Novartis International AG
Novartis Communication
CH-4002 Basel
Switzerland

Tel + 41 61 324 2200
Fax + 41 61 324 3300
Internet Address:
http://www.novartis.com

NOVARTIS

MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

Lescol® following angioplasty sharply reduces risk of cardiac events in patients with advanced coronary artery disease down to that of patients with early stage disease

New Findings from LIPS presented at ACC

Basel, Switzerland, 31 March, 2003 – Lescol® (fluvastatin sodium) administered immediately following first angioplasty reduces the risk of fatal and non-fatal serious cardiac events in high-risk patients with more than one blocked coronary artery down to that of lower-risk patients with only one blocked artery, according to a new analysis of the Lescol Intervention Prevention Study (LIPS).[1] These findings were presented at ACC 03 – the 52nd Annual Scientific Session of the American College of Cardiology by researchers from the Erasmus Medical Centre, University Hospital, Rotterdam, The Netherlands.

"What we are seeing is that fluvastatin therapy begun at the time of angioplasty is, in effect, virtually equalizing the long-term outcomes of multi-vessel and single-vessel diseased patients – and that clearly supports a new paradigm for treating the post-percutaneous coronary intervention (PCI) population. The data provides compelling evidence to initiate Lescol therapy as a standard follow-up to an angioplasty procedure, in order to reduce the risk of further cardiac complications," said Professor Serruys, MD, PhD, Professor of Interventional Cardiology at Erasmus Medical Centre.

The new data analysis shows that, without Lescol treatment, patients with multiple blocked coronary arteries had an almost 50 percent higher risk (RR, 1.49; 95% CI, 1.13-1.96) of having a major adverse coronary event (MACE) than patients with only one blocked artery. But in patients who received Lescol following angioplasty, no difference was observed between single and multi-vessel diseased patients in terms of future occurrence of MACE, the researchers concluded. In fact, the patients with multiple blocked arteries who received Lescol experienced a 34 percent reduction (p=0.01) versus placebo in their risk of having a major coronary event.[1] The data also indicate that the patients benefited from treatment with Lescol even if they had cholesterol levels within the normal range.

"The new LIPS data suggest that Lescol therapy brings the risk of multi-vessel disease back to that of an earlier stage in the disease process in post-angioplasty patients. The data also shows that Lescol is beneficial regardless of patients' stage of disease," said Michele Bortolini, MD, clinical program leader, Novartis. "We are excited and intrigued by these findings and will be further studying the anti-atherosclerotic effect of Lescol in existing and new trials."

In addition to further analysis from LIPS, data from new Lescol trials will be available throughout the year. The Assessment of Lescol in Renal Transplantation (ALERT) study is the largest intervention trial in renal transplant patients, and the first attempt to modify cardiovascular outcomes in this high-risk patient population. ALERT will provide insights

into Lescol and its effects on MACE reduction among 2,100 patients who were followed for a period of five years or more.[2] It is expected that the results of ALERT will be presented at the American Transplant Congress (ATC) in Washington, DC in June, 2003. The Hypertension High Risk Management Trial or HYRIM, will determine whether Lescol therapy prevents the development or retards the progression of carotid artery atherosclerosis and left ventricular hypertrophy in patients with high blood pressure.[3]

Background on LIPS

The LIPS study, which involved 1,677 patients in 10 countries, was designed to determine whether treatment with Lescol reduces MACE in post-angioplasty patients. The study showed that Lescol 80 mg (40 mg twice daily) significantly reduced MACE by 22 percent (p=0.013), even in patients with normal cholesterol levels. In certain high-risk patients, the benefits of Lescol were even more profound. For example, patients with diabetes experienced a 47 percent reduction (p=0.041) in the risk of a serious cardiac event compared with placebo.

Based on the LIPS findings, both Lescol and Lescol XL® 80 mg extended release tablets have already been approved in several countries including the United Kingdom for the secondary prevention of cardiovascular events in patients who have undergone angioplasty and other PCI procedures. Applications for this additional indication are pending in the U.S. and in other markets.

The LIPS data underscored the excellent safety profile of Lescol: there was no significant difference in elevations of serum creatine phosphokinase (CPK) between Lescol patients and placebo patients. Also, in patients taking Lescol, there were no cases of CPK elevations of 10x upper limits of normal (ULN) or greater. Elevated CPK is an indication of muscle breakdown and is a potential side effect of statin therapies.

These safety data match those from a recent analysis involving more than 9,000 patients of all randomised, controlled clinical trials with Lescol/Lescol XL administered as monotherapy, in which the rate of clinically relevant CPK elevations was similar between Lescol and placebo patients. Additional pooled analysis demonstrates no difference in CK elevation with Lescol in combination with a fibrate compared to monotherapy and placebo.[4]

This release contains certain “forward-looking statements”, relating to the business of Novartis, which can be identified by the use of forward-looking terminology such as “will”, “expected”, or similar expressions, or by express or implied statements regarding the potential for additional sales of Lescol as a result of this new information, or by discussions of potential additional indications for Lescol. Such forward looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantees that the aforementioned data will result in additional sales or additional indications for Lescol in any market. Any such results can be affected by, amongst other things, uncertainties relating to clinical trial results and product development, regulatory actions or delays or government regulation generally, the ability to obtain or maintain patent or other proprietary intellectual property protection and competition in general, as well as factors discussed in the Company’s Form 20-F filed with the Securities and Exchange Commission. Should one or more of these risks or uncertainties

materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those described herein as anticipated, believed, estimated or expected.

Novartis AG (NYSE: NVS) is a world leader in pharmaceuticals and consumer health. In 2002, the Group's businesses achieved sales of CHF 32.4 billion (USD 20.9 billion) and a net income of CHF 7.3 billion (USD 4.7 billion). The Group invested approximately CHF 4.3 billion (USD 2.8 billion) in R&D. Headquartered in Basel, Switzerland, Novartis Group companies employ about 72 900 people and operate in over 140 countries around the world. For further information please consult http://www.novartis.com.

# # #

---

[1] Lemos P, et al. Fluvastatin Prevents Cardiac Events Following Successful Percutaneous Coronary Intervention in Patients with Multivessel Disease: The Lescol Intervention Prevention Study. Poster presented at ACC-03 – the 52nd Annual Scientific Session of the American College of Cardiology. March 2003.

[2] Randomized Double Blind Trial of Fluvastatin For Hypercholesterolemia In Renal Transplant Patients. American Transplant Congress Abstract, 2003.

[3] Hypertension High Risk Management Trial (HYRIM). Clinical Study Protocol.

[4] Bortolini. M, et al. Frequency of Creatine Kinase Elevation During Treatment with Fluvastatin in Combination with Fibrates (bezafibrate, fenofibrate, gemfibrozil), Results of A Pooled Analysis. Am J Card. Jan. 2003.