FOR IMMEDIATE RELEASE

Recordati Rare Diseases Introduces New PANHEMATIN® (Hemin for Injection) Dosage Strength for Treatment of Acute Intermittent Porphyria (AIP)

Updated Label Reflects More Than 30 Years of Clinical Experience

LEBANON, N.J. (Wed.,July 5)—Recordati Rare Diseases Inc., a biopharmaceutical company committed to providing orphan therapies to underserved rare disease communities in the U.S., today announced the launch of a 350-mg single-vial dosage strength of PANHEMATIN® (hemin for injection) for the amelioration of recurrent attacks of acute intermittent porphyria (AIP). AIP is a genetic metabolic disorder that affects the production of heme, a substance inside red blood cells that produces hemoglobin. The new dosage strength of PANHEMATIN – a product originally approved by the U.S. Food and Drug Administration (FDA) in 1983 – more accurately reflects the dose required to treat most patients with AIP in this country, and increases the number of patients potentially eligible for treatment with only one vial per day.

The label for the 350-mg single-vial product will reflect the new dosage strength as well as a summary of the extensive clinical experience with PANHEMATIN since its introduction more than 30 years ago. Label updates include the introduction of a clinical studies section, an updated adverse events section, and the elimination of the boxed warning. Recordati Rare Diseases is also introducing a Co-Pay Assistance program for PANHEMATIN, which, for the first time, will help eligible patients in the outpatient setting with their insurance co-pays.

“For more than three decades, physicians have relied upon PANHEMATIN as the only FDA-approved treatment indicated specifically for patients with acute intermittent porphyria,” said Paul Stickler, Vice President of Commerical Operations at Recordati Rare Diseases. “By making the dose needed for most patients available in a single vial, the new 350-mg dosage strength of PANHEMATIN may make treatment of this devastating and painful disease less burdensome, thus addressing the needs of patients, physicians, and healthcare systems.”

About Acute Intermittent Porphyria (AIP)

AIP is one of a group of blood conditions, known as porphyrias, that result from the lack of a specific enzyme the body needs to produce heme. This causes a build-up of intermediate products (unfinished heme) which is thought to cause the characteristic life-threatening symptoms of AIP. These symptoms include severe abdominal pain, vomiting, constipation, diarrhea, red or dark-colored urine, muscle weakness, breathing problems, fast heart rate, hypertension (high blood pressure), convulsions, psychological symptoms (such as minor behavioral changes, anxiety, confusion, or depression), and pain in the arms, hands, legs, feet, back, chest, neck, or head.

Indications and Usage

PANHEMATIN is a hemin for injection indicated for the amelioration of recurrent attacks of acute intermittent porphyria temporally related to the menstrual cycle in susceptible women, after initial carbohydrate therapy is known or suspected to be inadequate.

Limitations of Use

- Before administering PANHEMATIN, consider an appropriate period of carbohydrate loading (i.e., 400 grams of glucose per day for 1 to 2 days).
- Attacks of porphyria may progress to a point where irreversible neuronal damage has occurred. PANHEMATIN therapy is intended to prevent an attack from reaching the critical stage of neuronal degeneration. PANHEMATIN is not effective in repairing neuronal damage.

Important Safety Information

- Do not use in patients with known hypersensitivity to PANHEMATIN.
- Phlebitis is possible. Utilize a large arm vein or a central venous catheter for administration to minimize the risk of phlebitis.
- Elevated iron and serum ferritin may occur. Monitor iron and serum ferritin in patients receiving multiple administrations of PANHEMATIN.
- PANHEMATIN has transient and mild anticoagulant effect. Avoid concurrent anticoagulant therapy.
- Reversible renal shutdown has been observed with an excessive hematin dose (12.2 mg/kg in a single infusion). Strictly follow recommended dosage guidelines.
- PANHEMATIN may carry a risk of transmitting infectious agents, e.g., viruses, and theoretically, the Creutzfeldt-Jakob disease (CJD) agent.
- Most common adverse reactions in >1% of patients are headache, pyrexia, infusion site reactions, and phlebitis.
- **To report SUSPECTED ADVERSE REACTIONS, contact Recordati Rare Diseases Inc. at 1-888-575-8344, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**
- Avoid CYP inducing drugs such as estrogens, barbituric acid derivatives and steroid metabolites which induce δ-aminolevulinic acid synthetase 1 (ALAS1) through a feedback mechanism.

For more information about PANHEMATIN, visit www.panhematin.com.

About Recordati Rare Diseases Inc.
Recordati Rare Diseases Inc. is a biopharmaceutical company committed to providing often overlooked orphan therapies to the underserved rare disease communities of the United States. Recordati Rare Diseases and our sister company, Orphan Europe, are part of the rare disease business within the Recordati Group, a public global pharmaceutical company committed to the research and development of new specialties with a focus on treatments for rare diseases.

Recordati Rare Diseases' mission is to reduce the impact of extremely rare and devastating diseases by providing urgently needed therapies. We work side-by-side with rare disease communities to increase awareness, improve diagnosis and expand availability of treatments for people with rare diseases.

Recordati Rare Diseases focuses on inborn errors of metabolism and pediatrics. We began marketing products to treat rare diseases in 2013. The U.S. Food and Drug Administration (FDA) has granted four of our products orphan drug designation. For a full list of our products please click here.

The company's U.S. corporate headquarters is located in Lebanon, NJ, with global headquarter offices located in Milan, Italy.

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PANHEMATIN is a registered trademark of Recordati Rare Diseases Inc.

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