THEMIS
MEDICARE

TML: CS: BSE/NSE CORR: 2021-22 | 03rd March, 2022

The Manager
Corporate Relationship Department
BSE Limited
Floor 25, Phiroze Jeejeebhoy Towers
Dalal Street, Mumbai- 400001

Scrip Code – 530199

The Manager – Listing Department
National Stock Exchange of India Limited
Exchange Plaza,
Bandra Kurla Complex,
Bandra (East), Mumbai- 400051

Symbol: THEMISMED

Sub: Sub: Indian regulator approves VIRALEX for the treatment of mild to moderate COVID-19 in India

Ref: 1. Regulation 30 of the SEBI (LODR) Regulations, 2015
2. BSE Scrip Code: 530199
3. NSE Scrip Code: THEMISMED

Dear Sir/Madam,

In a landmark development for Themis Medicare Ltd (Themis), the Company has received approval for its immunomodulatory antiviral drug **VIRALEX®** (Generic name: Inosine Pranobex) for treatment of COVID-19, from Drug Controller General of India (DCGI) vide CDSCO letter no ND/CT21/FF/2021/25932 dated 02 Mar 2022.

The drug regulatory authority granted permission to manufacture and market this new drug for *restricted emergency use as add on therapy for treatment of mild and moderate COVID-19*, under NDCT Rules 2019 based on evaluation in consultation with the Subject Expert Committee (SEC) as part of *accelerated approval process* considering the *emergency situation* and *unmet medical need* in light of COVID-19 outbreak in the country.

VIRALEX® would be available on prescription.

Themis becomes the one of the few pharma companies to receive approval of a drug in India for treating COVID-19 based on data from a ***Randomised, Double Blind, Placebo-controlled, Multicentre Trial*** which is considered to be the clinical research methodology of highest global standard for evaluating drugs against diseases.

As per the results of the *Phase 3 Randomised, Double Blind, Placebo-controlled Trial* in mild to moderate COVID-19, ***significantly higher percentage of patients treated with VIRALEX® showed clinical improvement and cure*** than those who did not receive the drug on day 6 of treatment. There was early *improvement and cure* from symptoms in patients who received VIRALEX®. This drug was well tolerated by

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CIN No.: L24110GJ1969PLC001590 • **Tel / Fax No.: Regd. Off.** : 0260 2431447 / 2430219
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THEMIS MEDICARE LIMITED MUMBAI

the patients without any serious adverse events. The study was conducted during the Delta wave of the pandemic.

Based on the promising study results, VIRALEX® ***appears to offer immense benefit to the people suffering from mild to moderate COVID-19***, thus reducing the load on the health care system.

Themis Medicare Ltd. is committed to complete the phase 3 study and continue the development program to ensure that more evidence-based data is generated.

VIRALEX® is an ***immunomodulatory agent*** with **broad spectrum antiviral** properties. *It enhances both innate & adaptive immunity and strengthens body's defence response to viral infections.* In an *in vitro* study initiated by Themis, it showed ***dose-dependent inhibition of viral replication against SARS-CoV-2***.

VIRALEX® will be manufactured at an ***EU-GMP-certified facility*** with the highest safety standards and stringent manufacturing protocols in place, and the medication will be available in the form of a 500 mg tablet.

Kindly take this on record.

Thanking you,

Yours faithfully,

For Themis Medicare Ltd.

THEMIS MEDICARE LIMITED MUMBAI

Sangameshwar Iyer
Company Secretary& Compliance Officer

BUSINESS UPDATE RELEASE

Approval of antiviral drug VIRALEX® by Drug Controller General of India

Enhances both innate & adaptive immunity and strengthens body's immune response to viral infections

Viralex® has been found to be effective and well tolerated in mild to moderate COVID-19, in two Randomized Controlled Clinical Trials conducted on 499 Indian patients

Mumbai, India; 3 March 2022

In a landmark development for the treatment of COVID-19, **Themis Medicare Ltd. (Themis)**, a Pharmaceutical company headquartered in Mumbai with a legacy of over 50 years of making new treatment options available, announced the approval of its antiviral drug **VIRALEX®** by the Drug Controller General of India (DCGI). As per the results of a *double-blind randomized controlled trials (RCT),* the drug helps in *early relief of the clinical symptoms* in *mild to moderate* ***COVID-19*** *patients*.

