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The BSE Limited
Phiroze Jeejeebhoy Towers,
Dalal Street, Mumbai - 400 001
Scrip Code: 541540

The National Stock Exchange of India Limited
Exchange Plaza BandraKurla Complex Sandra (E)
Mumbai - 400 051
Scrip Code: SOLARA

Dear Sir/ Madam,

Sub: Successful completion of US FDA inspection at Visakhapatnam facility with Zero 483 inspectional observations - Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulation, 2015

Please find attached press release issued by the Company titled:

“Solara Visakhapatnam facility completes USFDA Inspection with Zero 483 inspectional observations.”

Thanking you,

Yours Truly,
For Solara Active Pharma Sciences Limited

S. Murali Krishna
Company Secretary

Encl. as above

USFDA concludes inspection at Solara's Visakhapatnam Facility with Zero 483 inspectional observations.

Chennai, India – May 20, 2024: Solara Active Pharma Sciences Limited (Solara), a leading pure play Active Pharmaceutical Ingredient provider is pleased to announce that its new state-of-the-art multipurpose API manufacturing facility at Visakhapatnam, Andhra Pradesh has completed successfully the inspection carried out by the US Food and Drug Administration (US FDA). The inspection established that the site is in an **“Acceptable State of Compliance” with Zero Form 483 inspectional observations from US FDA.** The Agency with their designated investigator inspected the facility from 14th to 17th May 2024.

Solara's Visakhapatnam (Vizag) facility is a green field project spread-over an area of 40 acres and has dedicated facilities for the manufacture of Ibuprofen API. The facility also manufactures its key starting material for Ibuprofen and thus achieved backward integration of its critical supply chain and ensures business continuity to its customers. Solara's (Vizag) facility has also started validation of other API's to register in various regulated markets across the globe.

Solara has two FDA inspected manufacturing sites (Puducherry and Visakhapatnam) for Ibuprofen drug substance.

Solara continues to stay focused on maintaining the highest level of compliance across its manufacturing facilities.

Commenting on the Inspection Outcome, Poorvank Purohit, MD & CEO said “We are very happy with the successful inspection outcome of our Visakhapatnam API site with Zero 483 inspectional observation. This is the second US FDA inspection we have undergone at this site. This continues to demonstrate our relentless focus on world-class quality and compliance, which remains a key pillar of our growth strategy. We remain agile to the increasing requirements on quality and compliance, and I am confident that we will sustain our quality culture and anchor it further.”

About Solara

Solara Active Pharma Sciences Ltd (BSE-541540, NSE-SOLARA) is a pure play global API manufacturer supported by state-of-the-art R&D and manufacturing facilities. With 6 manufacturing facilities and an R&D Centre, Solara offers a basket of diversified, high-value Commercial APIs and Contract manufacturing services. Its API facilities are approved by various international regulatory agencies including the USFDA, EDQM, MFDS, WHO, PMDA etc.

Investor / Analyst contact

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Statutory and corporate affairs

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