

# **PRESS RELEASE**

## **Zydus partners with Medicure to launch its NDA Product, ZYPITAMAG (pitavastatin) in the U.S.**

*This marks Zydus' first branded product launch in the U.S. and Medicure's second cardiovascular drug on the U.S. market*

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Ahmedabad, India (Zydus) and Winnipeg, Canada (Medicure)  
March 8, 2018

Zydus Cadila, a leading innovation-driven, global healthcare provider, announced that it has entered into a definitive agreement with Medicure International Inc., a subsidiary of Medicure Inc. (Medicure) to commercialize its 505(b)(2) New Drug Application (NDA) product, pitavastatin magnesium (ZYPITAMAG™) in the United States. The launch of ZYPITAMAG, which is used to manage cholesterol levels, marks the first branded product launch for Zydus in the U.S.

Medicure is a U.S. pharmaceutical company and has a proven track-record of successful commercialization of products in the therapeutic segments of cardiovascular and metabolic diseases. As a part of this agreement, Zydus will hold the NDA and Medicure will be responsible for the sales and marketing of ZYPITAMAG.

Speaking on the development, Dr. Sharvil Patel, Managing Director, Zydus Cadila said, “The launch of this proprietary drug is in continuation of our commitment to exploring new pathways in pharmaceutical technology with a thrust on enhancing patient care and well-being. In this endeavour, we are happy to partner with Medicure in reaching out to the patient community and helping them access this NDA for desired health outcomes”.

“Medicure is pleased to partner with Zydus Cadila and add ZYPITAMAG to its cardiovascular commercial operation. This partnership fits well with Medicure’s mission of being a significant cardiovascular pharmaceutical company focused on the U.S. market,” commented Medicure’s President and CEO, Dr. Albert D. Friesen.

Approved in strengths of 1 mg, 2 mg and 4 mg, ZYPITAMAG is an HMG-CoA reductase inhibitor indicated for Patients with primary hyperlipidemia or mixed dyslipidemia as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C). *(Further information is available in the annexure appended below)*

## About Zydus Cadila

Zydus Cadila is an innovative, global pharmaceutical company that discovers, develops, manufactures and markets a broad range of healthcare therapies. The group employs over 21,000 people worldwide and is dedicated to creating healthier communities globally. Zydus aspires to be a research-based pharmaceutical company by 2020. For more information, please visit [www.zyduscadila.com](http://www.zyduscadila.com)

## About Medicure

Medicure is a pharmaceutical company focused on the development and commercialization of therapeutics for the U.S. cardiovascular market. The primary focus of the Company is the marketing and distribution of AGGRASTAT (tirofiban hydrochloride) injection in the United States, where it is sold through the Company's U.S. subsidiary, Medicure Pharma, Inc. For more information on Medicure please visit [www.medicure.com](http://www.medicure.com).

## Annexure

### IMPORTANT SAFETY INFORMATION FOR ZYPITAMAG (pitavastatin)

#### INDICATIONS & USAGE

Drug therapy should be one component of multiple-risk-factor intervention in individuals who require modifications of their lipid profile. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol only when the response to diet and other nonpharmacological measures has been inadequate.

**Primary Hyperlipidemia and Mixed Dyslipidemia:** ZYPITAMAG is indicated as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia. **Limitations of Use:** Doses of ZYPITAMAG greater than 4 mg once daily were associated with an increased risk for severe myopathy in premarketing clinical studies. Do not exceed 4 mg once daily dosing of ZYPITAMAG. The effect of ZYPITAMAG on cardiovascular morbidity and mortality has not been determined. ZYPITAMAG has not been studied in Fredrickson Type I, III, and V dyslipidemias.

**CONTRAINDICATIONS:** ZYPITAMAG is contraindicated in patients with a known hypersensitivity to product components, in patients with active liver disease (which may include unexplained persistent elevations in hepatic transaminase levels), in women who are pregnant or may become pregnant, in nursing mothers, or in co-administration with cyclosporine.

#### 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 pitavastatin.

- These risks can occur at any dose level, but increase in a dose-dependent manner, with advanced age ( $\geq 65$  years), renal impairment, and inadequately treated hypothyroidism;

administer with caution in these patients, or when used concomitantly with fibrates or lipid-modifying doses of niacin, or colchicine. Avoid concomitant administration with gemfibrozil.

- Advise patients to promptly report unexplained and/or persistent muscle pain, tenderness, or weakness, particularly if accompanied by malaise or fever; discontinue ZYPITAMAG.
- If muscle signs and symptoms persist after discontinuation, this may be a sign of immune-mediated necrotizing myopathy (IMNM), an autoimmune myopathy associated with statin use, requiring immediate medical attention. IMNM is characterized by proximal muscle weakness and elevated serum creatine kinase, which persist despite discontinuation of statin treatment; muscle biopsy showing necrotizing myopathy without significant inflammation; improvement with immunosuppressive agents.
- ZYPITAMAG should be discontinued if markedly elevated creatine kinase levels occur or myopathy is diagnosed or suspected. ZYPITAMAG should also be temporarily withheld in any patient with an acute, serious condition suggestive of myopathy or predisposing to the development of renal failure secondary to rhabdomyolysis (e.g., sepsis, hypotension, dehydration, major surgery, trauma, severe metabolic, endocrine, and electrolyte disorders, or uncontrolled seizures).

#### Liver Enzyme Abnormalities:

- Persistent elevation in hepatic transaminases can occur. Check liver enzymes before initiating therapy and if signs or symptoms of liver injury occur; advise patients to report fatigue, anorexia, right upper abdominal discomfort, dark urine or jaundice.
  - Fatal and non-fatal hepatic failure can occur. Interrupt ZYPITAMAG if serious liver injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs. If an alternate etiology is not found do not restart ZYPITAMAG.
  - Use ZYPITAMAG with caution in patients who consume substantial quantities of alcohol and/or have a history of chronic liver disease. Do not use ZYPITAMAG if patient has active liver disease, which may include unexplained persistent transaminase elevations.
- Endocrine Function: Increases in HbA1c and fasting serum glucose levels have been reported.

**COMMON ADVERSE REACTIONS:** myalgia, back pain, diarrhea, constipation and pain in extremity (rate  $\geq$  2% in at least one marketed dose). This is not a complete list of all reported adverse events.

For additional information, refer to full [full Prescribing Information](#).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call [1-800-FDA-1088](tel:1-800-FDA-1088).