In line with the DCGI's current approach for approval of medicines for the management of the ongoing pandemic, approval for **VIRALEX®** (Generic name: Inosine pranobex) is based on the results of the robust phase 2 and phase 3 RCTs conducted in India, and the well-established safety profile of the drug.

As per the results of the *Phase 3 Randomized, Double-blind, Placebo-controlled Trial, **80.17%*** **of patients treated with VIRALEX® showed clinical improvement on day 6**, which is significantly higher (p<0.001) from that in the controlled group

(52.38%) among the *mild to moderate non-hospitalized COVID-19* patients. *Clinical Cure* was also significantly higher in the VIRALEX® group as compared to that in the placebo group on day 6 of treatment. There was early *improvement and cure* from symptoms in patients who received VIRALEX®. This drug was well tolerated by the patients without any serious side effects. The study was conducted during the Delta wave of the pandemic.

Randomized, Double-Blind, Placebo-controlled, Multicentre Trial is considered as the clinical research methodology of the highest global standard for evaluating drugs against diseases. Themis is one of the few companies to submit data from a higher number of patients from RCTs for approval in management of COVID-19.

After detailed deliberation, the drug regulatory authority granted permission to manufacture and market this new drug for *restricted emergency use* of *the drug as an add on therapy for treatment of mild and moderate COVID-19*.

VIRALEX® would be available on the prescription.

Based on the promising study results, ***the drug appears to offer immense clinical benefit to the patients in the early stages of COVID-19***, thus reducing the load on the health care system.

VIRALEX® is an ***immunomodulatory agent with broad-spectrum antiviral*** properties. *It enhances both innate & adaptive immunity and strengthens the body's defence response to viral infections*. In an *in vitro* study initiated by Themis, it showed ***dose-dependent inhibition of viral replication against SARS-CoV-2 (COVID-19)***.

According to Themis, **VIRALEX®** will be manufactured at an ***EU-GMP-certified facility*** with the highest safety standards and stringent manufacturing protocols in place, and the medication will be available in the form of a 500 mg tablet at a much affordable price.

Speaking at the release, *Dr. Sachin Patel, Managing Director*& CEO of Themis Medicare Ltd. said, "*Our endeavor has always been to develop medicines that*

benefit patients and make healthcare far, far more effective. Given the current scenario of grave health concerns and economic challenges surrounding COVID-19 in India, this is our effort to contribute to the wellbeing of people of India".

"Due to the frequently mutating trend of the virus, the uncertainties of the pandemic continue. We hope access to effective treatment such as ***VIRALEX®*** *will offer a much-needed therapeutic solution, and if* ***initiated early in the disease, it would reduce the load on the health care system****",*

Commenting on the significance of this development, *Dr. Ashok Swain, Head Clinical Development*, congratulated the entire Themis Medicare Ltd. team for achieving an ***important milestone of adding this effective medicine with an established safety profile to address the unmet need in the management of the pandemic.***

"VIRALEX® is a new ray of hope in these challenging times," he said.

Dr Raja Dhar, eminent pulmonologist and Director and Head of Department of Pulmonology, C K Birla Hospitals, said *"Inosine Pranobex is a drug which* ***enhances host immunity (immunomodulatory effect)*** *and can affect viral RNA and hence inhibits growth of several viruses.* ***Phase 3 Double blind RCTs are rare in COVID 19****. I am heartened to hear that Themis Medicare has come up with such a trial, which shows early clinical response and shortened period of recovery when used in mild to moderate COVID 19 cases. This drug, if successfully used in clinical practice would considerably reduce the burden on health care system.*

Dr Dhar is also the current Chair of Training and Education Initiatives, Indian Chest Society, and Director of Research and Training, National Allergy Asthma Bronchitis Institute.

