

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

Themis Medicare Limited

Corporate Office: 11/12, Udyog Nagar, S.V. Road, Goregaon (West), Mumbai- 400 104 India

Tel: 91 – 22 – 67607080 • Fax: 91 – 22 – 67607070 / 28746621

Regd. Office: Plot No.69-A, G.I.D.C. Industrial Estate, Vapi-396 195, Gujarat

CIN No: L24110GJ1969PLC001590 • Tel / Fax No: Regd. Off: 0260 2431447 / 2430219

• E-mail: themis@themismedicare.com • Website: www.themismedicare.com

(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*

Themis Medicare Limited

Corporate Office: 11/12, Udyog Nagar, S.V. Road, Goregaon (West), Mumbai- 400 104 India
Tel: 91 – 22 – 67607080 • **Fax:** 91 – 22 – 67607070 / 28746621
Regd. Office: Plot No.69-A, G.I.D.C. Industrial Estate, Vapi-396 195, Gujarat
CIN No: L24110GJ1969PLC001590 • **Tel / Fax No:** **Regd. Off:** 0260 2431447 / 2430219
• **E-mail:**themis@themismedicare.com • **Website:**www.themismedicare.com

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!

Themis Medicare Limited

Corporate Office: 11/12, Udyog Nagar, S.V. Road, Goregaon (West), Mumbai- 400 104 India
Tel: 91 – 22 – 67607080 • Fax: 91 – 22 – 67607070 / 28746621
Regd. Office: Plot No.69-A, G.I.D.C. Industrial Estate, Vapi-396 195, Gujarat
CIN No: L24110GJ1969PLC001590 • Tel / Fax No: Regd. Off: 0260 2431447 / 2430219
• E-mail:themis@themismedicare.com • Website:www.themismedicare.com



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	<i>Investor Relations:</i> 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.

Themis Medicare Limited

Corporate Office: 11/12, Udyog Nagar, S.V. Road, Goregaon (West), Mumbai- 400 104 India
Tel: 91 – 22 – 67607080 • **Fax:** 91 – 22 – 67607070 / 28746621
Regd. Office: Plot No.69-A, G.I.D.C. Industrial Estate, Vapi–396 195, Gujarat
CIN No: L24110GJ1969PLC001590 • **Tel / Fax No:** **Regd. Off:** 0260 2431447 / 2430219
• **E-mail:**themis@themismedicare.com • **Website:**www.themismedicare.com