

FDA Approves Althera's **Roszet** (rosuvastatin and ezetimibe) Tablets, a New Oral Therapy for Powerful Cholesterol Reduction

-**Roszet**[®] is indicated for adults with Primary Non-familial Hyperlipidemia and Homozygous Familial Hypercholesterolemia

- **Roszet** is a powerful and affordable way to significantly lower patients' cholesterol

-- Up to 72% LDL-C reduction expected from Baseline by **Roszet** --

-- 64% LDL-C reduction expected from **Roszet** 10 mg/10 mg --

Morristown, NJ,

Althera Pharmaceuticals, a company focused on heart health, today announced the FDA approval of **Roszet** (rosuvastatin and ezetimibe) tablets, as an adjunct to diet, for treatment of elevated low-density lipoprotein cholesterol (LDL-C) in adult patients with primary non-familial hyperlipidemia and in adults with homozygous familial hypercholesterolemia. **Roszet** contains rosuvastatin, a powerful statin for LDL-C reduction, and ezetimibe, an efficacious cholesterol absorption inhibitor. The two components work through distinct but complimentary mechanisms to give **Roszet** the power to significantly lower LDL-C.

"The optimal LDL-C levels in guidelines across the world have been shifting lower and now many patients need to get their LDL-C below 70 mg/dL," said Dr. Christie Ballantyne, Chief of Cardiology and Cardiovascular Research at Baylor College of Medicine. "These levels can be quite difficult to achieve with just a statin on top of diet and exercise. Rosuvastatin and ezetimibe have been extensively studied in combination therapy and have been shown to significantly reduce LDL cholesterol beyond the statin alone. Combination therapy has been widely used in hypertension to achieve lower blood pressure targets. This new therapy provides a high efficacy statin plus ezetimibe in a single once daily pill which is a powerful new option to help get patients to the desirable LDL goal without increasing pill burden or requiring addition of injectable therapies"

"With Roszet's approval in the U.S., we reaffirm our commitment to improving cholesterol treatment options for physicians and patients," said Sanjeev Agarwal, CEO of Althera Pharmaceuticals. "We are on a mission to positively impact patients' health. By making this highly effective medicine available and affordable, we hope to improve the long-term health of patients, including those with prior cardiovascular disease."

While a patient's out-of-pocket costs will vary depending on insurance status, the Roszet Savings Program aims to reduce co-pays to as little as \$20 per month for eligible patients with commercial insurance coverage. Althera is continuing to work with all stakeholders to ensure that Roszet is affordable and accessible to all. Please visit www.roszet.com for more information and updates about the Roszet Savings Program and eligibility.

Availability

Roszet will be available in pharmacies in June 2021.

Roszet Indications, Dosage and Other Select Information

Roszet is indicated, as an adjunct to diet, in adults with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C), and alone or as an adjunct to other LDL-C lowering therapies in adults with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C.

Roszet is available as a once-daily tablet with rosuvastatin/ezetimibe dosages of 5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg and 40 mg/10 mg.

Roszet has the potential to reduce LDL cholesterol by as much as 72% with the 40 mg/10 mg dose and by 64% with 10 mg/10mg dose. This level of LDL-reduction derives from both the statin component, rosuvastatin, which can reduce LDL cholesterol by 63% on the highest dose and 52% on 10 mg dose, and the ezetimibe component, which gives an 25% incremental LDL drop when added to statins.

Roszet Important Safety Information

Contraindications: Roszet should not be taken by anyone who has known hypersensitivity to any component of Roszet or patients with active liver failure or decompensated cirrhosis.

Use in Specific Populations: Discontinue Roszet when pregnancy is recognized as it may cause fetal harm. Breastfeeding is not recommended during treatment with Roszet.

Warnings and Precautions: Myopathy and rhabdomyolysis may occur with Roszet. Acute kidney injury secondary to myoglobinuria and rare fatalities have occurred as a result of rhabdomyolysis with statins, including rosuvastatin. Discontinue Roszet if markedly elevated CK levels occur or myopathy is diagnosed or suspected. Temporarily discontinue Roszet in patients experiencing an acute or serious condition at high risk of developing renal failure secondary to rhabdomyolysis.

That have been rare reports of IMNM, an autoimmune myopathy, associated with statin use. Increases in serum transaminases have occurred with rosuvastatin. Rare reports of fatal and non-fatal hepatic failure have occurred in patients taking statins. Promptly discontinue Roszet if serious hepatic injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs.

Adverse Reactions: Most frequent adverse reactions for rosuvastatin in clinical trials are headache, nausea, myalgia, asthenia, dizziness, constipation, and abdominal pain. For ezetimibe co-administered with a statin most frequent adverse reactions are nasopharyngitis, myalgia, upper respiratory tract infection, arthralgia, diarrhea, back pain, influenza, pain in extremity, and fatigue.

Drug Interactions: Concomitant use of Roszet with gemfibrozil, cyclosporin, antivirals should be avoided. Roszet dose should be adjusted or limited with antivirals, darolutamide, regorafenib, risk and benefits should be considered with fenofibrates, niacin, colchicine and INR obtained and monitored with initiation or dose adjustment with warfarin.

Please review Important Safety Information and full Prescribing Information available at roszet.com for more details on the risks with using Roszet.

About Lipid-lowering Market

Statins are the mainstay of lipid lowering market with atorvastatin (Lipitor®) and rosuvastatin (Crestor®), being among the largest prescribed statin medications in United States. Over the last five years, a new category, PCSK9 medications (Repatha® from Amgen Inc.(AMGN) and Praluent® from Regeneron Pharmaceuticals Inc. (REGN)), was introduced to the market. More recently, the FDA has approved Nexletol® and Nexlizet® by Esperion Therapeutics Inc (ESPR) and Evkeeza™ by Regeneron.

About Althera

Althera is a privately held pharmaceutical company located in Morristown, NJ. Althera is focused on advancing Heart Health and is committed to providing doctors and their patients important options for treating cardiovascular disease. Althera, along with its partners, has launched the rosuvastatin and ezetimibe combination in 25 countries in Europe and is working on additional launches across the world. For more information visit www.altherapharma.com.

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Please see full prescribing information for Roszet® (rosuvastatin and ezetimibe) at www.roszet.com/pi
Please contact Althera Pharmaceuticals at contact@altherainc.com