Mallinckrodt Completes Stannsoporfin New Drug Application Filing

stannsoporfin

Treatment for Hyperbilirubinemia

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STAINES-UPON-THAMES, United Kingdom, Jan. 4, 2018 /PRNewswire/ — Mallinckrodt plc (NYSE: MNK), a leading global specialty pharmaceutical company, today announced it has successfully completed the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) to seek approval of its recently acquired developmental product stannsoporfin. If approved, the drug is expected to become the first and only pharmacologic option in the U.S. indicated for treatment of neonates at risk for developing severe hyperbilirubinemia, or severe jaundice.

“We are pleased to complete this important milestone for stannsoporfin,” said Steve Romano, M.D., Chief Scientific Officer and Executive Vice President of Mallinckrodt. “This brings us one step closer to addressing an unmet need for therapies to treat thousands of infants at risk for severe jaundice, and we look forward to working closely with the FDA toward the goal of obtaining approval of stannsoporfin to treat this population.”

About Severe Hyperbilirubinemia and Stannsoporfin

In the U.S., the total number of term births is estimated at 3.97 million per year[1,2] and, of those, approximately 750,000[3] infants are treated for jaundice. Of those treated, some may be unresponsive to phototherapy – the current standard of care – even with extended and repeated courses of the treatment[4], and patients face the risk of developing severe jaundice prior to discharge. A small percentage of full-term infants may experience elevated bilirubin levels after discharge and be at risk of severe jaundice[5], requiring hospital readmission. The combined potential patient treatments required annually in the U.S. for severe jaundice is approximately 70,000 to 125,000.

Stannsoporfin, a heme oxygenase inhibitor, is under investigation for its potential to reduce the production of bilirubin. The safety and effectiveness of stannsoporfin have not yet been established by FDA. If approved, stannsoporfin is expected to be used for late-preterm and full-term infants at risk of developing complications associated with severe jaundice.

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.

1 https://www.cdc.gov/nchs/data/databriefs/db258.pdf
2 https://www.cdc.gov/nchs/nvss/births.htm
3 HCUP (Healthcare Cost and Utilization Project) KID Data
4 Mallinckrodt market research/management projections
5 http://pediatrics.aappublications.org/content/early/2013/04/03/peds.2012-2634

SOURCE Mallinckrodt plc

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stannsoporfin FDA Approval History