

MEDICAL TRADE PRESS RELEASE

Embargoed until: Monday 20th April 2009

**Clinically proven weight loss treatment
alli (orlistat 60mg) is now available OTC in pharmacy**

Monday, 20th April 2009 - GlaxoSmithKline (GSK) announced today that **alli** will be available from this week onwards in pharmacies throughout the country. **alli** can help adults with a Body Mass Index (BMI) of 28 kg/m² or more lose 50 per cent more weight than by dieting alone (1), so for every 2 kilos they lose with a reduced calorie, lower-fat diet, **alli** can help users lose an extra 1 kilo. It is important to remember that individual results may vary

alli is currently the only medicine to be granted a non-prescription licence for weight loss treatment in Ireland. It contains half the dose of prescription orlistat with over 80% of the efficacy (2, 3) and it is better tolerated. (4)

alli users will have access to tools and support to help them follow a sensible diet and become more active, encouraging sustainable weight loss. In addition the **alli** programme has a free online support programme for those who want personalised support.

GSK takes the need to market **alli** responsibly very seriously, and is training pharmacists to help them provide advice on weight loss to ensure they recommend **alli** to suitable patients only. Pharmacists are advised to refer the customer to their doctor when appropriate, for example, in the case of patients taking medicine for diabetes, high blood pressure or high cholesterol. Healthcare professionals can visit www.alli.ie for more information on **alli** and essential resources.

Professor Patrick Wall, Associate Professor of UCD School of Public Health and Population Science, who spoke at the launch event, commented; "Losing weight involves lifestyle modifications, such as having a healthy balanced diet and a good level of exercise. It is important that overweight people that take **alli** understand that a healthy diet and physical activity continue to play an important role. A person's health is their greatest asset and being overweight or obese is not conducive to a healthy lifestyle. The obesity epidemic is an ever increasing reality in Ireland and **alli** represents a new development in the fight against this problem, not the solution but one part of the jigsaw. Many other important factors play an important role and it is important that key stakeholders involved in the prevention and management of obesity come together to combat this problem."

"Obesity represents arguably the greatest health burden to Ireland, being related to so many other conditions such as diabetes and heart disease. The health community must now act as one to tackle this huge problem, including utilising the excellent skills and resource that pharmacists can – and are keen – to offer," **said Dr. Martin Henman, School of Pharmacy and Pharmaceutical Sciences, Trinity College Dublin**, who also spoke at the event. "As Pharmacy becomes more involved in providing health and lifestyle guidance to customers and has worked successfully in tandem with other healthcare professionals in areas such as tobacco control, we welcome this opportunity to play an integral role in helping people lose weight using **alli** and to live healthier lives."

Ms. Elizabeth Reynolds, General Manager, GSK Consumer Healthcare said, "With the excellent commitment and support shown by pharmacists, **alli** offers adults a real opportunity for losing weight safely and effectively. **alli** has been well received by millions of people in the US since its launch there in June 2007 and we are very excited about the number of people it could help in Ireland to achieve their weight loss goal."

-Ends-

alli is a registered trade mark of the GlaxoSmithKline group of companies.

Media Enquiries;

Susie Cunningham / Ciara Cauldwell, WHPR, (01) 669 0030
Susie 087 850 5055 and Ciara 087 220 2850

Notes to editors

How to use alli

alli 60 mg hard capsules contain orlistat. **alli** is indicated for weight loss in adults, with a BMI of 28 kg/m² or over, when used along with a reduced calorie, lower-fat diet. The recommended dose of **alli** is one 60 mg capsule three times a day with meals containing the recommended amount of fat. Always read the label/leaflet.

About alli

- The active ingredient in **alli** is orlistat 60 mg
- Orlistat acts locally within the digestive system to prevent fat absorption, so there is minimal absorption of the active ingredient in the bloodstream
- Orlistat 120 mg has been available as a prescription treatment for 10 years
- The safety and efficacy profile of orlistat is well documented and has been established through data from more than 100 clinical studies. (5)
- GlaxoSmithKline completed an agreement with Roche (who market prescription orlistat 120 mg) in February 2007 that allowed the company to seek regulatory authorisation for non-prescription orlistat 60 mg
- **alli** (orlistat 60 mg) was launched in the US in June 2007 as the only Food and Drug Administration (FDA) approved weight loss aid available without prescription.

Obesity in Ireland

- Almost two out of five Irish adults (38%) are overweight. In addition, more than one in five (23%) is obese. (6)
- When compared to an Irish survey from 2001 (7), overweight is down 1% and obesity is up 5% indicating that overweight adults are gaining weight and moving into the obese category.
- Ireland has the fourth highest prevalence of overweight and obesity in men in the EU and the seventh highest prevalence among women. (8)
- Costs for treating obesity in Ireland is estimated at €0.4 billion. The number of premature deaths annually attributable to obesity currently approximates to 2,000. (9)

References

1. **alli** Summary of Product Characteristics
2. Hauptman J, Lucas C, Boldrin MN et al. Orlistat in the long-term treatment of obesity in primary care settings. *Arch Fam Med* 2000; 9:160-7.
3. Rössner et al. Weight Loss, Weight Maintenance, and Improved Cardiovascular Risk Factors after 2 Years Treatment with Orlistat for Obesity Research 2000; 8:49-61
4. Bansal V, Schwartz S and Adams I. Low doses orlistat provides significant benefit. *Obesity Rev* 7 Suppl 2. 2006; 332
5. Jacob S, Togerson J. Orlistat treatment beneficial in both primary care and tertiary settings. *Obesity Reviews*. 2005;6(s1):166.
6. Harrington J, Perry I, Lutomski J, Morgan K, McGee H, Shelley E, Watson D and Barry M (2008). *SLÁN 2007: Survey of Lifestyle, Attitudes & Nutrition in Ireland. Dietary Habits of the Irish Population*, Department of Health and Children. Dublin: The Stationary Office.
7. Irish Universities Nutrition Alliance (2001) *North/South Ireland Food Consumption Survey*. www.iuna.net
8. International Obesity Taskforce and European Association for the Study of Obesity (2002) *Obesity in Europe – The Case for Action*.
9. National Taskforce on Obesity (2005) *Obesity - the Policy Challenges*. Department of Health and Children. Dublin: Government Publications Office.

GlaxoSmithKline – one of the world's leading research-based pharmaceutical and healthcare companies – is committed to improving the quality of human life by enabling people to do more, feel better and live longer.

Cautionary statement regarding forward-looking statements

Under the safe harbour provisions of the U.S. Private Securities Litigation Reform Act of 1995, GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Factors that may affect GSK's operations are described under 'Risk Factors' in the 'Business Review' in the company's Annual Report on Form 20-F for 2007.