Mallinckrodt Receives U.S. FDA Approval for Lisdexamfetamine Dimesylate Capsules and Launches Product Used to Treat Attention-Deficit/Hyperactivity Disorder (ADHD)

August 31, 2023

DUBLIN, Aug. 31, 2023 /PRNewswire/ -- Mallinckrodt plc (OTCMKTS: MNKTQ), a global specialty pharmaceutical company, today announced that its Specialty Generics segment, operating as SpecGx LLC, received approval on August 25, 2023 from the United States Food and Drug Administration (FDA) for its Abbreviated New Drug Application for Lisdexamfetamine Dimesylate Capsules 10mg, 20mg, 30mg, 40mg, 50mg, 60mg, and 70mg. The FDA determined SpecGx LLC's product was bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Vyvanse® Capsules of Takeda Pharmaceuticals U.S.A., Inc. (Takeda), in all seven of the RLD's approved strengths.

Lisdexamfetamine Dimesylate Capsules are a federally controlled substance (CII) used to treat Attention-Deficit/Hyperactivity Disorder (ADHD) and other indications and currently are on the FDA's drug shortage list. Global net sales of Lisdexamfetamine Dimesylate exceeded $3.0 billion in Takeda's fiscal year ended March 31, 2023.

Upon receiving approval, which came the day following the expiration of the RLD's pediatric exclusivity, Mallinckrodt began immediate commercialization of the product. SpecGx LLC's generic version is manufactured at its plant in Hobart, New York utilizing active pharmaceutical ingredient manufactured at its plant in St. Louis, Missouri.

"Lisdexamfetamine Dimesylate is included among the ADHD medications currently on the FDA's drug shortage list, so we are very pleased to be able to launch this product at this time to help address a critical need in the market," said Stephen Welch, Executive Vice President and Head of Specialty Generics. "We will be working closely with the Drug Enforcement Administration (DEA) to request and secure additional quota to increase our production following this approval because we understand the vital importance of patient access to affordable, high-quality generic ADHD medicines."

ABOUT MALLINCKRODT
Mallinckrodt is a global business consisting of multiple wholly owned subsidiaries that develop, manufacture, market and distribute specialty pharmaceutical products and therapies. The Company's Specialty Brands reportable segment's areas of focus include autoimmune and rare diseases in specialty areas like neurology, rheumatology, hepatology, nephrology, pulmonology, ophthalmology and oncology; immunotherapy and neonatal respiratory critical care therapies; analgesics; cultured skin substitutes and gastrointestinal products. Its Specialty Generics reportable segment includes specialty generic drugs and active pharmaceutical ingredients. 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.

CAUTIONARY STATEMENTS RELATED TO FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements, including with regard to the Mallinckrodt's launch of Lisdexamfetamine Dimesylate Capules used to treat ADHD. The statements are based on assumptions about many important factors, including the following, which could cause actual results to differ materially from those in the forward-looking statements: the impact of Mallinckrodt's pending Chapter 11 cases; issues with product quality, manufacturing or supply, or patient safety issues; Mallinckrodt's ability to work with the DEA to request and secure additional quota to increase its production of Lisdexamfetamine Dimesylate Capules following FDA approval; satisfaction of, and compliance with, regulatory and other requirements; actions of regulatory bodies and other governmental authorities; changes in laws and regulations; competition; pricing pressure on Mallinckrodt's products; and other risks identified and described in more detail in the "Risk Factors" section of Mallinckrodt's most recent Annual Report on Form 10-K and other filings with the SEC, all of which are available on its website. 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.

CONTACTS

Investor Relations
Daniel Speciale
Senior Vice President, Finance & Chief Financial Officer, Specialty Generics

314-654-3638
daniel.speciale@mnk.com

Derek Belz
Vice President, Investor Relations
314-654-3950
derek.belz@mnk.com

Media

Michael Freitag / Aaron Palash / Aura Reinhard
Joele Frank, Wilkinson Brimmer Katcher
212-355-4449

SOURCE Mallinckrodt plc