

**FOR IMMEDIATE RELEASE**

## **Sun Pharma Launches Ezallor Sprinkle (Rosuvastatin) in the U.S. for People Who Have Difficulty Swallowing**

- *First and only FDA-approved sprinkle formulation of rosuvastatin*
- *Extended-release-coated granules designed to facilitate once-daily administration especially for the 30-35% of long term care residents who have difficulty swallowing*
- *Ezallor Sprinkle™ (rosuvastatin) capsules is indicated for three types of lipid disorders in conjunction with diet in adults*

**Mumbai, India, and Princeton, NJ, July 15, 2019** – Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" including its subsidiaries and/or associate companies) today announced the U.S. launch of Ezallor Sprinkle™ (rosuvastatin) capsules for the treatment of three types of elevated lipid disorders in people who have difficulty swallowing, a problem that is estimated to affect approximately 30-35% of long-term care residents.

Ezallor Sprinkle is indicated as an adjunct to diet for the treatment of adult patients with hypertriglyceridemia, as an adjunct to diet for the treatment of adult patients with primary dysbetalipoproteinemia (type III hyperlipoproteinemia), and as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or as monotherapy if such treatments are unavailable, to reduce LDL-C, total cholesterol, and ApoB in adult patients with homozygous familial hypercholesterolemia. Ezallor Sprinkle has not been studied in Fredrickson type I and V dyslipidemias.

"With the introduction of Ezallor Sprinkle, Sun Pharma continues our commitment of providing a portfolio of alternative formulation products to address the needs of people who have difficulty swallowing, which is especially prevalent among residents in long-term care facilities," said Abhay Gandhi, CEO, North America, Sun Pharma. "These patients often encounter more medication errors and challenges with medication administration as compared to long-term care residents who do not have difficulty swallowing."

"The risk of medication errors increases when people have difficulty swallowing, due to crushing of medicines that shouldn't be crushed, or from residual medication left over in crushing devices," said Dr. Chris Chappel, certified Medical Director, Chappel Senior Care and Chappel Group Research. "This formulation will help in administering medication for patients with common types of elevated lipid disorders, especially in the geriatric population."

Ezallor Sprinkle is formulated as extended-release-coated pellets that may be sprinkled over soft food such as applesauce, can be swallowed whole, or administered via a nasogastric tube to facilitate long-term, once-daily administration. Ezallor Sprinkle joins Kaspargo Sprinkle™ (metoprolol succinate) extended-release capsules as the second product in the Sun Pharma portfolio designed for individuals in long-term care.

Ezallor Sprinkle is contraindicated in patients with any known hypersensitivity to rosuvastatin, which may include rash, pruritus, urticaria, and angioedema; patients with active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels, and females who are pregnant or breastfeeding. In the controlled clinical trials database, the most common adverse reactions with rosuvastatin were headache, myalgia, abdominal pain, asthenia, and nausea.

For more information about Ezallor Sprinkle, visit [EzallorSprinkleRx.com](http://EzallorSprinkleRx.com)

### **About Ezallor Sprinkle (Rosuvastatin) Capsules**

Ezallor Sprinkle (rosuvastatin) capsules, for oral use, is an HMG Co-A reductase inhibitor ("statin") indicated as:

- An adjunct to diet for the treatment of adult patients with hypertriglyceridemia
- An adjunct to diet for the treatment of adult patients with primary dysbetalipoproteinemia (type III hyperlipoproteinemia)
- An adjunct to other lipid-lowering treatments (e.g., LDL apheresis), or as monotherapy if such treatments are unavailable, to reduce LDL-C, total cholesterol, and ApoB in adult patients with homozygous familial hypercholesterolemia

Ezallor Sprinkle capsules are available in 5-mg, 10-mg, 20-mg, and 40-mg dose strengths. The dose range is 5 mg to 40 mg once daily; the 40-mg dose is only for patients not reaching their LDL-C goal with a 20-mg dose. The product can be taken with or without food, at any time of day.

### **Limitations and Use**

Ezallor Sprinkle has not been studied in Fredrickson type I and V dyslipidemias. Ezallor Sprinkle is indicated only for use in patients aged 18 years and older.

