Press Release

DR. REDDY'S LABORATORIES LTD.
8-2-337, Road No. 3, Banjara Hills,
Hyderabad - 500034. Telangana, India.

CONTACT	
INVESTOR RELATIONS	**MEDIA RELATIONS**
AMIT AGARWAL amita@drreddys.com (Ph: +91-40-49002135)	APARNA TEKURI aparnatekuri@drreddys.com (PH: +91-40- 49002446)

Dr. Reddy's Laboratories announces the launch of Vigabatrin Tablets, USP in the U.S. Market

Hyderabad, India, February 2, 2021 **For Immediate Release**

Hyderabad, India and Princeton, NJ, USA. February 2, 2021— Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY along with its subsidiaries together referred to as "Dr. Reddy's") today announced the launch of Vigabatrin Tablets USP, 500 mg, a therapeutic equivalent generic version of Sabril® (vigabatrin) Tablets, USP, approved by the U.S. Food and Drug Administration (USFDA).

"We are pleased that this product has been designated as a Competitive Generic Therapy (CGT) by the FDA," says Marc Kikuchi, Chief Executive Officer, North America Generics, Dr. Reddy's Laboratories. "With a CGT designation, we have 180-day CGT exclusivity to market this product."

The Sabril® brand and generic had U.S. sales of approximately $141 million MAT for the most recent twelve months ending in December 2020 according to IMS Health*.

Dr. Reddy's Vigabatrin Tablets, USP are available in 500 mg tablets in a bottle count size of 100.

Please see for full prescribing information including boxed warning.
https://www.drreddys.com/pi/vigabratintabs500mg.pdf
https://www.drreddys.com/pi/vigabratintabs500mg-leaflet.pdf

WARNING: PERMANENT VISION LOSS

- Vigabatrin can cause permanent bilateral concentric visual field constriction, including tunnel vision that can result in disability. In some cases, vigabatrin also can damage the central retina and may decrease visual acuity [see Warnings and Precautions (5.1)].
- The onset of vision loss from vigabatrin is unpredictable, and can occur within weeks of starting treatment or sooner, or at any time after starting treatment, even after months or years.
- Symptoms of vision loss from vigabatrin are unlikely to be recognized by patients or caregivers before vision loss is severe. Vision loss of milder severity, while often unrecognized by the patient or caregiver, can still adversely affect function.
- The risk of vision loss increases with increasing dose and cumulative exposure, but there is no dose or exposure known to be free of risk of vision loss.
- Vision assessment is recommended at baseline (no later than 4 weeks after starting vigabatrin), at least every 3 months during therapy, and about 3 to 6 months after the discontinuation of therapy.
- Once detected, vision loss due to vigabatrin is not reversible. It is expected that, even with frequent monitoring, some patients will develop severe vision loss.
- Consider drug discontinuation, balancing benefit and risk, if vision loss is documented.
- Risk of new or worsening vision loss continues as long as vigabatrin is used. It is possible that vision loss can worsen despite discontinuation of vigabatrin tablets.

• Because of the risk of vision loss, vigabatrin should be withdrawn from patients with refractory complex partial seizures who fail to show substantial clinical benefit within 3 months of initiation and within 2 to 4 weeks of initiation for patients with infantile spasms, or sooner if treatment failure becomes obvious. Patient response to and continued need for vigabatrin should be periodically reassessed.
• Vigabatrin should not be used in patients with, or at high risk of, other types of irreversible vision loss unless the benefits of treatment clearly outweigh the risks.
• Vigabatrin should not be used with other drugs associated with serious adverse ophthalmic effects such as retinopathy or glaucoma unless the benefits clearly outweigh the risks.
• Use the lowest dosage and shortest exposure to vigabatrin consistent with clinical objectives [see Dosage and Administration (2.1)].

Because of the risk of permanent vision loss, vigabatrin tablets are available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the Vigabatrin REMS Program [see Warnings and Precautions (5.2)]. Further information is available at www.vigabatrinREMS.com or 1-866-244-8175.

Sabril® is a trademark of Lundbeck.
*IMS National Sales Perspective: Retail and Non-Retail MAT December 2020
RDY-0121-327

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About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. ((BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, India, Russia & CIS countries, and Europe. For more information, log on to: www.drreddys.com

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