Mallinckrodt Files Suit against U.S. Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) to Protect Medicaid Patient Access to Acthar® Gel

May 21, 2019

-- Company challenges CMS' unexplained and unlawful reversal of its repeated 2012 written authorizations on calculation of Medicaid Rebates for Acthar Gel --

-- After extensive efforts to resolve matter, Mallinckrodt seeks Court intervention to ensure that CMS follows Administrative Procedure Act and other legal requirements --

-- Without court intervention, Acthar Gel Medicaid net sales, currently ~10% of total, would be eliminated by CMS' decision, placing drug's previous net sales 2019 guidance of >$1.0 billion at risk, with the potential for retroactive non-recurring charges of $0 to $600 million

-- Company plans vigorous defense of its position and believes changing guidance or taking reserve is inappropriate at this time --

-- CMS' decision, if implemented, could impede Mallinckrodt's efforts to develop new therapies for some of America's sickest patients with the fewest treatment options --

STAINES-UPON-THAMES, United Kingdom, May 21, 2019 /PRNewswire/ -- Mallinckrodt plc (NYSE: MNK), a global biopharmaceutical company, today confirmed its subsidiary, Mallinckrodt ARD LLC (Mallinckrodt), has filed suit in federal district court against the HHS and CMS (or the Agency). The action seeks to hold unlawful and set aside the Agency's recent unjustified decision to require that Mallinckrodt change the base date average manufacturer price (AMP) used to calculate Medicaid drug rebates for Acthar® Gel (repository corticotropin injection). The CMS decision attempts to reverse without explanation the Agency's 2012 express, written approval (on two occasions) of the base date AMP used since 2013, prior to Mallinckrodt's acquisition of Acthar Gel. The complaint can be viewed here, and CMS' written authorization letters may be viewed here.

"We are disappointed with the action taken by CMS. With our repeated attempts to engage both HHS and CMS in productive discussions ultimately rebuffed, we find ourselves with no other choice than to vigorously defend our position, through the courts, that Medicaid patients should have access to this important therapy," said **Mark Casey, General Counsel of Mallinckrodt**.

The effect of this attempted reversal, which CMS seeks unlawfully to make retroactive, would substantially eliminate Medicaid net sales of Acthar Gel, and significantly undermine Mallinckrodt's efforts to continue building on its investment in non-sales and marketing activities of more than $500 million to modernize Acthar Gel – value demonstrated, in part, by positive clinical results for challenging-to-manage sub-populations including, for example, in rheumatoid arthritis. Importantly, the CMS decision risks the availability of the drug for some of America's poorest and most vulnerable patients.

More broadly, if implemented, this CMS decision could impede Mallinckrodt's ability to continue its current pace of additional investment of hundreds of millions of dollars in research and development for a pipeline that seeks to benefit often very sick patient populations with some of the fewest treatment options available. The company's current research and development activities are focused on amyotrophic lateral sclerosis (also known as ALS, or Lou Gehrig's disease), Duchenne muscular dystrophy, Niemann-Pick disease type C, hepatorenal syndrome type-1 and severe burns, among others.

The context surrounding this matter and the company's rationale for the action it has taken follow.

Program background

The U.S. Congress established the Medicaid Drug Rebate Program in 1990 to reduce the federal and state costs of most outpatient prescription drugs dispensed to Medicaid patients. In order for manufacturers to help ensure access of eligible patients to those outpatient drugs covered by the Program, manufacturers are required to enter into, and have in effect, a national drug rebate agreement with the government in exchange for state Medicaid coverage of the applicable drug. In turn, a manufacturer provides rebates to the states, which facilitates access to medicine by America's poorest patient populations.

The Medicaid rebate amount is a complex calculation. One crucial component of that calculation is a drug's "base date AMP," a baseline measure related to the drug's price during a statutorily specified window of time. Because the base date AMP is used to calculate Medicaid rebates typically for the entire life of the relevant drug product, it is critically important that it be accurate.

The facts and Mallinckrodt's arguments in the lawsuit

Based on submission of supportive clinical data, the U.S. Food and Drug Administration (FDA) approved Acthar Gel in 2010 for treatment of a new indication – infantile spasms (IS) – while also reaffirming approval of 18 other Acthar Gel indications and modernizing the label. Upon the basis that Acthar Gel with the IS indication was approved in 2010 under an original New Drug Application (NDA), CMS expressly authorized (twice) in writing in 2012 the establishment of a new "base date AMP" for Acthar Gel. The new base date AMP took effect at the beginning of 2013 and has been used to calculate Medicaid rebates ever since. For more than three years, Acthar's previous owner and Mallinckrodt relied on CMS's written authorization to determine the appropriate calculation for Acthar Medicaid rebates, which CMS readily accepted and approved. Not until 2016 did CMS raise any issue.