### **IMPORTANT SAFETY INFORMATION**

#### **Contraindications**

- Patients with a known hypersensitivity to any component of this product. Hypersensitivity reactions including rash, pruritus, urticaria, and angioedema have been reported with rosuvastatin.
- Patients with active liver disease, which may include unexplained persistent elevations of hepatic transaminase levels.
- Pregnancy: advise females of reproductive potential to use effective contraception during treatment with Ezallor Sprinkle.
- Lactation: limited data indicate that rosuvastatin is present in human milk. Because statins have the potential for serious adverse reactions in nursing infants, women who require Ezallor Sprinkle treatment should not breastfeed their infants.

#### **Warnings & Precautions**

- Skeletal Muscle Effects: Cases of myopathy and rhabdomyolysis with acute renal failure secondary to myoglobinuria have been reported with HMG-CoA reductase inhibitors, including rosuvastatin. These risks can occur at any dose level, but are increased at the highest dose (40 mg). Ezallor Sprinkle should be prescribed with caution in patients with predisposing factors for

myopathy (e.g., aged  $\geq 65$  years, inadequately treated hypothyroidism, renal impairment). The risk of myopathy during treatment with Ezallor Sprinkle may be increased with concurrent administration of some other lipid-lowering therapies (fibrates or niacin), gemfibrozil, cyclosporine, lopinavir/ritonavir, atazanavir/ritonavir, or simeprevir. Ezallor Sprinkle therapy should be discontinued if markedly elevated creatine kinase (CK) levels occur or myopathy is diagnosed or suspected. There have been rare reports of immune-mediated necrotizing myopathy (IMNM), an autoimmune myopathy associated with statin use. All patients should be advised to promptly report unexplained muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever, and if muscle signs and symptoms persist after discontinuing Ezallor Sprinkle.

- **Liver Enzyme Abnormalities:** It is recommended that liver enzyme tests be performed before the initiation of Ezallor Sprinkle, and if signs or symptoms of liver injury occur. There have been rare post marketing reports of fatal and non-fatal hepatic failure in patients taking statins, including rosuvastatin. If serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs during treatment with Ezallor Sprinkle, promptly interrupt therapy. If an alternate etiology is not found, do not restart Ezallor Sprinkle. Ezallor Sprinkle should be used with caution in patients who consume substantial quantities of alcohol and/or have a history of chronic liver disease. Active liver disease, which may include unexplained persistent transaminase elevations, is a contraindication to the use of Ezallor Sprinkle.
- **Concomitant Coumarin Anticoagulants:** Caution should be exercised when anticoagulants are given in conjunction with Ezallor Sprinkle because of its potentiation of the effect of coumarin-type anticoagulants in prolonging the prothrombin time/international normalized ratio (INR). In patients taking coumarin anticoagulants and Ezallor Sprinkle concomitantly, INR should be determined before starting Ezallor Sprinkle and frequently enough during early therapy to ensure that no significant alteration of INR occurs.
- **Proteinuria and Hematuria:** Dipstick-positive proteinuria and microscopic hematuria were observed among patients treated with CRESTOR. These findings were more frequent in patients taking rosuvastatin 40 mg, though it was generally transient and was not associated with worsening renal function. Although the clinical significance of this finding is unknown, dose reduction should be considered for patients on Ezallor Sprinkle therapy with unexplained persistent proteinuria and/or hematuria during routine urinalysis testing.
- **Endocrine Effects:** Increases in HbA1c and fasting serum glucose levels have been reported with statins, including rosuvastatin. Based on clinical trial data with rosuvastatin, in some instances these increases may exceed the threshold for the diagnosis of diabetes mellitus.

## ADVERSE REACTIONS

In the controlled clinical trials database, the most common adverse reactions were headache, myalgia, abdominal pain, asthenia, and nausea. There have been rare reports of immune-mediated myopathy associated with statin use. There have been rare post marketing reports of cognitive impairment (e.g., memory loss, forgetfulness, amnesia, memory impairment, and confusion) associated with statin use. These cognitive issues have been reported for all statins.

The reports are generally nonserious, and reversible upon statin discontinuation, with variable times to symptom onset (1 day to years) and symptom resolution (median of 3 weeks).

Please see Full Prescribing Information by clicking [here](#).

