Mallinckrodt To Sell Intrathecal Therapy Business To Piramal Enterprises Limited For Approximately $203 Million

-- Transaction advances Mallinckrodt's strategic portfolio transformation --

STAINES-UPON-THAMES, United Kingdom, Jan. 30, 2017 /PRNewswire/ -- Mallinckrodt plc (NYSE: MNK), a leading specialty pharmaceutical company, announced today it has entered into an agreement under which it will sell its Intrathecal Therapy business to Piramal Enterprises Limited's subsidiary in the U.K., Piramal Critical Care, for approximately $203 million, including fixed and contingent consideration. Piramal Critical Care is an integral business unit of Piramal Enterprises Limited and a global leader in the field of anesthesia.

Mallinckrodt Pharmaceuticals

Mallinckrodt's Intrathecal Therapy business markets products for the treatment of spasticity via intrathecal (spinal column) drug delivery. The key asset is Gablofen® (baclofen injection), a product approved by the U.S. Food and Drug Administration (FDA) for use in management of severe spasticity of cerebral or spinal origin in adult and pediatric patients age 4 years and above. Gablofen is the only FDA-approved baclofen in prefilled syringes and factory-sealed vials. Mallinckrodt also has a higher Gablofen concentration in late-stage development which, if approved, would help address physicians' demand for more refill options. Both currently marketed intrathecal products and those in development are included in the transaction.

"Mallinckrodt is transforming its portfolio to become a top-performing specialty pharmaceutical company, systematically divesting non-core businesses to build upon our growth platforms in autoimmune and rare diseases and hospital therapies," said **Mark Trudeau, President and Chief Executive Officer of Mallinckrodt**. "While net sales for our Intrathecal Therapy business have increased approximately 50% since 2012 and it has become significantly more profitable, the products have limited commercial synergy with other parts of our growing Specialty Brands segment. The sale of this business to Piramal is the best solution to meet patient needs and will free resources for us to invest in additional growth."

Fiscal 2016 net sales of Intrathecal Therapy products were $44.6 million and reported as part of Mallinckrodt's Specialty Brands segment within the "Other" line. The sale of the business does not qualify for GAAP[1] treatment as a discontinued operation, and therefore historical sales and earnings results will not be recast to reflect the divestiture. Assuming the transaction closes in the first quarter of 2017, the sale is expected to dilute 2017 earnings per share from continuing operations by between $0.20 and $0.25, with anticipated dilution declining in 2018 and beyond. Mallinckrodt believes the majority of the negative earnings impact will be offset by expense management, strength of the continuing businesses and further reduction in share count through ongoing share repurchases.

"This divesture is in line with our ongoing focus on driving return on invested capital decisions we make on behalf of shareholders," said **Matt Harbaugh, Executive Vice President and Chief Financial Officer of Mallinckrodt**. "The transaction is a perfect example of how we pursue activities that have positive economic outcomes."

The approximately $203 million transaction will consist of $171 million of fixed consideration of which 10%, or $17 million, will be paid at closing, and an additional $154 million will be paid on the first anniversary of the close date. The remaining total consideration of up to $32 million is contingent, based on the gross profit of the Gablofen products in 2018 and 2019. The transaction is subject to customary closing conditions, and Mallinckrodt expects to complete the transaction in the first quarter of 2017.

About Gablofen
Gablofen is indicated for use in the management of severe spasticity of cerebral or spinal origin. Approved by the FDA in late 2010, Gablofen is a branded, AP-rated alternative for Lioresal® Intrathecal (baclofen injection) and is listed in the FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations.

PLEASE SEE IMPORTANT RISK INFORMATION, INCLUDING BOXED WARNING BELOW.

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

WARNING: DO NOT DISCONTINUE ABRUPTLY

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 made 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.

SERIOUS ADVERSE EVENTS:

- 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 that 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 EVENTS:

- 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.

materials and specialized chemistry, formulation and manufacturing capabilities. The company's Specialty Brands segment includes branded medicines and its Specialty Generics segment includes specialty generic drugs, active pharmaceutical ingredients and external manufacturing. To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt uses its website as a channel of distribution of important company information, such as press releases, investor presentations and other financial information. It also uses its website to expedite public access to time-critical information regarding the company in advance of or in lieu of distributing a press release or a filing with the U.S. Securities and Exchange Commission disclosing the same information. Therefore, investors should look to the Investor Relations page of the website for important and time-critical information. Visitors to the website can also register to receive automatic e-mail and other notifications alerting them when new information is made available on the Investor Relations page of the website.

Cautionary Statements Related to Forward-Looking Statements

Statements in this document that are not strictly historical, including statements regarding future financial condition and operating results, economic, business, competitive and/or regulatory factors affecting Mallinckrodt's businesses and any other statements regarding events or developments that we believe or anticipate will or may occur in the future, may be "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995, and involve a number of risks and uncertainties.

There are a number of important factors that could cause actual events to differ materially from those suggested or indicated by such forward-looking statements and you should not place undue reliance on any such forward-looking statements. These factors include risks and uncertainties related to, among other things: the parties' ability to satisfy the conditions to the divestiture of the Intrathecal Therapy business and complete the divestiture on the anticipated timeline or at all; general economic conditions and conditions affecting the industries in which Mallinckrodt operates; the commercial success of Mallinckrodt's products; Mallinckrodt's ability to realize anticipated growth, synergies and cost savings from acquisitions; conditions that could necessitate an evaluation of Mallinckrodt's goodwill and/or intangible assets for possible impairment; changes in laws and regulations; Mallinckrodt's ability to successfully integrate acquisitions of operations, technology, products and businesses generally and to realize anticipated growth, synergies and cost savings; Mallinckrodt's ability to successfully develop or commercialize new products; Mallinckrodt's ability to protect intellectual property rights; Mallinckrodt's ability to receive procurement and production quotas granted by the U.S. Drug Enforcement Administration; customer concentration; Mallinckrodt's reliance on certain individual products that are material to its financial performance; cost containment efforts of customers, purchasing groups, third-party payers and governmental organizations; the reimbursement practices of a small number of public or private insurers; pricing pressure on certain of Mallinckrodt's products due to legal changes or changes in insurers' reimbursement practices resulting from recent increased public scrutiny of healthcare and pharmaceutical costs; limited clinical trial data for H.P. Acthar Gel; complex reporting and payment obligations under healthcare rebate programs; Mallinckrodt's ability to navigate price fluctuations; future changes to U.S. and foreign tax laws; Mallinckrodt's ability to achieve expected benefits from restructuring activities; complex manufacturing processes; competition; product liability losses and other litigation liability; ongoing governmental investigations; material health, safety and environmental liabilities; retention of key personnel; conducting business internationally; the effectiveness of information technology infrastructure; and cybersecurity and data leakage risks.

These and other factors are identified and described in more detail in the "Risk Factors" section of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended September 30, 2016. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt does not assume any obligation to update or revise any forward-looking statement, whether as a result of new information, future events and developments or otherwise, except as required by law.

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