In the lawsuit, Mallinckrodt has argued that CMS' 2012 decision that Acthar Gel with the IS indication is eligible for a new base date AMP was and is legally and factually correct for several independent reasons, including:

- First, the U.S. Congress has mandated that each covered outpatient drug produced or distributed under an FDA-approved "original NDA[1]" must be treated as a distinct "single source drug[2]" eligible for its own base date AMP under the Program[3]. **Acthar Gel with the IS Indication is produced and distributed under an original NDA approved by the FDA.**
- Second, **Acthar Gel with the IS Indication falls squarely within the definition of "single source drug" contained in CMS' own Medicaid drug rebate regulations**.
- And, third, **in both August and September 2012, CMS expressly *agreed with* the then-owner of the drug, Questcor Pharmaceuticals, in writing, that Acthar Gel with the IS indication is eligible for its own base date AMP.**

After more than three years of emails, letters, and discussions between the company and CMS – including significant periods of delay and dramatically shifting arguments by the agency – CMS has now directed Mallinckrodt to revert to Acthar Gel's prior base date AMP, which has the practical effect of imposing as much as $600 million dollars in retroactive rebates and prospective rebate increases of approximately 10% of Acthar Gel net sales annually. Even more troublesome, CMS now asserts that its first communication to Mallinckrodt on this issue in late 2016 was its final decision on the matter, amounting to an arbitrary and capricious reversal by the Agency on a matter of critical importance to the company and the Medicaid patients benefiting from Acthar Gel.

Despite Mallinckrodt's repeated attempts to engage CMS in a productive discussion to resolve this matter, CMS now seeks to impose an untenable and unlawful position on the company. Thus, in order to hold CMS to well-settled standards of fair notice and due process and ensure that Acthar Gel is available to very sick infants and other patients, who are among America's poorest, the company finds itself in the unfortunate position of being forced to take this legal action.

Quantifying the potential impact

Based on current Acthar Gel Medicaid net sales, should Mallinckrodt ARD LLC be unsuccessful in its efforts to have this latest CMS decision overturned, the company estimates the potential future financial impact to be a reduction in Acthar Gel-related net sales of approximately 10% annually, likely putting previous Acthar Gel 2019 net sales guidance of exceeding $1.0 billion at risk. Further, depending on the Court's determination, the potential retroactive financial impact could be from $0 to $600 million. Mallinckrodt plans to vigorously defend its position, and believes changing guidance or taking a reserve is inappropriate at this time.

Conclusion

In the lawsuit, Mallinckrodt argues that CMS' determination that Acthar Gel with the IS indication is not entitled to its own base date AMP violates the federal Administrative Procedure Act and well-settled and basic notions of fair notice, due process, and the prohibition on retroactive rulemaking. Among other things, CMS' decision conflicts with the plain language of the Medicaid drug rebate statute, violates CMS' binding regulations, and deviates from the Agency's own (repeated) prior express decisions to the contrary without adequate explanation or notice. As such, Mallinckrodt's strongly held position is that CMS' decision should be overturned and held unlawful.

ABOUT MALLINCKRODT

Mallinckrodt ARD LLC is a subsidiary of Mallinckrodt Pharmaceuticals, a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. Mallinckrodt Pharmaceuticals' Specialty Brands reportable segment's 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. Its Specialty Generics and Amitiza reportable segment includes specialty generic drugs, active pharmaceutical ingredients and AMITIZA® (lubiprostone). To learn more about Mallinckrodt, visit www.mallinckrodt.com.

Mallinckrodt Pharmaceuticals 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 concerning the pending dispute between Mallinckrodt, HHS and CMS with regard to Medicaid drug rebates for Acthar Gel, the litigation filed by Mallinckrodt against HHS and CMS in connection with this dispute, the impact of such dispute and any such litigation on Mallinckrodt's future financial condition, operating results, ability to fund future investments in Acthar Gel, and patients' ability to access Acthar Gel, and any other statements regarding events or developments that Mallinckrodt believes or anticipates 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 pending dispute between Mallinckrodt, HHS and CMS, including the outcome of the lawsuit filed by Mallinckrodt, as well as the time and expense of litigating this dispute; the impact of this dispute on Mallinckrodt's previously issued financial guidance for the 2019 fiscal year, as well as the potential retroactive financial impact on Mallinckrodt of an adverse outcome; complex reporting and payment obligations under healthcare rebate programs, including as they relate to the pending dispute with HHS and CMS; general economic conditions and conditions affecting the industries in which Mallinckrodt operates; conditions that could necessitate an evaluation of Mallinckrodt's goodwill and/or intangible assets for possible impairment; changes in laws and regulations; 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 Acthar Gel; Mallinckrodt's ability to navigate price fluctuations; competition; product liability losses and other litigation liability; and ongoing governmental investigations.

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 December 28, 2018. 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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[1] Recent legislation deleted the term "original" from the phrase "original NDA" included in the definition of single source drug, effective April 18, 2019. This revision supports Mallinckrodt's position that Acthar Gel with the IS indication qualifies as a distinct single source drug eligible for its own base date AMP. The statute also recognizes a "narrow exception" that is inapplicable here.

[2] https://www.medicaid.gov/medicaid/prescription-drugs/medicaid-drug-rebate-program/index.html

[3] 42 U.S.C. § 1396r-8(k)(7)(iv)

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