November 2, 2017

Mallinckrodt to Acquire Ocera Therapeutics and OCR-002, its Proprietary Therapy in Development for Treatment of Hepatic Encephalopathy

-- Mallinckrodt to commence cash tender offer to purchase Ocera Therapeutics for $1.52 per share, plus Contingent Value Right --

-- Hepatic encephalopathy (HE) is a neuropsychiatric syndrome associated with hyperammonemia (excess ammonia in the blood) that occurs as complications of liver disease, such as cirrhosis --

-- Roughly 200,000 U.S. hospitalizations result from acute HE each year; approximately 1.5 to 2 million patients are at risk of recurrent HE --

-- Average of $30,000-$60,000 per hospital stay; total acute and recurrent HE market potential opportunity of $5.0-$7.0 billion --

-- If approved, OCR-002 is expected to become the first intravenous pharmacologic option indicated for treatment of acute HE in the U.S.; FDA Orphan Drug designation and Fast Track status granted; EMA Orphan Drug designation --

-- Acquisition further expands Mallinckrodt's focus on treatments for severe and critical diseases in hepatic and renal conditions; diversifies portfolio pipeline with differentiated, highly durable product which aligns well with company's terlipressin development asset --

-- Assuming expected 2017 close, company expects dilution from acquisition to adjusted diluted earnings per share of approximately $0.25 to $0.35 annually beginning in 2018 --

STAINES-UPON-THAMES, United Kingdom and REDWOOD CITY, Calif., Nov. 02, 2017 (GLOBE NEWSWIRE) -- Mallinckrodt plc (NYSE:MNK), a leading global specialty pharmaceutical company, and Ocera Therapeutics, Inc. (NASDAQ:OCRX), today announced that they have entered into an agreement under which Mallinckrodt will acquire Ocera, a clinical stage biopharmaceutical company focused on the development and commercialization of novel therapeutics for orphan and other serious liver diseases with high unmet medical need. Ocera's developmental product OCR-002, an ammonia scavenger, is being studied for treatment of hepatic encephalopathy, a neuropsychiatric syndrome associated with hyperammonemia, a complication of acute or chronic liver disease.

OCR-002 is a Phase 2 asset with both intravenous (IV) and oral formulations. Despite inability to meet statistical significance in its primary endpoint, Ocera's Phase 2 STOP-HE trial[1] achieved secondary endpoints that revealed differentiated clinical impact, including demonstrated effect on lowering serum ammonia levels. Mallinckrodt believes that trial design elements, in part, drove the primary outcome and, on acquisition, will invest to establish the optimal dosing regimen prior to initiating a Phase 3 program. Mallinckrodt will have continued engagement with the U.S. Food and Drug Administration (FDA) to confirm the regulatory pathway to gain FDA approval and subsequently launch the IV formulation, expected by 2022, and the oral formulation, expected by 2024.

The FDA granted OCR-002 its Orphan Drug Designation, and the resulting seven years' exclusivity would be applied upon first approval of the drug. The FDA also granted its Fast Track designation, a process designed to facilitate development and expedite the review of drugs to treat serious conditions and fill an unmet medical need[2]. The European Medicines Agency (EMA) also granted Orphan Drug status to OCR-002. If approved, the drug will have substantial durability through its Orphan Drug status and additionally through intellectual property that extends to at least 2030[3].

"Hepatic encephalopathy can be a debilitating condition, affecting brain function and, in some cases, resulting in coma or death," said **Steven Romano, M.D., Chief Scientific Officer and Executive Vice President of Mallinckrodt.** "We look forward to bringing this much-needed treatment option to patients who suffer from this condition."

"We believe OCR-002 has the potential to help thousands of patients whose hepatic encephalopathy is insufficiently treated by current therapies," said **Linda S. Grais, M.D., President and Chief Executive Officer, Ocera**. "We're excited by the additional development capability and commercial reach that can be gained by becoming part of Mallinckrodt. With this focus, I'm confident this important treatment can be successfully brought to market."

Understanding Hepatic Encephalopathy

Roughly 30 to 35 million U.S. patients have chronic liver disease[4], which can develop into liver cirrhosis in some cases, a condition where the liver becomes damaged and irreversibly scarred. Cirrhosis can be brought on by a wide range of underlying causes such as nonalcoholic steatohepatitis, or fatty liver disease; alcohol use; hepatitis; autoimmune diseases; diabetes; and obesity. Approximately 5.5 million patients in the U.S. have liver cirrhosis[5].

