Communication Address:
Solara Active Pharma Sciences Limited
2nd Floor, Admin Block
27, Vandaloor Kelambakkam Road,
Keelakottaiyur Village, Melakottaiyur (Post)
Chennai – 600 127, India
Tel: +91 44 43446700
Fax: +91 44 47406190
E-mail: investors@solara.co.in
www.solara.co.in

August 07, 2023

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: Completion of the USFDA Inspection at the Cuddalore facility of the Company

We would like to update you that **Solara Active Pharma Sciences Limited** (**Solara**) has successfully completed the inspection carried out by the US Food and Drug Administration (US FDA or Agency) at its Cuddalore facility (Tamil Nadu).

The Agency, with its designated investigators, inspected the Cuddalore facility between July 31, 2023 – August 04, 2023. The inspection established that the facility is in an **"Acceptable State of Compliance**" with **Zero Form 483 inspectional observations** from the Agency.

With this successful inspection outcome, the current inspection classification of Cuddalore site shall be reinstated to NAI (No Action Indicated).

The Cuddalore API site is a multi-product facility, caters wide range of APIs to various regulated markets across the globe, including U.S., Europe, Japan and other markets.

This is for your information and records.

Thanking you,

Yours Truly,
For Solara Active Pharma Sciences Limited

SUDDAPALLI MURALIKRISHNA
Digitally signed by SUDDAPALLI MURALIKRISHNA
Date: 2023.08.07 08:22:21 +05'30'

S. Murali Krishna
Company Secretary

Press Release

USFDA concludes inspection at Solara's Cuddalore facility with Zero 483 inspectional observations

Bengaluru, India – August 7, 2023: Solara Active Pharma Sciences Ltd (Solara) (NSE: SOLARA; BSE: 541540), a leading Active Pharmaceutical Ingredient / CRAMS company, today announced that its multi-product manufacturing facility at Cuddalore, completed successfully the inspection carried out by the US Food and Drug Administration (US FDA or Agency). The Agency, with its designated investigators, inspected the Cuddalore facility between July 31, 2023 – August 04, 2023. The inspection established that the facility is in an "Acceptable State of Compliance" with Zero Form 483 inspectional observations from the Agency.

With this successful inspection outcome, the current inspection classification of Cuddalore site shall be reinstated to NAI (No Action Indicated).

This facility has also successfully completed the regulatory inspections carried out by the World Health Organization (WHO) between January 23 – 26, 2023 and EU-GMP Inspection carried out jointly by the "State Institute for Drug Control (SUKL), Ministry of Health of the Czech Republic" and "National Authority of Medicines and Health Products (INFARMED), Portugal" between February 07 – 09, 2023.

Poorvank Purohit (MD and CEO), commented, "We are happy with the outcome of the FDA inspection with Zero 483 inspectional observations. This is the third consecutive successful regulatory inspections outcome (USFDA, EU-GMP and WHO-GMP inspections) at our Cuddalore site and gives us confidence in our quality systems and oversight of our manufacturing infrastructure. The result of these inspections demonstrates our commitment to regulatory excellence at our global manufacturing sites and our relentless focus on world-class quality and compliance. We stay committed to exhibit the highest level of compliance and constant focus on world-class quality with the validated quality systems established across Solara's manufacturing network.

The Cuddalore multi-product API manufacturing facility was established in the year 1991 and is equipped with appropriate infrastructure to include several independent production blocks and related packaging sections. This site is inspected by various Regulatory Authorities including US FDA, MHRA, EDQM, WHO, PMDA, TGA, KFDA, and COFEPRIS.

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.

Investor / Analyst contact
Abhishek Singhal
✉ abhishek.singhal@solara.co.in
✆ +91 99877 66968

Statutory and corporate affairs
Murali Krishna S
Raghavan. V
✉ investors@solara.co.in