Par Pharmaceutical, Inc. Issues Voluntary Nationwide Recall of One Lot of Mycophenolate Mofetil for Injection, USP Due to the Presence of a Glass Fragment Observed in One Vial of Reconstituted Product

May 1, 2019

DUBLIN, May 1, 2019 /CNW/ -- Endo International plc, announced today that one of its operating companies, Par Pharmaceutical, Inc., is voluntarily recalling one lot of Mycophenolate Mofetil for Injection, USP to the hospital and retail pharmacy level. One vial of product was observed containing a glass fragment after reconstitution.

The administration of a glass particulate, if present in an intravenous drug, may result in local irritation or swelling in response to the foreign material. More serious potential outcomes would include blockage and clotting in blood vessels, which may be life-threatening. To date, Par Pharmaceutical, Inc. has not received any reports of adverse events related to this recall.

Mycophenolate Mofetil for Injection, USP is indicated for the prophylaxis of organ rejection in patients receiving allogeneic renal, cardiac or hepatic transplants. Mycophenolate Mofetil for Injection, USP should be used concomitantly with cyclosporine and corticosteroids. The affected Mycophenolate Mofetil for Injection, USP includes lot AD812, expiry 09/2020. The product, manufactured for Par Pharmaceutical, Inc. by Gland Pharma Limited, is packaged in cartons of 4 single use vials with NDC 42023-172-04. Mycophenolate Mofetil for Injection, USP, lot AD812 was distributed nationwide in the U.S. to wholesale distribution locations between January 23, 2019, and February 11, 2019.

Vials from the affected lot bear this label:

Par Pharmaceutical, Inc. is providing written notification to national wholesale accounts and direct customer locations that have received the affected lot and is arranging for return of all recalled product through Inmar, Inc. Wholesale distributors, retail pharmacies, and hospital pharmacies that have the product being recalled should immediately stop further distribution and use of vials from Lot AD812 and return any unused product by following the instructions below:

- Please contact Inmar, Inc. either by phone at 1-800-967-5952, extension 1 (Monday through Friday between 9 am and 5 pm ET), or by email at rxrecalls@inmar.com to obtain return authorization labels and return shipping instructions.
- Upon contacting Inmar, Inc. please be prepared to provide proof of purchase to receive reimbursement for returned product.

Wholesalers, retailers, pharmacies, and consumers with questions regarding this recall can contact Inmar, Inc. either by phone at 1-800-967-5952, extension 1 (Monday through Friday between 9 am to 5 pm ET), or by email at rxrecalls@inmar.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: https://www.accessdata.fda.gov/scripts/medwatch/index.cfm
- **Regular Mail or Fax**: Download form https://www.fda.gov/safety/reporting-serious-problems-fda/forms-reporting-fda?source=govdelivery&utm_medium=email&utm_source=govdelivery or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

About Endo International plc

Endo International plc (NASDAQ: ENDP) is a highly focused generics and specialty branded pharmaceutical company delivering quality medicines to patients in need through excellence in development, manufacturing and commercialization. Endo has global headquarters in Dublin, Ireland, and U.S. headquarters in Malvern, PA. Learn more at www.endo.com.

About Par Pharmaceutical

Par Pharmaceutical, headquartered in Chestnut Ridge, NY, develops, manufactures and markets safe, innovative and cost-effective generic pharmaceutical and branded injectable products that help improve patient quality of life. Par, among the top leaders in the U.S. generics industry, possesses a portfolio that includes sterile injectables, alternative dosage forms and many other differentiated products. Par is advancing a robust research and development (R&D) pipeline of potential products. Par is an operating company of Endo International plc. Learn more at www.endo.com or www.parpharm.com.

Cautionary Note Regarding Forward-Looking Statements

Certain information in this press release contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 and applicable Canadian securities legislation. Statements including words such as "believes," "expects," "anticipates," "intends," "estimates," "plan," "will," "may," "look forward," "intend," "guidance," "future" or similar expressions are forward-looking statements. Because these statements reflect Endo's current views, expectations and beliefs concerning future events, these forward-looking statements involve risks and uncertainties. Investors should note that many factors, as more fully described under the caption "Risk Factors" in Endo's Form 10-K, Form 10-Q and Form 8-K filings with the Securities and Exchange Commission and in Canada on the System for Electronic Data Analysis and Retrieval and as otherwise enumerated herein or therein, could individually or in the aggregate affect Endo's future financial results and could cause Endo's actual results to differ materially from those expressed in the forward-looking statements or from historical results. The forward-looking statements in this press release are qualified by these risk factors. Endo assumes no obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise, except as may be required under applicable securities laws.

View original content to download multimedia:http://www.prnewswire.com/news-releases/par-pharmaceutical-inc-issues-voluntary-nationwide-recall-of-one-lot-of-mycophenolate-mofetil-for-injection-usp-due-to-the-presence-of-a-glass-fragment-observed-in-one-vial-of-reconstituted-product-300842285.html

SOURCE Endo International plc