### **About Hypertriglyceridemia, Primary Dysbetalipoproteinemia, and Homozygous Familial Hypercholesterolemia**

Hypertriglyceridemia is a common disorder characterized by elevated levels of triglycerides, a type of blood fat that requires insulin to remove it from the blood.<sup>i</sup> It is often caused or exacerbated by uncontrolled diabetes, obesity, and a sedentary lifestyle, all of which are prevalent in industrialized societies.<sup>ii</sup> Among U.S. adults aged 20 years and older, an estimated 35% of men and 25% of women have hypertriglyceridemia (defined as triglyceride levels of at least 150 mg/dL<sup>iii</sup>).<sup>iv</sup>

Dysbetalipoproteinemia (also known as type III hyperlipoproteinemia) is a rare metabolic disorder characterized by abnormally elevated concentrations of intermediate-density lipoprotein (IDL), and by the body's decreased ability to convert very low-density lipoprotein (VLDL) and IDL (a VLDL remnant) to low-density lipoprotein particles in the blood. Patients with dysbetalipoproteinemia typically have elevated total cholesterol (from 300 to 600 mg/dL) and triglyceride levels (usually above 400 mg/dL, though some may exceed 1000 mg/dL).<sup>2</sup>

Homozygous familial hypercholesterolemia (HoFH) is the most severe form of familial hypercholesterolemia<sup>v</sup>, an autosomal dominant (a pattern of inheritance in which a child inherits one copy of a mutated [changed] gene from one parent<sup>vi</sup>) disorder that causes severe elevations in total cholesterol and LDL-C.<sup>vii</sup> The disorder results in aggressive atherosclerosis (narrowing and blockage of the arteries). If left untreated, HoFH can lead to heart attack and sudden death in childhood and adulthood. HoFH is a rare disease, estimated to affect up to 1 in 160,000 individuals around the world.<sup>5</sup>

### **About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050)**

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and a skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 100 countries across the world. Sun Pharma's global presence is supported by 44 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. In India, the company enjoys leadership across 10 different classes of doctors with 30 brands featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 3 global markets. Its API business footprint is strengthened through 14 world class API manufacturing facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and R&D investments of approximately 8% of annual revenues. For further information, please visit [www.sunpharma.com](http://www.sunpharma.com) & follow us on Twitter @SunPharma\_Live.

## Disclaimer

Statements in this "Document" describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events may be "forward looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied.

## References:

- <sup>i</sup> Triglyceride. Diabetes Dictionary. T-1 Today, Inc. (d/a/a/ Children with Diabetes); 2018. Available at: <https://archive.childrenwithdiabetes.com/dictionary/t.htm#triglycerides>. Accessed May 17, 2019.
- <sup>ii</sup> Sweeney MET. Hypertriglyceridemia. Medscape.com; 2018. Available at: <https://emedicine.medscape.com/article/126568-overview#showall>. Accessed May 17, 2019.
- <sup>iii</sup> Executive Summary of the Third Report of The National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). *JAMA*. 2001;285(19):2486-97.
- <sup>iv</sup> Ford ES, Giles WH, Dietz WH. Prevalence of the metabolic syndrome among US adults: findings from the third National Health and Nutrition Examination Survey. *JAMA*. 2002;287(3):356-9.
- <sup>v</sup> Homozygous familial hypercholesterolemia. The FH Foundation; 2019. Available at: <https://thefhfoundation.org/familial-hypercholesterolemia/homozygous-familial-hypercholesterolemia>. Accessed May 17, 2019.
- <sup>vi</sup> Autosomal dominant inheritance. NCI Dictionary of Cancer Terms; 2019. Available at: <https://www.cancer.gov/publications/dictionaries/cancer-terms/def/793860>. Accessed May 17, 2019.
- <sup>vii</sup> July M. Familial hypercholesterolemia. Medscape.com; 2018. Available at: <https://emedicine.medscape.com/article/121298-overview#showall>. Accessed May 17, 2019.

## Contacts:

### Investors:

Nimish Desai  
Tel +91 22 4324 4324, Xtn 2778  
Tel Direct +91 22 4324 2778  
Mobile +91-98203 30182  
E mail [nimish.desai@sunpharma.com](mailto:nimish.desai@sunpharma.com)

### Media:

Gaurav Chugh  
Tel +91 22 4324 4324, Xtn 5373  
Tel Direct +91 22 4324 5373  
Mobile +91 98104 71414  
E mail [gaurav.chugh@sunpharma.com](mailto:gaurav.chugh@sunpharma.com)