

Basel, 22 March 2001

### **Xenical: Type 2 Diabetes indication filed in the US**

Roche announced today that a supplemental New Drug Application (sNDA) has been submitted to the US Food and Drug Administration (FDA) for Xenical (orlistat), as an adjunct to other anti-diabetic medications for the treatment of type 2 diabetes in patients who are overweight or obese. Approval of this indication would provide an additional market opportunity for Xenical in the US, where it is already approved for weight management in patients who are overweight or obese.

Xenical is a unique weight management treatment that acts locally by preventing fat being absorbed in the gut. Xenical not only helps patients lose weight, it also encourages more healthy eating habits, so helping them maintain their weight loss.

Clinical studies with Xenical in diabetes have shown:

- overweight and obese patients with type 2 diabetes taking Xenical lost up to three times more weight than those on diet alone
- Xenical patients had clinically significant improvements in blood sugar control
- more patients treated with Xenical were able to reduce the dose of, or even discontinue their anti-diabetic medications
- additional data have also shown that Xenical can improve certain risk factors for cardiovascular disease, such as total cholesterol levels and blood pressure in diabetic patients<sup>1,2,3</sup>.

Type 2 diabetes is a major global public health problem with the incidence and prevalence of diabetes escalating towards a world-wide epidemic. In the USA the prevalence of type 2 diabetes increased by one-third between 1990 and 1998<sup>4</sup>. Many other countries report a similar experience and it has been estimated that, on a global level, almost 300 million people could have type 2 diabetes by the year 2025<sup>5</sup>. The major underlying cause of this diabetes epidemic is the increasing prevalence of obesity. Almost 90 per cent of patients with type 2 diabetes are overweight or obese. Weight is the most important modifiable risk factor in patients with type 2 diabetes. Type 2 diabetes is associated with a high risk of several complications that may lead to premature cardiovascular morbidity and mortality. Weight management is the first-line treatment of type 2 diabetes. Even a modest reduction of initial body weight improves blood sugar control in patients with type 2 diabetes and also reduces the severity of cardiovascular risk factors such as high cholesterol levels and high blood pressure.

### **About Xenical**

Xenical is a breakthrough in weight management treatment and is the most extensively studied pharmacological weight management treatment to date, with over 30,000 overweight or obese patients participating in clinical trials with Xenical. Over 2,500 patients with type 2 diabetes have been involved in Xenical clinical trials. It is an effective therapy which not only helps patients lose weight, but also helps them maintain their weight loss. It is the only available weight loss medication that works locally in the gut to prevent dietary fat absorption by about 30 percent. Xenical is well tolerated and unlike other weight loss medications it does not act on the central nervous system. In clinical trials, non-diabetic people taking Xenical in conjunction with a mildly reduced calorie diet have shown twice as much weight loss as diet alone. Since it was first marketed in 1998, there have been more than 8.5 million patient treatments with Xenical world-wide. Xenical is licensed for weight management in patients who are overweight or obese in over 100 countries around the world.

### **About Roche**

Headquartered in Basel, Switzerland, Roche is one of the world's leading research-oriented healthcare groups in the fields of pharmaceuticals, diagnostics and vitamins. Roche's innovative products and services address prevention, diagnosis and treatment of diseases, thus enhancing people's well being and quality of life.

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