

# Althera Launches Roszet (rosuvastatin and ezetimibe) Tablets, an FDA Approved Therapy for Powerful Cholesterol Reduction

*Up to 72% expected LDL-C reduction from baseline with Roszet - 64% expected reduction with 10mg/10mg dose. Roszet is affordable for a wide range of patients.*

MORRISTOWN, NJ, UNITED STATES, July 12, 2021 /EINPresswire.com/ -- Althera Pharmaceuticals, a company focused on heart health, today announced the commercial availability of Roszet

(rosuvastatin and ezetimibe) tablets. Roszet is approved by the FDA for treatment of elevated low-density lipoprotein cholesterol (LDL-C), as an adjunct to diet, in adult patients with primary non-familial hyperlipidemia and, alone or as an adjunct to other LDL-C lowering therapies, in adult patients with homozygous familial hypercholesterolemia. Roszet contains rosuvastatin, a

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*Dr. Christie Ballantyne*

powerful statin for LDL-C reduction, and ezetimibe, an efficacious cholesterol absorption inhibitor. The two components work through distinct but complementary mechanisms to give Roszet the power to significantly lower LDL-C.

“Roszet is an important tool in helping us get our patients to achieve optimal reductions in LDL-C which should be to below the threshold of 70 mg/dL for many of them,” said Dr. Christie Ballantyne, Chief of Cardiology and Cardiovascular Research at Baylor College of Medicine.

“Increasingly, guidelines are recommending greater reductions in LDL-C levels, and these can be quite difficult to achieve with just a statin on top of diet and exercise. As in hypertension, combination therapy is often needed in hyperlipidemia to achieve optimal LDL-C reductions. Both rosuvastatin and ezetimibe have been extensively studied in combination therapy and their additive effect on reducing LDL cholesterol is well understood by physicians. Because of its powerful action, Roszet is an important option as a single once daily pill to help get patients to



**Roszet**<sup>®</sup>  
rosuvastatin and  
ezetimibe tablets

5 mg/10 mg  
10 mg/10 mg  
20 mg/10 mg  
40 mg/10 mg

Roszet (rosuvastatin and ezetimibe) tablets

the desirable LDL goal without increasing pill burden or requiring addition of injectable therapies.”

"We are thrilled to have Roszet available in the U.S. as it is a powerful cholesterol treatment, including for those with prior cardiovascular disease," said Sanjeev Agarwal, CEO of Althera Pharmaceuticals. "We believe Roszet can positively impact patients' health and that is why we are also making this highly effective medicine affordable for a wide range of patients."

The Roszet Savings Program aims to reduce co-pays to as low as \$20 per month<sup>□</sup> for eligible patients when covered by their commercial insurance. Importantly, for other eligible patients who will self-pay, Roszet will be available at Walgreens for as little as \$49 per month\*<sup>□</sup>. Althera will continue to work with stakeholders to ensure that Roszet is affordable and accessible to more patients. Please visit [www.roszetrx.com](http://www.roszetrx.com) for more information and updates about the Roszet Savings Program and eligibility.

\* \$147 for three months and \$59 for one month prescription.

□ Restrictions apply. Please see [Roszetrx.com/savings](http://Roszetrx.com/savings) for more information.

#### 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, asthenia, 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 and antivirals should be avoided. Roszet dose should be adjusted or limited with antivirals, darolutamide and regorafenib, risk and benefits should be considered with fenofibrates, niacin and 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](https://roszet.com) for more details on the risks with using Roszet.

#### 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](https://www.altherapharma.com).

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Please see full prescribing information for Roszet® (rosuvastatin and ezetimibe) at [www.roszet.com/pi](https://www.roszet.com/pi)

Please contact Althera Pharmaceuticals at [contact@altherainc.com](mailto:contact@altherainc.com)

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