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**FOR IMMEDIATE RELEASE**

## **Sun Pharma Launches Novel Drug Kaspargo Sprinkle™ in USA**

*First USFDA approved, extended-release sprinkle formulation of metoprolol succinate indicated for treatment of patients with Hypertension, Angina Pectoris and Heart Failure*

*Extended-release-coated pellets may be sprinkled over soft food or administered via a nasogastric tube to facilitate long-term, once-daily administration for patients who have difficulty swallowing*

**Mumbai, India, and Princeton, NJ, August 6, 2018** – 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 that Sun Pharma has launched Kaspargo Sprinkle (metoprolol succinate) extended-release capsules in the US, for the treatment of hypertension (to lower blood pressure), angina pectoris (chest pain), and heart failure (to reduce the risk of cardiovascular mortality and heart-failure hospitalization in patients with heart failure).

Kaspargo Sprinkle, a U.S. Food and Drug Administration (FDA) approved, novel, patented formulation of metoprolol succinate, is the first and only extended-release sprinkle formulation of this beta<sub>1</sub>-selective adrenoceptor blocking agent (beta-blocker). It is covered by United States Patent numbers 9,504,655 and 9,700,530, expiring Jul 09, 2035.

Kaspargo Sprinkle pellets can be sprinkled over soft food (such as applesauce, yogurt or pudding) or administered via a nasogastric tube, and are designed to facilitate long-term, once-daily administration, particularly for patients who have difficulty swallowing.

"Roughly 40% of patients requiring long-term care have difficulty swallowing, a problem that may result in patient non-adherence to medications as well as medication errors," said Abhay Gandhi, CEO-North America, Sun Pharma. "Kaspargo Sprinkle capsules may make it easier for patients to take their antihypertensive medication. This innovative product is the latest example of Sun Pharma's use of advanced technology to create novel formulations of proven medications."

### **About Kaspargo Sprinkle extended-release capsules**

Kaspargo Sprinkle is a novel formulation of metoprolol succinate, a beta<sub>1</sub>-selective (cardioselective) adrenoceptor blocking agent, for oral administration. It is available as extended-release capsules that comprise a multiple unit system containing metoprolol succinate in a multitude of controlled-release pellets. Each pellet acts as a separate drug delivery unit that is designed to deliver metoprolol continuously over the dosage interval. The extended-release capsules are available in dosage strengths of 25 mg, 50 mg, 100 mg and 200 mg.

Kaspargo Sprinkle is contraindicated in patients with (1) known hypersensitivity to the product components; (2) severe bradycardia, greater than first-degree heart block, or sick sinus syndrome without a pacemaker; and (3) cardiogenic shock or decompensated heart failure. In clinical trials, most common adverse reactions were tiredness, dizziness, depression, shortness of breath, bradycardia, hypotension, diarrhea, pruritus, and rash.

### **Important Administration Instructions**

Kaspargo Sprinkle is to be administered once-daily in a single dose for all approved indications. For patients with swallowing difficulty, Kaspargo Sprinkle can be opened and its contents can be sprinkled over soft food. The contents of the capsules should be swallowed along with a small amount (teaspoonful) of soft food such as applesauce, pudding, or yogurt. The drug/food mixture should be swallowed within 60 minutes and not stored for future use.

The extended-release pellets contained in Kaspargo Sprinkle capsules allow for administration through a nasogastric tube. This involves opening and adding the contents of a capsule to an all-plastic oral tip syringe and adding 15 mL of water, followed by gentle shaking of the syringe for approximately 10 seconds and prompt delivery through a 12 French or larger nasogastric tube. Ensure no granules are left in the syringe. Rinse with additional water if needed.

Kaspargo Sprinkle extended-release capsules require no crushing, therefore it eliminates the risk of leaving trace medication behind after crushing.

