LialdaÃ,® (Mesalamine) Now Approved in U.S. for Maintenance of Remission of Ulcerative Colitis

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PHILADELPHIA, July 18, 2011 /PRNewswire/ -- Shire plc (LSE: SHP; NASDAQ: SHPGY [1]), the global specialty biopharmaceutical company, today announced that the U.S. Food and Drug Administration (FDA) approved Lialda® (mesalamine) Delayed Release Tablets for the maintenance of remission in patients with ulcerative colitis. This approval is based on results from a six-month study demonstrating the safety and effectiveness of Lialda in maintaining endoscopic remission in adult patients. This approval follows the previous indication of Lialda approved by the FDA in 2007 for the induction of remission in patients with active, mild to moderate ulcerative colitis.

"At Shire, we strive to create meaningful therapies for patients with our clinical programs, and this approval based on our large clinical trial underscores our commitment and dedication to the ulcerative colitis community," said Roger Adsett, Senior Vice President of Shire's Gastrointestinal business. "This new indication is an important milestone for Lialda as it provides a once-daily option for both inducing remission in patients with active, mild to moderate ulcerative colitis and maintaining remission of ulcerative colitis."

Lialda's new indication is based on results from a multicenter, randomized, double-blind, active comparator, non-inferiority study conducted in 826 adult patients in remission from ulcerative colitis. Maintenance of remission was assessed using a modified Ulcerative Colitis Disease Activity Index (UC-DAI) and was based on maintaining endoscopic remission defined as a modified UC-DAI endoscopy subscore of less than or equal to 1. The endoscopy subscore of less than or equal to 1 represented normal or mild disease with no friability.

Of the patients receiving Lialda 2.4 g/day (n=343) administered once daily, 83.7% maintained remission at Month 6, which was similar to that seen
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[1] http://studio-5.financialcontent.com/prnews?Page=Quote&Ticker=SHPGY

[2] http://www.bio-medicine.org/medicine-technology-1/Lialda-AE--28Mesalamine-29-Now-Approved-in-U-S--for-Maintenance-of-Remission-of-Ulcerative-Colitis-18807-1/