otherwise inadequate to provide sufficient management of pain.

MORPHABOND is not indicated as an as-needed (prn) analgesic.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: ADDICTION, ABUSE, and MISUSE; LIFE-THREATENING RESPIRATORY DEPRESSION; ACCIDENTAL INGESTION; and NEONATAL OPIOID WITHDRAWAL SYNDROME

Addiction, Abuse, and Misuse

MORPHABOND™ exposes patients and other users to the risks of opioid addiction, abuse, and misuse, which can lead to overdose and death. Assess each patient's risk prior to prescribing MORPHABOND, and monitor all patients regularly for the development of these behaviors or conditions.

Life-Threatening Respiratory Depression

Serious, life-threatening, or fatal respiratory depression may occur with use of MORPHABOND. Monitor for respiratory depression, especially during initiation of MORPHABOND or following a dose increase. Instruct patients to swallow MORPHABOND tablets whole; crushing, chewing, or dissolving MORPHABOND tablets can cause rapid release and absorption of a potentially fatal dose of morphine.

Accidental Ingestion

Accidental ingestion of even one dose of MORPHABOND, especially by children, can result in a fatal overdose of morphine.

Neonatal Opioid Withdrawal Syndrome

Prolonged use of MORPHABOND during pregnancy can result in neonatal opioid withdrawal syndrome, which may be life-threatening if not recognized and treated, and requires management according to protocols developed by neonatology experts. If opioid use is required for a prolonged period in a pregnant woman, advise the patient of the risk of neonatal opioid withdrawal syndrome and ensure that appropriate treatment will be available.

CONTRAINDICATIONS

MORPHABOND is contraindicated in patients with: significant respiratory depression; acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment; known or suspected gastrointestinal obstruction, including paralytic ileus; and hypersensitivity (e.g., anaphylaxis) to morphine.

WARNINGS AND PRECAUTIONS

Addiction, Abuse, and Misuse

MORPHABOND contains morphine, a Schedule II controlled substance, and thus exposes its users to the risks of addiction, abuse, and misuse. As extended-release products such as MORPHABOND deliver the opioid over an extended period of time, there is a greater risk for overdose and death due to the larger amount of morphine present. Although the risk of addiction in any individual is unknown, it can occur in patients appropriately prescribed MORPHABOND and in those who obtain the drug illicitly. Addiction can occur at recommended doses and if the drug is misused or abused.

Assess each patient's risk for opioid addiction, abuse, or misuse prior to prescribing MORPHABOND, and monitor all patients receiving MORPHABOND for development of these behaviors or conditions. Risks are increased in patients with a personal or family history of substance abuse (including drug or alcohol abuse or addiction) or mental illness. The potential for these risks should not, however, prevent the proper management of pain in any given patient. Patients at increased risk may be prescribed extended-release opioid formulations such as MORPHABOND, but use in such patients necessitates intensive counseling about the risks of proper use of MORPHABOND along with intensive monitoring for signs of addiction, abuse, and misuse.

Abuse or misuse of MORPHABOND by crushing, chewing, snorting, or injecting the dissolved product will result in the uncontrolled delivery of morphine and can result in overdose and death. Opioid agonists such as MORPHABOND are sought by drug abusers and people with addiction disorders and are subject to criminal diversion. Consider these risks when prescribing or dispensing MORPHABOND. Strategies to reduce these risks include prescribing the drug in the smallest appropriate quantity and advising the patient on the proper storage and disposal of unused drug.

Life-Threatening Respiratory Depression
Serious, life-threatening, or fatal respiratory depression has been reported with the use of modified-release opioids, even when used as recommended, and if not immediately recognized and treated, may lead to respiratory arrest and death. Management of respiratory depression may include close observation, supportive measures, and use of opioid antagonists, depending on the patient's clinical status. Carbon dioxide (CO_2) retention from opioid-induced respiratory depression can exacerbate the sedating effects of opioids.

While serious, life-threatening, or fatal respiratory depression can occur at any time during the use of MORPHABOND, the risk is greatest during the initiation of therapy or following a dosage increase. Closely monitor patients for respiratory depression, especially within the first 24-72 hours of initiating therapy with and following dosage increases with MORPHABOND. To reduce the risk of respiratory depression, proper dosing and titration of MORPHABOND are essential. Overestimating the MORPHABOND dosage when converting patients from another opioid product can result in a fatal overdose with the first dose.

Risks due to Interactions with Central Nervous System Depressants
Hypotension, profound sedation, respiratory depression, coma, and death may result if MORPHABOND is used concomitantly with alcohol or other central nervous system (CNS) depressants (e.g., sedatives, tranquilizers, general anesthetics, phenothiazines, anxiolytics, hypnotics, neuroleptics, other opioids). When considering the use of MORPHABOND in a patient taking a CNS depressant, assess the duration of use of the CNS depressant and the patient's response, including the degree of tolerance that has developed to CNS depression. Additionally, evaluate the patient's use of alcohol and/or illicit drugs that cause CNS depression. If the decision to begin MORPHABOND is made, start with a lower dosage of MORPHABOND,

monitor patients for signs of sedation, respiratory depression, and hypotension, and consider using a lower dosage of the concomitant CNS depressant.

