October 23, 2019

BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai – 400 001

Scrip code: 532531

The National Stock Exchange of India Limited
Exchange Plaza , Bandra-Kurla Complex
Bandra (E) Mumbai - 400 051

Scrip code: STAR

Dear Sirs,

Sub: Press Release

Please find attached Press Release issued by the Company titled:

'TGA, Australia announces Ranitidine test results'

Thanks & Regards,
For Strides Pharma Science Limited

Manjula R.

Manjula Ramamurthy
Company Secretary

STRIDES PHARMA SCIENCE LIMITED

Encl: As Above

Strides Pharma Science Limited
(Formerly Strides Shasun Limited)
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Strides

Press Release

October 23, 2019

TGA, Australia announces Ranitidine test results

Of 24 oral solid dosage batches meeting the acceptable NDMA limits, 20 were manufactured by Strides for its partner Arrow Pharma

October 23, 2019: Strides Pharma Science Limited (Strides or Company) today shared further updates regarding the supplies of its Ranitidine Tablets. The Company, on September 27, 2019, temporarily suspended the manufacturing and sale of its Ranitidine tablets for the US and Australia markets given the concerns around impurity called N-nitrosodimethylamine (NDMA) which is associated with an increased risk of cancer. As per European Medicines Agency (EMA), NDMA is present in some foods and in water supplies but is not expected to cause harm when ingested in very low levels[3].

Summary of the announcement made by Therapeutic Goods Administration, Australia(TGA)[1]:

- The TGA Laboratories tested samples of Ranitidine medications available in the Australian market.
- A total of 135 batches from 10 Australian companies were tested for NDMA adapting the newly issued US Food and Drug Administration (USFDA)[2] test method using liquid chromatography with high resolution mass spectrometric detection(LC-HRMS).
- TGA has now taken a decision to recall all Ranitidine products with levels of NDMA at or above 0.3 ppm while **all batches with levels below 0.3 ppm are available for sale.**

Results from the TGA Laboratories Tests

- Out of the **135 batches** of Ranitidine which were tested by TGA, **109 batches** were found to have NDMA level at or above the acceptable limit of 0.3 ppm. These batches include **3 batches** from Strides supplied to its Australian partner Arrow Pharma Pty Ltd(Arrow).
- Only **24 *oral solid dosage batches*** were found to have levels of NDMA within the acceptable limit of 0.3 ppm of which **20 batches were manufactured by Strides for its partner Arrow with API supplied by Solara Active Pharma Sciences.**

Next Steps for Australia

- At Strides, product quality and patient safety is of paramount importance, and we are confident of consistently meeting the acceptable limits of NDMA in Ranitidine.
- Batches manufactured by Strides are now available for sale in Australia through its partner Arrow.

Additional Update on US

- Strides has submitted all requested data to the USFDA in response to the Information Request received on Ranitidine.
- Strides is awaiting further feedback from the USFDA on the NDMA limits for Ranitidine.

[1] https://www.tga.gov.au/tga-laboratories-testing-ranitidine-medicines
[2] https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-zantac-ranitidine
[3] https://www.ema.europa.eu/en/news/ema-review-ranitidine-medicines-following-detection-ndma

About Strides

Strides, listed on the BSE Limited (532531) and National Stock Exchange of India Limited (STAR), is a global pharmaceutical company headquartered in Bangalore, India. The Company mainly operates in the regulated markets and has an "in Africa for Africa" strategy along with an institutional business to service donor-funded markets. The Company's global manufacturing sites are located in India- Bangalore (two locations), Pondicherry, and Chennai, Singapore, Italy- Milan, Kenya- Nairobi and United States-Florida. The Company focusses on "difficult to manufacture" products that are sold in over 100 countries. Additional information is available at the Company's website at www.strides.com

For further information, please contact:

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