## INDICATIONS AND USAGE

Kaspargo Sprinkle extended-release capsules are beta<sub>1</sub>-selective adrenoceptor blocking agent indicated for the treatment of:

- Hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily stroke and myocardial infarction.
- Angina pectoris. Long-term treatment to reduce angina attacks and to improve exercise tolerance
- Heart failure, to reduce the risk of cardiovascular mortality and hospitalization in patients with heart failure

## IMPORTANT SAFETY INFORMATION

### Contraindications

Kaspargo Sprinkle is contraindicated in patients with:

- Known hypersensitivity to the product components
- Severe bradycardia, greater than first-degree heart block, or sick sinus syndrome without a pacemaker
- Cardiogenic shock or decompensated heart failure

### Warnings and Precautions

- **Abrupt Cessation of Therapy:** Following abrupt cessation of therapy with certain beta-blocking agents, exacerbations of angina pectoris and, in some cases, myocardial infarction have occurred. When discontinuing chronically administered metoprolol succinate, particularly in patients with ischemic heart disease, gradually reduce the dosage over a period of 1 to 2 weeks and monitor the patient. If angina markedly worsens or acute coronary ischemia develops, promptly reinstate metoprolol succinate, and take measures appropriate for the management of unstable angina. Warn patients not to interrupt therapy without their physician's advice. Because coronary artery disease is common and may be unrecognized, avoid abruptly discontinuing metoprolol succinate in patients treated only for hypertension.
- **Heart Failure:** Worsening cardiac failure may occur during up-titration of metoprolol succinate. If such symptoms occur, increase diuretics and restore clinical stability before advancing the dose of metoprolol succinate.
- **Bronchospastic Disease:** PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RECEIVE BETA-BLOCKERS. Because beta<sub>1</sub>-selectivity is not absolute, use the lowest possible dose of metoprolol succinate. Bronchodilators, including beta<sub>2</sub>-agonists, should be readily available or administered concomitantly.
- **Pheochromocytoma:** If metoprolol succinate is used in the setting of pheochromocytoma, it should be given in combination with an alpha blocker, and only after the alpha blocker has been initiated. Administration of beta-blockers alone in the setting of pheochromocytoma has been associated with a paradoxical increase in blood pressure due to the attenuation of beta-mediated vasodilatation in skeletal muscle.
- **Major Surgery:** Avoid initiation of a high-dose regimen of extended-release metoprolol in patients undergoing noncardiac surgery, since such use in patients with cardiovascular risk factors has been

associated with bradycardia, hypotension, stroke, and death. Do not routinely withdraw chronic beta-blocker therapy prior to surgery.

- **Masked Symptoms of Hypoglycemia:** Beta-blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected.
- **Thyrotoxicosis:** Beta-adrenergic blockade may mask certain clinical signs of hyperthyroidism, such as tachycardia. Abrupt withdrawal of beta-blockade may precipitate a thyroid storm.
- **Peripheral Vascular Disease:** Beta-blockers can precipitate or aggravate symptoms of arterial insufficiency in patients with peripheral vascular disease.

### Adverse Reactions

- In clinical trials, most common adverse reactions were tiredness, dizziness, depression, shortness of breath, bradycardia, hypotension, diarrhea, pruritus, and rash.

### Drug Interactions

- **Catecholamine-Depleting Drugs** may have an additive effect when given with beta-blocking agents. Observe patients treated with metoprolol succinate plus a catecholamine depleter for evidence of hypotension or marked bradycardia, which may produce vertigo, syncope, or postural hypotension.
- **Epinephrine:** Patients with a history of severe anaphylactic reactions to a variety of allergens may be more reactive and may be unresponsive to the usual doses of epinephrine used to treat allergic reaction.
- **CYP2D6 Inhibitors:** Drugs that are strong inhibitors of CYP2D6, such as quinidine, fluoxetine, paroxetine, and propafenone, were shown to double metoprolol concentrations.
- **Digitalis, Clonidine, and Calcium Channel Blockers:** Concomitant use of glycosides, clonidine, diltiazem, and verapamil with beta-blockers can increase the risk of bradycardia. Beta-blockers including metoprolol may exacerbate the rebound hypertension that can follow the withdrawal of clonidine.
- **Alcohol:** Metoprolol succinate is released faster from Kapsargo Sprinkle in the presence of alcohol. Avoid alcohol consumption when taking Kapsargo Sprinkle.

### Use in Specific Populations

- **Hepatic Impairment:** Consider initiating therapy with metoprolol at low doses, and gradually increase dosage to optimize therapy while monitoring closely for adverse events.

### Please see full Prescribing Information

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### 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.

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

Sun Pharma is the world's fifth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely 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 150 countries across the world. Sun Pharma's global presence is supported by 41 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 13 different classes of doctors with 31 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

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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.

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