



Sinclair Pharma plc

Decapinol® Approved in EU Aloclair™ Gel Approved in US And Year End Trading Update

Godalming, UK, 1 July 2004: Sinclair Pharma plc ("Sinclair" or the "Company"), the pharmaceutical company focused on the exploitation of niche patented products, today announces the receipt of regulatory approvals for two of its key products, Decapinol® and Aloclair™ Gel, and also provides a year end trading update in advance of its preliminary results for the year ending 30 June 2004.

Decapinol® EU Approval

The Company has received registration approval as a medical device for Decapinol® mouthwash in the EU. Decapinol® is a new product for the treatment of gingivitis, which can lead to periodontitis, both of which are caused by accumulation of bacteria within dental plaque. These bacteria cause local inflammation of the gum, causing it to bleed easily, and can eventually lead to tooth loss.

Decapinol® acts by interfering with the attachment of bacteria to the teeth and gum surfaces, in contrast to antiseptics and antibiotics such as chlorhexidine, which kill all oral bacteria and affect the natural balance of beneficial oral bacteria. Chlorhexidine, a current market leading treatment of gingivitis is recognised as leading to staining of the teeth requiring mechanical removal. Clinical trials have shown Decapinol® to have less side effects and to be better tolerated than chlorhexidine. Decapinol® has also been recently designated a medical device in the US and was filed for 510(k) registration in the US in June 2004.

Sinclair believes that Decapinol® is the first new chemical entity for gingivitis for the past 30 years and that it has the potential to grow the existing market. It is estimated that approximately 80% of the US adult population has some degree of gum inflammation resulting in a market worth over \$300 million. Sinclair will now commence partnering discussions ahead of schedule.

Aloclair™ Gel US Approval

Sinclair also announces today that it has received 510(k) approval in the US for the use of Aloclair™ Gel for the pain relief of mouth ulcers and other minor oral lesions. Aloclair™ Liquid has already received registration approval in both the EU and US and the approval of Aloclair™ Gel will expand its use for the treatment of large, single ulcers and also for paediatric use. Partnering discussions for this product will also now commence, ahead of Sinclair's previous expectations.

Sebclair™

Sinclair has also been informed by the FDA that Sebclair™, the Company's cream for the treatment of seborrhoeic dermatitis, will be designated in the US in its current configuration as a drug rather than a medical device because of the presence of salicylic acid. The Company's expectation for the launch of Sebclair™ in 2006 is not affected by this decision as the Company has alternative formulations of Sebclair™, which do not require salicylic acid, which will now be substituted.



Trading Update

Revenues for the year ended 30 June 2004 are expected to be approximately £3.0 million. Sales of the Company's leading product, Aloclair™, a liquid or gel for the pain relief of mouth ulcers and other minor oral lesions, are in line with the Board's expectations in volume terms, although actual revenues have been affected by the weakening of the euro. Royalties from Gelclair™, a gel for painful, severe oral ulceration, are now beginning to flow following the signing last year of the worldwide licensing agreement with Helsinn Healthcare, the private Swiss pharmaceutical company.

Licensing discussions with distribution partners, particularly for Atopiclair™, continue to make good progress, though in the case of Atopiclair™ are taking longer than the Company had originally anticipated. Sinclair remains confident that it will strike a good deal for the product and is firmly of the opinion that it is in shareholders' best interests to get the right deal, rather than an early deal.

Sinclair will announce its preliminary results for the year ended 30 June 2004 on 14 October 2004.

Dr Michael Flynn, Chief Executive of Sinclair, commented: "Sinclair's business is built around developing a portfolio of products through the sourcing and acquisition of late stage patented products and the application of our regulatory expertise to secure early approval. We have made excellent progress in obtaining the two regulatory approvals announced today well ahead of schedule and discussions with potential partners for Atopiclair™ continue to move forward."

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**Notes to Editors**

Sinclair Pharma plc is an international pharmaceutical company focused on the acquisition and development of niche patented products in the fields of oral health, oncology support and dermatology and brings them to the international market place. The Company combines product evaluation, product development, regulatory and business development expertise to add value to its acquired and in-house developed products. A key element of the Sinclair business model is to minimise risk and exposure by avoiding involvement in lengthy R&D programmes and rapidly achieving global distribution through a network of marketing partners. The Company has already licensed distribution in over 40 countries for the Group's products.

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