

DR REDDYS LABORATORIES LTD

Form 6-K

November 05, 2014

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**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**FORM 6-K**

**Report of Foreign Private Issuer**

**Pursuant to Rule 13a-16 or 15d-16**

**of the Securities Exchange Act of 1934**

**Month of October 2014**

**Commission File Number 1-15182**

**DR. REDDY S LABORATORIES LIMITED**

**(Name of Registrant)**

**8-2-337, Road No. 3, Banjara Hills**

**Hyderabad, Andhra Pradesh 500 034, India**

**+91-40-4900-2900**

(Address of Principal Executive Offices)

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

Form 20-F  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):

**Note:** Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

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):

**Note:** Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's home country), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes  No

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

Not applicable.

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- (1) Press Release, Dr. Reddy's announces the Launch of Sirolimus Tablets, 1 mg and 2 mg, October 28, 2014.

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**Press Release**

Dr. Reddy's Laboratories Ltd.  
8-2-337, Road No. 3  
Banjara Hills, Hyderabad - 500 034  
Andhra Pradesh, India

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**Dr. Reddy's announces the Launch of Sirolimus Tablets, 1 mg and 2 mg**

*Hyderabad, India, October 28, 2014*

Dr. Reddy's Laboratories (NYSE: RDY) announced today that it has launched Sirolimus Tablets 1 mg and 2 mg, a therapeutic equivalent generic version of RAPAMUNE® (Sirolimus) tablets in the US market on October 27, 2014, following the approval by the United States Food & Drug Administration (USFDA).

The RAPAMUNE® tablets brand had U.S. sales of approximately \$206 Million MAT for the most recent twelve months ending in August 2014 according to IMS Health\*.

Dr. Reddy's Sirolimus tablets in 1 mg and 2 mg are available in bottle counts of 100.

**BOX WARNING: IMMUNOSUPPRESSION, USE IS NOT RECOMMENDED IN LIVER OR LUNG TRANSPLANT PATIENTS**

**Increased susceptibility to infection and the possible development of lymphoma and other malignancies may result from immunosuppression**

**Increased susceptibility to infection and the possible development of lymphoma may result from immunosuppression. Only physicians experienced in immunosuppressive therapy and management of renal transplant patients should use sirolimus. Patients receiving the drug should be managed in facilities equipped and staffed with adequate laboratory and supportive medical resources. The physician responsible for maintenance therapy should have complete information requisite for the follow-up of the patient [see Warnings and Precautions.**

**The safety and efficacy of sirolimus as immunosuppressive therapy have not been established in liver or lung transplant patients, and therefore, such use is not recommended [see Warnings and Precautions.**

**Liver Transplantation Excess Mortality, Graft Loss, and Hepatic Artery Thrombosis (HAT)**

**The use of sirolimus in combination with tacrolimus was associated with excess mortality and graft loss in a study in *de novo* liver transplant patients. Many of these patients had evidence of infection at or near the time of death.**

**In this and another study in *de novo* liver transplant patients, the use of sirolimus in combination with cyclosporine or tacrolimus was associated with an increase in HAT; most cases of HAT occurred within 30 days post-transplantation and most led to graft loss or death.**

## **Warnings and Precautions**

### **Lung Transplantation    Bronchial Anastomotic Dehiscence**

**Cases of bronchial anastomotic dehiscence, most fatal, have been reported in *de novo* lung transplant patients when sirolimus has been used as part of an immunosuppressive regimen [see Warnings and Precautions]**

## **Disclaimer**

This press release includes forward-looking statements, as defined in the U.S. Private Securities Litigation Reform Act of 1995. We have based these forward-looking statements on our current expectations and projections about future events. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results to differ materially. Such factors include, but are not limited to, changes in local and global economic conditions, our ability to successfully implement our strategy, the market acceptance of and demand for our products, our growth and expansion, technological change and our exposure to market risks. By their nature, these expectations and projections are only estimates and could be materially different from actual results in the future.

## **About Dr. Reddy s**

Dr. Reddy s Laboratories Ltd. (NYSE: RDY) is an integrated global pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses – Pharmaceutical Services and Active Ingredients, Global

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Generics and Proprietary Products Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Major therapeutic focus is on gastro-intestinal, cardiovascular, diabetology, oncology, pain management and anti-infective. Major markets include India, USA, Russia-CIS and Europe apart from other select geographies within Emerging Markets. For more information, log on to: [www.drreddys.com](http://www.drreddys.com)

RAPAMUNE® is a registered trademark of WYETH LLC LIMITED LIABILITY COMPANY

\* IMS National Sales Perspectives: Retail and Non-Retail MAT August 2014

**For more information, please contact:**

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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.

DR. REDDY S LABORATORIES LIMITED  
(Registrant)

By: /s/ Sandeep Poddar  
Name: Sandeep Poddar  
Title: Company Secretary

Date: November 5, 2014