TARO PHARMACEUTICAL INDUSTRIES LTD
Form 6-K
August 10, 2015
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16 UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of August, 2015

Commission File Number 001-35463

Taro Pharmaceutical Industries Ltd.

(Translation of registrant's name into English)

14 Hakitor Street, Haifa Bay 2624761, Israel
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F.
Form 20-F x Form 40-F ¨

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): _____

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): _____

Indicate by check mark whether the registrant by furnishing the information contained in this Form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934. Yes ¨ No x

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b): 82-_____.

Taro Pharmaceutical Industries Ltd.
c/o Taro Pharmaceuticals U.S.A., Inc.
Three Skyline Drive
Hawthorne, New York 10532
(NYSE: TARO)

FOR IMMEDIATE RELEASE

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FDA Approves Taro's Keveyis™ (dichlorphenamide) 50 mg Tablets for Primary Hyperkalemic and Hypokalemic Periodic Paralysis

Orphan Drug is First Approved Treatment for Patients Living with Rare Debilitating Disease

Hawthorne, NY, August 10, 2015 – Taro Pharmaceutical Industries Ltd. (NYSE: TARO) announced today that the U.S. Food and Drug Administration (FDA) has approved Keveyis™ (dichlorphenamide) 50 mg Tablets for the treatment of primary hyperkalemic and hypokalemic periodic paralysis, a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis [1]. Keveyis is the first medicine approved by the FDA for the treatment of primary periodic paralysis, which is estimated to affect approximately 5,000 people in the United States [2].

"The approval of Keveyis demonstrates the importance of industry, scientific researchers, patient advocates and the FDA working together to identify and bring to market a treatment for primary periodic paralysis," said Kal Sundaram, Chief Executive Officer of Taro. "Taro is proud of its commitment to this community, which has been waiting for a new, effective treatment option for many years. We thank the FDA for their continued partnership in making this important day a reality."

Taro expects Keveyis will be available for patients during the third quarter of 2015. The company has created the Keys2Care program which will provide a suite of patient support services to ensure people diagnosed with periodic paralysis can receive treatment with Keveyis as soon as possible. As part of this program, the company is working with Diplomat Pharmacy, Inc., a specialty pharmacy, to offer access and support to patients who are prescribed Keveyis and their caregivers.

"Because of the very-rare nature of periodic paralysis, it is not unusual for patients to go years before receiving an accurate diagnosis," said Robert Griggs, MD, principal investigator and professor, Department of Neurology, University of Rochester Medical Center. "For those living with often debilitating symptoms, the approval of Keveyis is both an important and much needed treatment advance and an opportunity for greater disease awareness and understanding, something that has long been a challenge for these people."

To be notified when Keveyis becomes available, enroll at www.keveyis.com.

About Periodic Paralysis

Periodic paralyses are a group of rare hereditary disorders that cause episodes of muscle weakness or paralysis. Types of periodic paralyses are differentiated by criteria including underlying genetic mutations and changes in blood-potassium during attack. Hypokalemic and hyperkalemic are two common types of periodic paralyses [1].

INDICATION

Keveyis is indicated for the treatment of primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants.

IMPORTANT SAFETY INFORMATION

In clinical studies, the most common side effects of Keveyis were a burning or pricking sensation, difficulty thinking and paying attention, changes in taste, and confusion. These are not all of the possible side effects you may experience with Keveyis. Talk to your doctor if you have any symptoms that bother you or do not go away.

Keveyis is not for everyone. Do not take Keveyis if you

- Are on a high-dose aspirin regimen
- Are allergic to sulfa-based drugs
- Have liver, kidney, or certain lung conditions
- Are pregnant, planning to become pregnant, or nursing
- Are under 18 years old

Taking Keveyis may cause a drop in the amount of potassium (an electrolyte) in your body, which can lead to heart problems. Ask your doctor if you need to eat foods that contain high amounts of potassium while taking Keveyis.

Your body may produce too much acid or may not be able to remove enough acid from body fluids while taking Keveyis. Your doctor will run tests on a regular basis to check for signs of acid buildup and may reduce your dose or stop your treatment with Keveyis.

Keveyis may also increase the risk of falls, especially in elderly patients and patients taking high doses of Keveyis. Use caution when driving, operating machinery, or performing any other hazardous activities while taking Keveyis, as this medication may cause drowsiness.

Tell your doctor if you experience worsening of your periodic paralysis symptoms.

For additional safety information, please see Full Prescribing Information at www.keveyis.com.

The release will be accessible on Taro’s website at www.taro.com.

About Taro
Taro Pharmaceutical Industries Ltd. is a multinational, science-based pharmaceutical company, dedicated to meeting the needs of its customers through the discovery, development, manufacturing and marketing of the highest quality healthcare products. For further information on Taro Pharmaceutical Industries Ltd., please visit the Company’s website at www.taro.com.

SAFE HARBOR STATEMENT

Certain statements in this release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements made by the Company’s CEO and statements about the availability of Keveyis to patients in the second and third paragraphs of this press release. These statements include, but are not limited to, statements that do not describe historical facts or that refer or relate to events or circumstances that the Company “estimates,” “believes,” or “expects” to happen or similar language. Although the Company believes the expectations reflected in such forward-looking statements to be based on reasonable assumptions, it can give no assurances that its expectations will be attained. Factors that could cause actual results or events to differ include risks related to commercializing Keveyis, industry, market and regulatory conditions, delays or prevention caused by

governmental regulation of pharmaceutical products, and other risks detailed from time to time in the Company's SEC reports, including its Annual Reports on Form 20-F. Forward-looking statements are applicable only as of the date on which they are made. The Company undertakes no obligations to update, change or revise any forward-looking statement, whether as a result of new information, additional or subsequent developments or otherwise.

References

[1] National Institute of Neurological Disorders and Stroke. NINDS Familial Periodic Paralyses Information Page. http://www.ninds.nih.gov/disorders/periodic_paralysis/periodic_paralysis.htm. National Institute of Neurological Disorders and Stroke. Published March 12, 2012. Accessed July 1, 2015.

[2] inVentiv Health, United Health Claims Database Analysis, October 2014.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 10, 2015

TARO PHARMACEUTICAL INDUSTRIES LTD.

By: /s/ Subramanian Kalyanasundaram
Name: Subramanian Kalyanasundaram
Title: Chief Executive Officer and Director