Recordati Rare Diseases, Inc. Announces Transfer of U.S. Marketing Rights to SIGNIFOR® (pasireotide) Injection and SIGNIFOR LAR® (pasireotide) for Injectable Suspension

Lebanon, NJ, February 20, 2020—Recordati Rare Diseases, Inc., a biopharmaceutical company committed to providing orphan therapies to underserved rare disease communities in the U.S., today announced the transfer of U.S. marketing rights to SIGNIFOR® (pasireotide) injection and SIGNIFOR LAR® (pasireotide) for injectable suspension. SIGNIFOR is a prescription medication indicated for the treatment of patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative. SIGNIFOR LAR is the only once-a-month injectable prescription medication approved by the U.S. Food & Drug Administration (FDA), indicated for the treatment of patients with Cushing's disease and acromegaly for whom pituitary surgery is not an option or has not been curative.

SIGNIFOR and SIGNIFOR LAR will continue to be available uninterrupted to patients and healthcare providers and without changes to the direct distribution model with a specialty pharmacy. The products will be marketed through Recordati Rare Diseases' newly established Endocrinology franchise.

Cushing's syndrome is an endocrine disorder caused by excessive cortisol, a vital hormone that regulates metabolism, maintains cardiovascular function and helps the body respond to stress. Cushing's disease is a form of Cushing's syndrome, in which excess cortisol production is triggered by a pituitary adenoma secreting excess adrenocorticotropic hormone (ACTH). It is a rare but serious disease that affects approximately one to two patients per million per year. Cushing's disease most commonly affects adults as young as 20 to 50 years and affects women three times more often than men. It may present with weight gain, central obesity, a round, red full face, severe fatigue and weakness, striae (purple stretch marks), high blood pressure, depression and anxiety. Cushing's disease can cause severe illness and death with mortality up to four times higher than in the healthy population.

Acromegaly is a rare, debilitating endocrine disorder caused by the excess production of growth hormone (GH) and insulin-like growth factor-1 (IGF-1). In the majority of cases, the disease is caused by a non-cancerous tumor on the pituitary gland. Prolonged exposure to GH and IGF-1 may cause patients to experience extreme physical changes including the enlargement of hands, feet and facial features. Acromegaly is also associated with two- to three-fold increased mortality rates and serious health complications, including heart disease, hypertension, diabetes, and arthritis and colon cancer. In fact, heart disease is responsible for approximately 60% of deaths among people with acromegaly.

In an effort to facilitate patient access to SIGNIFOR and SIGNIFOR LAR, Recordati Rare Diseases, Inc., offers a Copay Assistance Program to help eligible patients with their insurance copayments or co-insurance, and a Patient Assistance Program to help eligible uninsured or underinsured patients receive SIGNIFOR and SIGNIFOR LAR.

SIGNIFOR Indications and Usage

SIGNIFOR is a somatostatin analog indicated for the treatment of:

- adult patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

SIGNIFOR Important Safety Information

Warnings and Precautions

- **Hypocortisolism:** Treatment with SIGNIFOR leads to suppression of adrenocorticotropic hormone (ACTH) secretion in Cushing's disease. Suppression of ACTH may lead to a decrease in circulating levels of cortisol and potentially hypocortisolism. Monitor and instruct patients on the signs and symptoms associated with hypocortisolism (e.g., weakness, fatigue, anorexia, nausea, vomiting, hypotension, hyponatremia, or hypoglycemia). If hypocortisolism occurs, consider temporary dose

reduction or interruption of treatment with SIGNIFOR, as well as temporary, exogenous glucocorticoid replacement therapy.

