



Press Release

## **Cipla receives final approval for generic version of Migranal® (Dihydroergotamine Mesylate Nasal Spray 4mg/mL) with a Competitive Generic Therapy Designation**

**Mumbai, India; May 21, 2020:** Cipla Limited (BSE: 500087; NSE: CIPLA EQ; and hereafter referred to as "Cipla") today announced that it has received final approval for its Abbreviated New Drug Application ("ANDA") for Dihydroergotamine Mesylate Nasal Spray 4mg/mL from the United States Food and Drug Administration (U.S. FDA) with a Competitive Generic Therapy ("CGT") designation. Cipla is the "first approved applicant" for such CGT and, is therefore, eligible for 180 days of CGT exclusivity which will begin to run from the commercial marketing of Cipla's product. This 180-day CGT exclusivity will not block the commercialization of the existing approvals of Dihydroergotamine Mesylate Nasal Spray, 4 mg/mL.

Cipla's Dihydroergotamine Mesylate Nasal Spray 4mg/mL is AB-rated generic therapeutic equivalent version of Bausch Health US LLC's Migranal®. This is Cipla's first ANDA approval for a nasal spray. It is indicated for the acute treatment of migraine headaches with or without aura.

According to IQVIA (IMS Health), Migranal® and its authorized generic equivalents had U.S. sales of approximately \$102M for the 12-month period ending March 2020.

Cipla's product is available for shipping immediately.

## **About Cipla:**

Established in 1935, Cipla is a global pharmaceutical company focused on agile and sustainable growth, complex generics, and deepening portfolio in our home markets of India, South Africa, North America, and key regulated and emerging markets. Our strengths in the respiratory, anti-retroviral, urology, cardiology, anti-infective and CNS segments are well-known. Our 46 manufacturing sites around the world produce 50+ dosage forms and 1,500+ products using cutting-edge technology platforms to cater to our 80+ markets. Cipla is ranked 3rd largest in pharma in India (IQVIA MAT Mar'20), 3rd largest in the pharma private market in South Africa (IQVIA MAT Mar'20), and is among the most dispensed generic players in the U.S. For over eight decades, making a difference to patients has inspired every aspect of Cipla's work. Our paradigm-changing offer of a triple anti-retroviral therapy in HIV/AIDS at less than a dollar a day in Africa in 2001 is widely acknowledged as having contributed to bringing inclusiveness, accessibility and affordability to the centre of the HIV movement. A responsible corporate citizen, Cipla's humanitarian approach to healthcare in pursuit of its purpose of 'Caring for Life' and deep-rooted community links wherever it is present make it a partner of choice to global health bodies, peers and all stakeholders. For more, please visit [www.cipla.com](http://www.cipla.com), or click on [Twitter](#), [Facebook](#), [LinkedIn](#).

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