With a strong R&D backup, skilled domestic & export teams, and 4 state-of-the-art manufacturing sites, the endeavour at Themis. has always been to support the medical fraternity with solutions for major unmet medical needs like VIRALEX® for COVID-19… and still counting!

About Themis Medicare Ltd.

Themis Medicare was incorporated in 1969 as a joint venture partnership at Vapi. Today, it is one of the fastest growing pharma Company specializing in the development of complex molecules. With strong research focus on injectables, complex generic products and drug-delivery systems, the Company has evolved into being a formidable player in the complex generics space.

It has a diversified business model with presence across the B2B model and strong presence in domestic B2C market. The Company also has a significant export presence in the RoW geographies. The qualified and experienced Management team is complemented by highly skilled R&D workforce. The Company has three vertically integrated manufacturing facilities, of which two are focused on developing APIs – 1 each involved in manufacturing Synthetic API and Fermentation based API, and 1 is involved in manufacturing of Finished Dosage Formulations. Themis offers products in various dosage forms in multiple therapeutics areas with leadership in Pain Management and Critical Care. The Company has a strategy to focus and grow its injectables portfolio and develop its NDDS presence.

For more details, please visit: www.themismedicare.com

Company: *Mr. Sangameshwar Iyer* Company Secretary *Themis Medicare Ltd.* Email: sangameshwar.iyer@themismedicare.com	*Investor Relations:* *Mr. Amit Sharma / Ms. Disha Shah* *Mob.: 9867726686 / 9699060134* *Bridge Investor Relations Pvt. Ltd* Email: amit@bridge-ir.com / disha@bridge-ir.com

Caution Concerning Forward- Looking Statements:

This document includes certain forward-looking statements. These statements are based on Management's current expectations or beliefs and are subject to uncertainty and changes in circumstances. Actual results may vary materially from those expressed or implied by the statements herein due to changes in economic, business, competitive, technological and/or regulatory factors. The Company is under no obligation to, and expressly disclaims any such obligation to, update or alter its forward-looking statements, whether as a result of new information, future events, or otherwise.

VIRALEX®

(Inosine Pranobex 500 mg Tablets)

M/s Themis Medicare Ltd.
11/12 Udyog Nagar, S.V. Road, P. B. No., 17529,
Goregaon (West), Mumbai-400104

VIRALEX®

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- **Viralex®** *(Inosine Pranobex, Methisoprinol or Inosine Acidoben Dimeparanol) – an* a **immunomodulatory** agent with broad spectrum **antiviral properties**.
- *Enhances both* ***innate & adaptive immunity*** *and* ***strengthens body's immune response*** *to viral infections*.
- In vitro studies have reported dose-dependent inhibition of viral replication against SARS-CoV-2.
- **Viralex®** has been found to be ***effective and well tolerated in mild to moderate COVID-19,*** in two Randomized Controlled Clinical Trials conducted on 499 Indian patients.

Viralex® Development Program for COVID-19

Viralex® development program undertaken by Themis provides strong evidence of efficacy & safety of **Inosine Pranobex 500mg Tablets** in management of **COVID-19**

PCD → Phase 1 → Phase 2 → Phase 3

Preclinical Development

- In vitro- 2 studies
- In vivo- 3 studies

Exploratory CD:

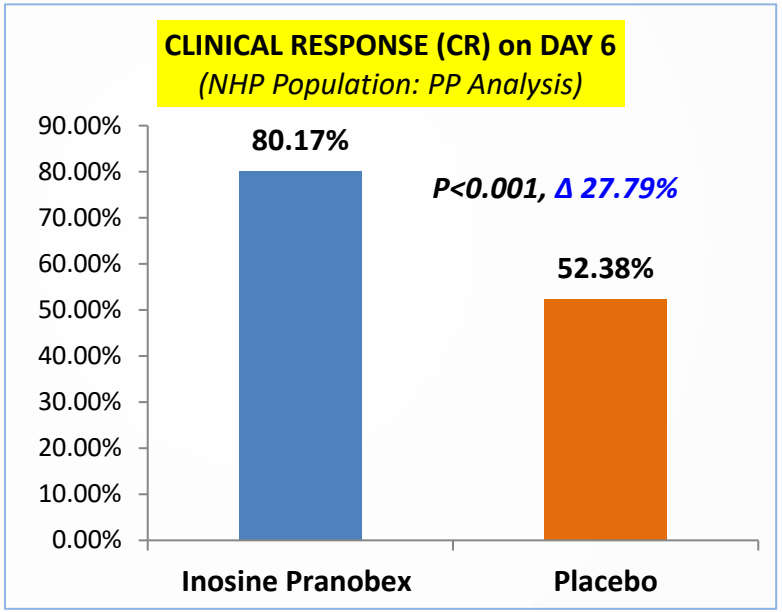
- Phase 2 (PoC) RCT
- **83 patients**

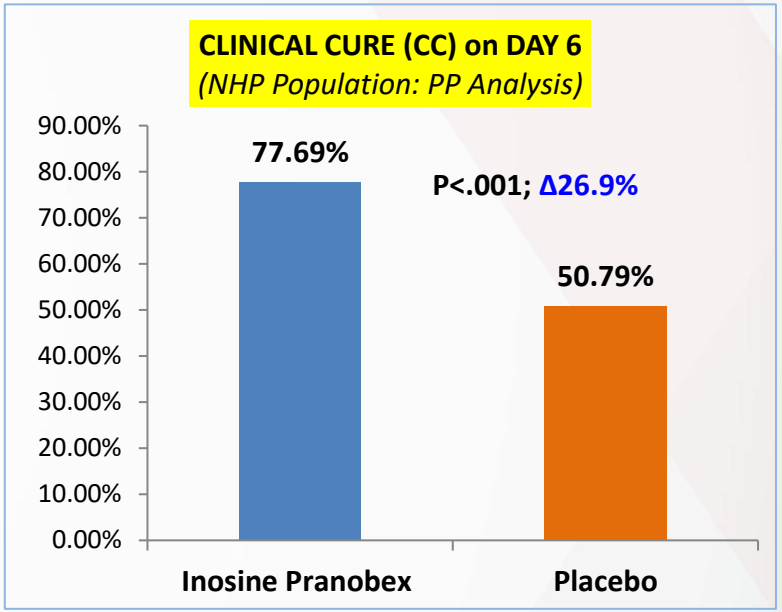
Confirmatory CD:

- Phase 3 RCT
- Double Blind
- Placebo controlled
- **416 Patients**

Total no of patients studied (India)= 83 + 416= 499

Phase 3 study of Viralex® in mild to moderate COVID-19





Compared to Placebo:

- CR & CC was observed significantly early in Viralex® group
- Higher no. of patients in the Viralex® group had CR & CC starting from ***Day 3***
- No serious adverse event in the Viralex® group (*vs. 02 deaths in placebo group*)

VIRALEX®

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- Due to frequently mutating trend of the virus, uncertainties of the COVID-19 outbreak continues; endemic doesn't mean harmless!
- ***Strengthening body's immune response to viral infections*** is a much awaited treatment option to manage COVID-19.
- ***Viralex® is a new ray of hope in these challenging times.*** It enhances host immunity and continue to provide its beneficial effect to fight viral infections.
- **Viralex®** is an ***effective medicine with an established safety profile.*** Initiated early in the disease, this would considerably reduce the load on the health care system.
- Access to **Viralex®** will offer a much-needed therapeutic solution to address the unmet medical need in the management of viral infections like COVID-19, ***pandemic or endemic!***

THANK YOU