- **Hyperglycemia and Diabetes:** Assess the patient's glycemic status prior to starting treatment with SIGNIFOR. If hyperglycemia develops in a patient treated with SIGNIFOR, the initiation or adjustment of anti-diabetic treatment per standard of care is recommended. Intensive glucose monitoring is recommended and may require initiation or adjustment of anti-diabetic treatment per standard of care. If uncontrolled hyperglycemia persists, despite appropriate medical management, the dose of SIGNIFOR should be reduced or discontinued.
- **Bradycardia and QT Prolongation:** Bradycardia has been reported with the use of SIGNIFOR. Patients with cardiac disease and/or risk factors for bradycardia, such as history of clinically significant bradycardia, high-grade heart block, or concomitant use of drugs associated with bradycardia, should be carefully monitored. Dose adjustments of beta-blockers, calcium channel blockers, or correction of electrolyte disturbances may be necessary. Use with caution in at-risk patients; ECG testing prior to dosing and on treatment.
- **Liver Test Elevations:** Evaluate liver enzyme tests prior to and during treatment. Please see section 5.4 in full Prescribing Information.
- **Cholelithiasis and Complications of Cholelithiasis:** Cholelithiasis has been frequently reported in clinical studies with SIGNIFOR. Ultrasonic examination of the gallbladder before, and periodically during SIGNIFOR therapy is recommended. If complications of cholelithiasis are suspected, discontinue SIGNIFOR and treat appropriately.

Adverse Reactions

- Most common adverse reactions occurring in ≥20% of patients are diarrhea, nausea, hyperglycemia, cholelithiasis, headache, abdominal pain, fatigue, and diabetes mellitus.
- **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.**

Drug Interactions

- **Drugs that Prolong QT:** Use with caution in patients who are at significant risk of developing QTc prolongation.
- **Cyclosporine:** Consider additional monitoring.
- **Bromocriptine:** Consider bromocriptine dose reduction.

Use In Specific Populations

- **Females and Males of Reproductive Potential:** Advise premenopausal females of the potential for an unintended pregnancy.
- Safety and effectiveness of SIGNIFOR in children under 18 years have not been established.

SIGNIFOR LAR Indications and Usage

SIGNIFOR LAR is a somatostatin analog indicated for the treatment of:

- Patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option.
- Patients with Cushing's disease for whom pituitary surgery is not an option or has not been curative.

SIGNIFOR LAR Important Safety Information

Warnings and Precautions

- **Hyperglycemia and Diabetes:** SIGNIFOR LAR can cause increases in blood glucose levels which are sometimes severe. Patients who develop significant hyperglycemia on SIGNIFOR LAR may require initiation of anti-diabetic therapy or adjustment in their current anti-diabetic therapy per standard of care. The optimal treatment for the management of SIGNIFOR LAR-induced hyperglycemia is not known. If hyperglycemia cannot be controlled despite medical management, the dose of SIGNIFOR LAR should be reduced or SIGNIFOR LAR should be discontinued.

- **Bradycardia and QT Prolongation:** Bradycardia has been reported with the use of SIGNIFOR LAR. Patients with cardiac disease and/or risk factors for bradycardia, such as history of clinically significant bradycardia, high grade heart block, or concomitant use of drugs associated with bradycardia, should be monitored. Adjustments in the dose of drugs known to slow the heart rate (e.g., beta-blockers, calcium channel blockers) and correction of electrolyte disturbances may be necessary when initiating or during the course of SIGNIFOR LAR treatment. Use with caution in at-risk patients; evaluate ECG and electrolytes prior to dosing and periodically while on treatment.
- **Liver Test Elevations:** Evaluate liver enzyme tests prior to and during treatment. Please see sections 2.1, 5.3 in full Prescribing Information.
- **Cholelithiasis and Complications of Cholelithiasis:** Monitor periodically. Discontinue if complications of cholelithiasis are suspected. Please see section 5.4 in full Prescribing Information.
- **Pituitary Hormone Deficiency(ies):** Monitor for occurrence periodically and treat if clinically indicated. Please see section 5.5 in full Prescribing Information.

Adverse Reactions

- Adverse drug reactions associated with SIGNIFOR LAR and occurring in ≥20% of patients were diarrhea, cholelithiasis, hyperglycemia and diabetes mellitus.
- **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.**

Drug Interactions

- **Drugs that Prolong QT:** Use with caution in patients who are at significant risk of developing QTc prolongation.
- **Cyclosporine:** Consider additional monitoring.
- **Bromocriptine:** Consider bromocriptine dose reduction

Females and Males of Reproductive Potential

- Advise premenopausal females of the potential for an unintended pregnancy

Please see Full Prescribing Information for SIGNIFOR and SIGNIFOR LAR at www.recordatirarediseases.com/us/products.

For general inquiries, please email info@recordatirarediseases.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 is a part of the rare disease business within the Recordati Group, a public international 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.

For a full list of our products please click here: www.recordatirarediseases.com/us/products

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

PP-SIGSIGL-US-0005