RECORDATI

NEWS RELEASE

RECORDATI PROVIDES UPDATE ON ISTURISA® U.S.

Company maintains its position that generic entry is not expected before 2033

Milan, 20th October 2026 – Recordati announces that it has received a Paragraph IV Notice Letter from a generic Abbreviated New Drug Filer notifying Recordati that it has filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to market a generic version of Isturisa® (osilodrostat) in the United States. Paragraph IV Notice Letters are a customary feature of the U.S. generic pharmaceutical approval process and additional similar notices from generic manufacturers may follow. Recordati continues to believe that generic entry for ISTURISA® will not be possible prior to at least 2033, with additional Orange Book patents expiring in 2035.

ISTURISA® is protected by five unexpired patents listed in the FDA's Orange Book with expiration dates in 2031, 2033 and 2035. The Notice Letter contains Paragraph IV certifications challenging these patents. Recordati is reviewing the details of the filing and intends to defend and enforce its intellectual property rights.

Under U.S. law, when Recordati initiates qualifying patent infringement litigation within 45 days of receiving the Notice Letter, FDA approval of the generic application would generally be subject to a 30-month stay, subject to applicable statutory exceptions and court decisions.

In addition, ISTURISA® benefits from orphan-drug exclusivity in the United States extending to April 2032 for its expanded indication in Cushing's syndrome, subject to the scope of the applicable regulatory protection.

Rob Koremans, Chief Executive Officer of Recordati, commented, "These kinds of challenges are common in the pharma industry and we are well prepared to deal with them. We remain confident in the strength of our intellectual property portfolio and are committed to protecting this important medicine. Our assessment of the expected timing of generic competition remains unchanged, and we continue to focus on delivering ISTURISA® to patients who need it."

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Company subject to the Management and Coordination Activity of Rossini Luxembourg S.àr.l

Recordati is an international pharmaceutical Group listed on the Italian Stock Exchange (XMIL: REC), with roots dating back to a family-run pharmacy in Northern Italy in the 1920s. We are uniquely structured to provide treatments across specialty and primary care and rare diseases. Our fully integrated operations span clinical development, manufacturing of active ingredients and finished products, commercialization and licensing. We operate in approximately 150 countries across EMEA, the Americas and APAC, with around 4,700 employees. We believe that health is a fundamental right, not a privilege. Today, our purpose "Unlocking the full potential of life" aims to empower individuals to live life to the fullest, from common conditions to the rarest.

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