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The Manager
Corporate Relationship Department
BSE Limited
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The Manager – Listing Department
National Stock Exchange of India Limited
Exchange Plaza,
Bandra Kurla Complex,
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Scrip Code – 530199

Symbol: THEMISMED

Sub: Press Release

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 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** (complete relief from symptoms) **was also seen in significantly higher number of patients in the VIRALEX® group as compared to that in the placebo group on day 6 of treatment**. There was *early improvement and complete relief* from symptoms in patients who received VIRALEX®. This drug was well tolerated by the patients

Themis Medicare Limited

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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 add-on therapy for treatment of mild and moderate COVID-19.*

VIRALEX® would be available on 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).**

Professor Jiri Beran, a clinician, academician and a long-time researcher on this drug and viral diseases from Czech Republic said "Natural Killer (NK) cells play an important role in the control of viral infections. A study done in University of Birmingham showed that Inosine Pranobex increased the NK cell level just after 90 minutes of oral administration and this increased by double of the base level by day 5. Inosine Pranobex stimulates immune system by lymphocyte proliferation, and elevation of NK cell level and cytokine production by Th 1 response."

Dr Jiří Beran is the Professor & Head of the Department for Tropical, Travel Medicine and Vaccination, at Institute for Postgraduate Health Education in Prague and is also the Director of the Vaccination and Travel Medicine Centre in Hradec Králové. Dr Beran has studied the drug in elderly nursing home patients who were exposed to COVID-19 and as per his research Inosine pranobex reduced case fatality rate in these elderly patients.

Inosine pranobex is an immunomodulatory drug approved in several countries for the treatment of various viral infections such as *Acute Viral Respiratory infections like influenza, and infections caused by Human Herpes Virus and Human papillomavirus,*

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and measles virus. Use of Inosine Pranobex is well established with a good safety profile in developed western countries like UK, Canada, France, Germany, Ireland, Poland and also in Japan, Hong Kong, Singapore etc.

It clearly indicates benefits in conditions associated with viral infections and reinforce the potential to uplift where immune performance is compromised. It is a good choice for non-specific viral infections including immunosuppression happening in COVID-19 - the Professor added.

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 an affordable price Viralex will be made available across the country by mid-April.

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**", *Dr. Sachin Patel* added.

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.

With a strong R&D backup, skilled domestic & export teams, and 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!

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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

Kindly take this on record.

Thanking you,

Yours faithfully,

For Themis Medicare Ltd.

Sangameshwar Iyer
Company Secretary & Compliance Officer

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