

Basel, 15 May 1997

FDA Advisory Committee Unanimously Recommends Xenical (orlistat) For Weight Loss

On May 14, 1997, the US Food and Drug Administration's (FDA) Endocrinologic and Metabolic Drugs Advisory Committee unanimously recommended the approval of Xenical (orlistat) to help people lose weight and decrease other health risks.

Xenical was discovered and developed by Hoffmann-La Roche. Xenical is currently under regulatory review in many other countries and is not yet commercially available.

Xenical represents the first of a new class of non-systemic anti-obesity drugs called lipase inhibitors, or fat blockers, which act in the gastrointestinal tract to prevent the absorption of fat by about 30 percent. Drugs in this class do not achieve their effect through brain chemistry.

According to the data presented, almost three times as many patients on Xenical with a moderately reduced calorie diet lost 10 percent or more of body weight compared to placebo with diet. Nearly twice as many patients on Xenical lost at least 5 percent of body weight compared to placebo with diet. The average patient in the one-year clinical trials weighed 100 kilos and lost 10 kilos, or about 10 percent of body weight, after taking Xenical and being on a moderately reduced calorie diet. Many patients who continued into the second year of the studies were able to keep off the lost weight.

In addition, Xenical-treated patients had statistically significant reductions in total and LDL cholesterol and systolic and diastolic blood pressure, as well as improvement in blood concentrations of glucose and insulin after one year over placebo with diet.

"We are very pleased that the members of the Advisory Committee confirm that Xenical will be an important new treatment for obesity and its medical consequences", said Dr. Franz B. Humer, Chief Operating Officer and Head of the Pharmaceuticals Division of F. Hoffmann-La Roche Ltd., headquartered in Basel, Switzerland.

Efficacy From Comprehensive Clinical Program

The Advisory Committee's recommendation was based on double-blind, placebo-controlled and randomized studies involving more than 4,000 patients conducted in the US and Europe.

In the clinical trials, people took Xenical orally in 120 mg capsules three times daily in conjunction with a moderately reduced calorie diet containing 30 percent fat. Because low vitamin levels are an existing problem among the overweight and obese population, people following a moderately reduced calorie diet, including those using Xenical, should be sure they have adequate vitamin intake through supplementation.

Data Support Tolerability and Quality of Life Improvement

The clinical trials showed that Xenical was well tolerated. The most common side effects reported were non-systemic and were primarily gastrointestinal. These effects generally occurred early in treatment and were self-limited and of short duration in most cases. Roche supports the Advisory Committee recommendation to continue studying the long-term effects of Xenical.

Data provided to the Advisory Committee found statistically significant improvements in patient quality of life measurements, including overweight distress and satisfaction with treatment.

Roche, headquartered in Basel, Switzerland, is a multinational company and world leader in research based health care. Its principal businesses are in pharmaceuticals, diagnostics, vitamins, and fragrances and flavours. Roche discovers, develops and markets prescription drugs in key therapeutic areas such as virology, infectious diseases, oncology, cardiology, transplantation and obesity. The company's commitment to metabolic research and development stems from its recognition of obesity as a chronic disease needing long term therapy.