

new class of drugs: cholesterol absorption inhibitors

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Pharmacology

Cholesterol Absorption Inhibitors: A New Class in Cholesterol-Lowering Drugs May Serve as 'Statin Saviors'

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Forbes Medi-Tech Inc., today announced that it has commenced a 90-day toxicity study for its cholesterol-lowering drug, FM-VP4. This study is required to support an extended US Phase II human trial planned for later this year. Results from an earlier 28 day European trial of FM-VP4 suggest that LDL cholesterol levels may continue to decrease when FM-VP4 is given to patients for longer than 4 weeks and that optimal efficacy may not have been achieved.

"The toxicity study is an important precursor to our US Phase II trials for FM-VP4 and an opportunity to further demonstrate the drug's positive safety profile," said Charles Butt, President and CEO of Forbes Medi-Tech Inc. "An excellent safety profile represents a distinct advantage in potential therapies for cardiovascular and related diseases."

FM-VP4 is a novel analogue representing a new class in cholesterol-lowering drugs called cholesterol absorption inhibitors. FM-VP4 has demonstrated dramatic cholesterol-lowering and anti-atherosclerotic properties in pre-clinical studies.

The National Cholesterol Education Program (NCEP) ATP III guidelines in the United States have been increased to include a significant number of people with marginally high cholesterol. These people potentially could achieve their treatment goals with a non-systemic, safe treatment such as FM-VP4.

Almost 20% of the target population are hyper-absorbers of cholesterol and cannot be effectively treated with statins. Intolerance to statins based on drug interactions as well as both real and perceived safety concerns further increase the market potential for FM-VP4.

The strength of a cholesterol absorption inhibitor, such as FM-VP4, will likely be as a combination dosage form with statins. With a different mechanism of action, the LDL cholesterol lowering effect of absorption inhibitors may be additive when the drugs are used in combination with statins.

A combination therapy may allow for a significant reduction in statin dosage and hence may reduce the risk of dose dependent side effects, without compromising efficacy. A cholesterol absorption inhibitor-statin combination could essentially extend the patent life of currently protected statins, or restore patent protection to generic statins. For this reason, it has been suggested that a cholesterol absorption inhibitor could serve as a 'statin savior'.

Preclinical studies indicate the FM-VP4 may be developed for other indications that address a broader range of Cardiovascular disease (CVD) risk factors, or Metabolic Syndrome X. This syndrome is of epidemic proportions in the Western World, affecting 25% of the population, and includes lipid and non-lipid risk factors such as abdominal obesity and insulin resistance.

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