

April 2, 2020

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

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

Scrip Code: 541540

Scrip Code: SOLARA

Dear Sir / Madam,

**Sub:** Announcement under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulation, 2015

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We are enclosing herewith a press release issued by the Company titled:

***“Updates on Ranitidine Hydrochloride API”***

Thanking you,

Yours faithfully,

**For Solara Active Pharma Sciences Limited**



**S. Murali Krishna**  
Company Secretary



Encl:- as above

## Solara shares new updates on Ranitidine Hydrochloride API

- ▶ **USFDA published a statement requesting removal of all Ranitidine Products from the market immediately**
- ▶ **A new development in the ongoing investigation of a contaminant known as N-Nitrosodimethylamine (NDMA) in Ranitidine medications**

**Bangalore, India – April 02, 2020:**

Solara Active Pharma Sciences Ltd (Solara) (NSE: SOLARA; BSE: 541540) today shared updates on its Ranitidine API as USFDA publishes a statement on April 1, 2020<sup>1</sup>, requesting all finished dosage formulations manufacturers to withdraw prescription and over-the-counter (OTC) Ranitidine drugs in all dosage formats from the US market immediately.

As per USFDA's statement, the agency has determined that the NDMA impurity in some Ranitidine formulation products increases over time and when stored at higher than room temperatures it may result in consumer exposure to unacceptable levels of NDMA impurity. As a result of this immediate market withdrawal request for all Ranitidine products, **Solara has stopped further manufacturing and distribution of Ranitidine API for the US market.** The Company shall engage with its formulation partners to understand the next steps and additional data that it needs to generate for supporting their product's relaunch to the market in an extended period.

**Ranitidine API is amongst its top 10 APIs for Solara and contributes ~7% to its total revenues. Solara does not foresee any significant impact on its growth trajectory and continues to maintain a positive outlook for the future.**

### About Solara

Solara Active Pharma Sciences Ltd (BSE-541540, NSE-SOLARA) headquartered in Bengaluru, India offers a basket of diversified, high-value Commercial APIs and Contract manufacturing services in over 75 countries. It has a manufacturing base comprising five globally compliant API facilities, with approvals including the USFDA, EU GMP and PMDA in Japan.

#### Investor / Analyst contact

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#### Statutory and corporate affairs

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*Disclaimer: Certain statements in this document that are not historical facts are forward-looking statements. Such forward-looking statements are subject to certain risks, and uncertainties like government actions, local, political or economic developments, technological risks, and many other factors that could cause actual results to differ materially from those contemplated by the relevant forward-looking statements Solara Active Pharma Sciences Ltd will not be in any way responsible for any action taken based on such statements and undertakes no obligation to publicly update these forward-looking statements to reflect subsequent events or circumstances.*

<sup>1</sup> <https://www.fda.gov/news-events/press-announcements/fda-requests-removal-all-ranitidine-products-zantac-market>