Cirrhosis impedes the liver's ability to remove toxins from the body, including ammonia. **Hepatic encephalopathy** (HE) is a critical neuropsychiatric condition resulting from hyperammonemia (excess ammonia in the blood).While many patients who develop HE will have cirrhosis, incidents of HE are also reported in patients with other types of liver disease such as acute liver failure or bypass shunts. Progression of HE is measured through neurocognitive symptoms[6], including personality changes, disorientation, stupor and, in severe cases, coma or death.

Acute HE is usually initially diagnosed in the emergency department, and treated by a hepatologist or gastroenterologist; outside the hospital, HE is largely treated by gastroenterologists. Hospitalized HE patients with other underlying triggers or conditions, e.g., gastrointestinal bleeding or infection, will be sent to the intensive care unit (ICU). Severe acute HE patients will also likely be sent to the ICU. The typical length of overall hospital stay for an acute HE episode is five to seven days, though it may be longer for patients with concomitant conditions. Many acute HE patients have a recurrence and will be readmitted to the hospital with subsequent acute HE episodes.

OCR-002 Eliminates Ammonia from Bloodstream through Novel Method of Action

Although the STOP-HE study[7] did not meet its primary endpoint, it achieved secondary endpoints that validated OCR-002 as a potent ammonia scavenger, leading to significant reduction in circulating ammonia (p=0.017). In a subsequent, post-hoc analysis of the data, it was observed that the degree of ammonia reduction in patients correlated strongly with clinical improvement. As the response rate also appeared to increase proportionally to dose level, this suggests that some patients in the Phase 2 trial may have been under-dosed.

Treatment with OCR-002 rapidly eliminates ammonia in the bloodstream, excreting it through the kidneys, a more effective and less burdensome method of addressing HE than existing treatment options. Those alternatives include lactulose, a laxative that frequently causes severe diarrhea, and Rifaximin, an antibiotic indicated only for reduction of recurrent HE, which can cause broad gastrointestinal issues and is restricted for patients with severe liver issues.

OCR-002's active ingredients are ornithine and phenylacetic acid (PAA). The unique method of action includes:

- Ornithine contributes to glutamate, which combines with ammonia to create glutamine, a carrier of ammonia that "pushes" ammonia through the body.
- PAA combines with glutamine to form phenylacetylglutamine, "pulling" ammonia into the urine and excreting it through the kidneys.

The IV formulation of OCR-002, if approved, is expected to provide rapid reduction in symptoms of acute HE, and potentially reduce hospitalization stay. A subset of patients continues to have HE symptoms after discharge. OCR-002's oral formulation, if approved, is expected to provide post-discharge continuity of care for the HE patient, reducing the risk of recurrent HE episodes and rehospitalization. It is also anticipated that patients may transition from the IV to the oral formulation prior to discharge from the hospital setting.

"We believe OCR-002 has the potential to significantly alter the treatment paradigm for patients suffering from this serious condition," said **Mark Trudeau, Chief Executive Officer and President of Mallinckrodt**. "The addition of this highly durable, unique developmental asset to our portfolio is an excellent example of Mallinckrodt's strategic vision as a patient-centric, innovation driven specialty pharmaceutical growth company focusing on severe and critical conditions."

Hepatic Encephalopathy Market

Approximately 200,000 U.S. patients are hospitalized with acute HE annually. Acute HE patients' average hospital stay is five to seven days, at an average cost of $30,000 to $60,000 per stay[8]. There is a 40 to 50 percent recurrence rate and potential rehospitalization within the first year of an acute event, with the likelihood of recurrence increasing with severity[9]. Only 50 to 60% of high-risk patients are receiving current standard of care and fewer stay on therapy due to poor compliance[10].

The U.S. potential market opportunity is estimated at $5 to $7 billion[11,[12]], with $2 to $3 billion in acute treatment and $3 to $4 billion for recurrent incidents. Approximately 1.5 to 2 million patients are at risk of HE[13]. As noted, no intravenous FDA-approved therapy exists for the treatment of acute HE.

Ocera holds worldwide rights to OCR-002, and Mallinckrodt estimates the market for HE patients in Europe and Japan to be in the range of 150,000 to 200,000 annually. Mallinckrodt will assess regulatory pathways for approvals in markets outside the U.S. post-acquisition.

