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January 30, 2023

The BSE Limited

Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai - 400 001

Scrip Code: 541540

Dear Sir/ Madam,

Regulation, 2015

The National Stock Exchange of India Limited

Exchange Plaza BandraKurla Complex Sandra (E)

Mumbai - 400 051 **Scrip Code: SOLARA** 

Sub: Press release - Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements)

Please find attached press release issued by the Company titled:

"USFDA concludes inspection at Solara's Visakhapatnam (Vizag) facility with zero 483 inspectional observations."

Thanking you, Yours Truly,

For Solara Active Pharma Sciences Limited

S. Murali Krishna Company Secretary

Encl. as above



## **Press Release**

## USFDA concludes inspection at Solara's Visakhapatnam (Vizag) facility with Zero 483 inspectional observations

Bengaluru, India – January 30, 2023: Solara Active Pharma Sciences Ltd (Solara) (NSE: SOLARA; BSE: 541540), a leading Active Pharmaceutical Ingredient / CRAMS company, today announced that its new state-of-the-art multipurpose API manufacturing facility at Visakhapatnam (Vizag), Andhra Pradesh completed successfully the inspection carried out by the US Food and Drug Administration (US FDA or Agency). The Agency, with its designated investigator, inspected the facility from 23rd to 26th January 2023. The inspection established that the site is in an "Acceptable State of Compliance" with Zero Form 483 inspectional observations from the agency.

**Jitesh Devendra, Managing Director,** commented, "We are happy with the successful inspection outcome of our new greenfield API site at Vizag with Zero 483 inspectional observations. This is the first regulatory inspection we have undergone at the site since its commissioning. This outcome demonstrates our relentless focus on world-class quality and compliance, which remains a key pillar of our strategy and validates the quality systems the Company has institutionalized across its manufacturing network. The Vizag facility is differentiated in design and supports the manufacturing of APIs to ensure supply security and cost leadership."

The Vizag facility of the Company is a green field project spread over 40 acres and has dedicated facilities for manufacturing Ibuprofen API and multipurpose facility in phase 1. The facility has also started validating other APIs to register in various regulated markets across the globe. The site offers a unique capability to the Company for manufacturing various APIs with scale and operational flexibility to achieve a competitive advantage.

The site positions Solara as the only Global Company offering Ibuprofen from two USFDA-approved manufacturing sites (Puducherry and Vizag), enhancing supplies for its global partners. Earlier, in November 2022, Solara's Vizag facility had received a **Certificate of Suitability (CEP)** approval for the manufacture of Ibuprofen API from the **European Directorate for the Quality of Medicines (EDQM),** the first international regulatory approval for this new facility.

## **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 six globally compliant API facilities, with approvals including the USFDA, EU GMP, and PMDA in Japan.

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Statutory and corporate affairs

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Disclaimer: Certain statements in this document are not historical facts and 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.