



GEDEON RICHTER

## **FDA has granted 6-month additional exclusivity for Cariprazine in the U.S.**

**Budapest, 15 December 2025** – Gedeon Richter Plc. (“Richter”) announces today that the U.S. Food and Drug Administration (“FDA”) has determined that AbbVie has fairly responded to the pediatric written request (PWR) issued by the FDA for Cariprazine. Cariprazine is commercialized in the U.S. under the brand name Vraylar® by AbbVie. As a result, the FDA has granted AbbVie an additional 6-month market exclusivity period in the U.S., expiring on 17 March 2030.

### **About Richter**

Richter aspires to be a global innovator in some key scientific fields, while dedicated to making medicines more accessible worldwide. Founded in 1901, headquartered in Hungary, with a market capitalization of EUR 4.7bn and sales of EUR 2.2bn in 2024, it operates Central Europe's largest R&D hub. Its research drives breakthroughs in Neuropsychiatry and Women's Healthcare, while Biotechnology and General Medicines strengthen its affordable treatment portfolio. Committed to sustainable growth, Richter invests in R&D, manufacturing excellence, and digitalization to advance medical innovation. Learn more at [www.gedeonrichter.com](http://www.gedeonrichter.com)

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