Commercialization
If approved, Mallinckrodt expects OCR-002 to be commercialized by the company's existing sales organizations. At launch, patient access to this unique treatment option would also be supported and enhanced by the company's strong relationships with hospital networks, insurance companies and group purchasing organizations. Mallinckrodt's existing infrastructure of clinical and medical affairs experts will also support approval and launch of both formulations of the product. Mallinckrodt will work with the Ocera development team to ensure smooth integration of the development and regulatory plan.

Financial Considerations and Closing
A subsidiary of Mallinckrodt will commence a cash tender offer to purchase all of the outstanding shares of Ocera Therapeutics common stock for $1.52 per share (approximately $42 million), plus one Contingent Value Right to receive one or more payments in cash of up to $2.58 per share (up to approximately $75 million) based on the successful completion of certain development and sales milestones.

Mallinckrodt expects dilution from the acquisition to adjusted diluted earnings per share by $0.25 to $0.35 annually beginning in 2018, assuming the expected 2017 close. Guidance on the impact of the acquisition to the company's GAAP[14] diluted earnings per share has not been provided due to the inherent difficulty of forecasting the timing or amount of items that would be included in calculating such impact. Subject to customary closing conditions, the company estimates the transaction will close in the fourth quarter of 2017.

ABOUT OCERA
Ocera Therapeutics, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of OCR-002 (ornithine phenylacetate) in both intravenous (IV) and oral formulations. OCR-002 is an ammonia scavenger and has been granted Orphan Drug designation and Fast Track status by the U.S. Food and Drug Administration (FDA) for the treatment of hyperammonemia and resultant hepatic encephalopathy (HE) in patients with acute liver failure and acute-on-chronic liver disease.

Ocera's HE clinical development efforts include a recently completed Phase 2b clinical trial, STOP-HE, which evaluated the safety and efficacy of intravenously-administered OCR-002 in resolving neurocognitive symptoms of acute HE in hospitalized patients with elevated ammonia. Ocera is preparing to meet with the FDA later this year to review the IV program and discuss potential development paths forward.

Ocera is currently evaluating its oral tablet form of OCR-002 in a Phase 2a study in patients with cirrhosis as a chronic use option to maintain remission of HE. Results of this study are expected to be published by the end of 2017. For additional information, please see www.oceraInc.com.

ABOUT MALLINCKRODT
Mallinckrodt is a global business that develops, manufactures, markets and distributes specialty pharmaceutical products and therapies. Areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, nephrology, pulmonology and ophthalmology; immunotherapy and neonatal respiratory critical care therapies; and analgesics and hemostasis products. The company's core strengths include the acquisition and management of highly regulated raw 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 (SEC) 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.

NON-GAAP FINANCIAL MEASURES
This press release references adjusted diluted earnings per share, which is considered a "non-GAAP" financial measure under applicable SEC rules and regulations.

Adjusted diluted earnings per share represent adjusted net income divided by the number of diluted shares. Adjusted net

income represents amounts, prepared in accordance with accounting principles generally accepted in the U.S. (GAAP), adjusted for certain items (on an after-tax basis) that management believes are not reflective of the operational performance of the business. Adjustments to GAAP amounts include restructuring and related charges, net; amortization and impairment charges; discontinued operations; acquisition-related expenses, changes in fair value of contingent consideration obligations; inventory step-up expenses; significant legal and environmental charges ; pension settlement charges; recurrent cash tax payments to the U.S. Internal Revenue Service associated with internal installment sales transactions; and other items identified by the company.

The company has provided these adjusted financial measures because they are used by management, along with financial measures in accordance with GAAP, to evaluate the company's operating performance. In addition, the company believes that they will be used by certain investors to measure Mallinckrodt's operating results. Management believes that presenting these adjusted measures provides useful information about the company's performance across reporting periods on a consistent basis by excluding items that the company does not believe are indicative of its core operating performance.

These adjusted measures should be considered supplemental to and not a substitute for financial information prepared in accordance with GAAP. The company's definition of these adjusted measures may differ from similarly titled measures used by others.

Because adjusted financial measures exclude the effect of items that will increase or decrease the company's reported results of operations, management strongly encourages investors to review the company's consolidated financial statements and publicly filed reports in their entirety.