Risk of Life Threatening Respiratory Depression in Elderly, Cachectic, and Debilitated Patients

Life-threatening respiratory depression is more likely to occur in elderly, cachectic, or debilitated patients as they may have altered pharmacokinetics or altered clearance compared to younger, healthier patients. Monitor such patients closely, particularly when initiating and titrating MORPHABOND and when MORPHABOND is given concomitantly with other drugs that depress respiration.

Risk of Apnea in Patients with Chronic Pulmonary Disease

The use of MORPHABOND in patients with acute or severe bronchial asthma in an unmonitored setting or in the absence of resuscitative equipment is contraindicated. MORPHABOND-treated patients with significant chronic obstructive pulmonary disease or cor pulmonale, and those with a substantially decreased respiratory reserve, hypoxia, hypercapnia, or pre-existing respiratory depression are at increased risk of decreased respiratory drive including apnea even at recommended dosages of MORPHABOND. Therefore, closely monitor these patients especially when initiating and titrating MORPHABOND. Alternatively, consider the use of alternative non-opioid analgesics in these patients.

Severe Hypotension

MORPHABOND may cause severe hypotension including orthostatic hypotension and syncope in ambulatory patients. There is an increased risk in patients whose ability to maintain blood pressure has already been compromised by a reduced blood volume or concurrent administration of certain CNS depressant drugs. Monitor these patients for signs of hypotension after initiating or titrating the dosage of MORPHABOND. In patients with circulatory shock, MORPHABOND may cause vasodilation that can further reduce cardiac output and blood pressure. Avoid the use of MORPHABOND in patients with circulatory shock.

Risks of Use in Patients with Increased Intracranial Pressure, Brain Tumors, Head Injury, or Impaired Consciousness

In patients who may be susceptible to the intracranial effects of CO2 retention (e.g., those with evidence of increased intracranial pressure or brain tumors), MORPHABOND may reduce respiratory drive, and the resultant CO2 retention can further increase intracranial pressure. Monitor such patients for signs of sedation and respiratory depression, particularly when initiating therapy with MORPHABOND. Avoid the use of MORPHABOND in patients with impaired consciousness or coma.

Risks of Use in Patients with Gastrointestinal Conditions

MORPHABOND is contraindicated in patients with gastrointestinal obstruction, including paralytic ileus. The morphine in MORPHABOND may cause spasm of the sphincter of Oddi. Opioids may cause increases in the serum amylase. Monitor patients with biliary tract disease, including acute pancreatitis, for worsening symptoms.

Increased Risk of Seizures in Patients with Seizure Disorders
The morphine in MORPHABOND may increase the frequency of seizures in patients with seizure disorders, and may increase the risk of seizures occurring in other clinical settings associated with seizures. Monitor patients with a history of seizure disorders for worsened seizure control during MORPHABOND therapy.

Withdrawal
Avoid the use of mixed agonist/antagonist (e.g., pentazocine, nalbuphine, and butorphanol) or partial agonist (e.g., buprenorphine) analgesics in patients who have received or are receiving a course of therapy with a full opioid agonist analgesic, including MORPHABOND. In these patients, mixed agonists/antagonist and partial agonist analgesics may reduce the analgesic effect and/or may precipitate withdrawal symptoms. When discontinuing MORPHABOND, gradually taper the dosage. Do not abruptly discontinue MORPHABOND.

Risks of Driving and Operating Machinery
MORPHABOND may impair the mental or physical abilities needed to perform potentially hazardous activities such as driving a car or operating machinery. Warn patients not to drive or operate dangerous machinery unless they are tolerant to the effects of MORPHABOND and know how they will react to the medication

Adverse Reactions
In clinical trials, the most common adverse reactions were constipation, dizziness, sedation, nausea, vomiting, sweating, dysphoria, and euphoric mood.

Drug Interactions
- Concomitant use of CNS depressants can increase the risk of respiratory depression, profound sedation, coma and death.
- Mixed agonist/antagonist and partial agonist opioid analgesics may reduce the analgesic effect of MORPHABOND and/or may precipitate withdrawal symptoms.
- Morphine may enhance the neuromuscular blocking action of skeletal muscle relaxants and produce an increased degree of respiratory depression.
- The concomitant use of MAOIs can potentiate the effects of morphine and can increase the risk of hypotension, respiratory depression, profound sedation, coma, and death.
- The concomitant use of cimetidine can potentiate morphine effects and increase risk of hypotension, respiratory depression, profound sedation, coma, and death.
- Opioids can reduce the efficacy of diuretics by inducing the release of antidiuretic hormone.
- The concomitant use of anticholinergic drugs may increase risk of urinary retention and/or severe constipation, which may lead to paralytic ileus.
- The concomitant use of PGP-inhibitors can increase the exposure to morphine by about two-fold and can increase risk of hypotension, respiratory depression, profound sedation, coma, and death.

These are not all the possible side effects of MorphaBond. Please see Full Prescribing Information, including BOXED WARNINGS, and Medication Guide. Patients and health care providers may report side effects to FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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REFERENCES

[i] Food and Drug Administration (FDA). Guidance for Industry: Abuse-deterrent opioids – evaluation and labeling 2015 [Accessed October 11, 2016]. Available at: http://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm334743.pdf.