Cautionary Statements Related to Forward-Looking Statements

Statements in this document that are not strictly historical, including the proposed acquisition of Ocera Therapeutics, Inc., the expected timetable for completing the transaction, statements regarding future financial condition and operating results, economic, business, market opportunity, competitive and/or regulatory factors affecting Mallinckrodt's and Ocera's businesses and any other statements regarding events or developments that the companies 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: general economic conditions and conditions affecting the industries in which Mallinckrodt and Ocera operate; Ocera's ability to obtain regulatory approval to market its product or the timing of such approval process; the commercial success of Mallinckrodt's products and Ocera's product; the parties' ability to satisfy the acquisition agreement conditions and complete the Ocera acquisition on the anticipated timeline or at all; Mallinckrodt's ability to realize anticipated growth, synergies and cost savings from acquisitions (including the Ocera acquisition); 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 (including with respect to the Ocera acquisition); Mallinckrodt's and Mallinckrodt's licensers' ability to successfully develop or commercialize new products; Mallinckrodt's and Mallinckrodt's licensers' 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" sections of Mallinckrodt's Annual Report on Form 10-K for the fiscal year ended September 30, 2016, as well as such sections of Ocera's Annual Report on Form 10-K for the fiscal year ended December 31, 2016. The forward-looking statements made herein speak only as of the date hereof and Mallinckrodt and Ocera do 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.

Additional Information and Notice to Investors

This communication is for informational purposes only and does not constitute an offer to purchase nor a solicitation of an offer to sell any securities of Ocera Therapeutics. The tender offer for the shares of Ocera Therapeutics common stock

described in this communication has not yet commenced. The solicitation and offer to purchase shares of Ocera Therapeutics common stock will only be made pursuant to a tender offer statement on Schedule TO and related exhibits, including the offer to purchase, letter of transmittal, and other related documents. Upon commencement of the tender offer, Mallinckrodt plc and its wholly-owned subsidiaries, MAK LLC and MEH Acquisition Co., will file with the SEC a tender offer statement on Schedule TO and related exhibits, including the offer to purchase, letter of transmittal, and other related documents. In addition, Ocera will file with the SEC a tender offer solicitation/recommendation statement on Schedule 14D-9 with respect to the tender offer. These documents will contain important information, including the terms and conditions of the tender offer. Investors and security holders are urged to read each of these documents and any amendments to these documents carefully when they are available prior to making any decisions with respect to the tender offer. Investors and security holders will be able to obtain free copies of these materials (when available) and other documents filed with the SEC through the web site maintained by the SEC at www.sec.gov. Copies of the documents filed by Mallinckrodt plc, MAK LLC and MEH Acquisition Co. with the SEC will also be available free of charge on the Investor Relations section of its website at www.mallinckrodt.com and copies of the documents filed by Ocera with the SEC will be available free of charge on Ocera's website at www.oceraInc.com.

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[1] Presentation at The Liver Meeting® the annual meeting of the American Association for the Study of Liver Diseases, held Oct. 20-24. https://liverlearning.aasld.org/aasld/2017/thelivermeeting/201404/stanley.bukofzer.ocr-002.28ornithine.phenylacetate29.is.a.potent.ammonia.html?f=topic=1572*media=3

[2] https://www.fda.gov/forpatients/approvals/fast/ucm405399.htm

[3] U.S. Patent and Trademark Office

[4] American Liver Foundation, Clinical Gastroenterology and Hepatology, 2011;9:524-530 Zobair et al

[5] Clin Liver Dis (2012) 73-89 Khungar et al

[6] West Haven score

[7] Presentation at The Liver Meeting® the annual meeting of the American Association for the Study of Liver Diseases, held Oct. 20-24. https://liverlearning.aasld.org/aasld/2017/thelivermeeting/201404/stanley.bukofzer.ocr-002.28ornithine.phenylacetate29.is.a.potent.ammonia.html?f=topic=1572*media=3

[8] HCUP, company estimate

[9] Int J Gen Med 2015 Saab et al

[10] Company market research

[11] Pharmacotherapy (2010) Neff

[12] Clin Gastroenterology and Hepatology 2012 Stepanova et al

[13] Clin Liver Dis (2012) 73-89 Khungar et al

[14] Accounting principles generally accepted in the U.S.

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