

## SINCLAIR PHARMA PLC

### SALES FORCE PROMOTING ATOPICLAIR™ IN USA EXPANDED AND SINCLAIR ACQUIRES NEW PRODUCT IP FOR ONYCHOMYCOSIS

**Godalming, 13 March 2006:** Sinclair Pharma plc ("Sinclair" or the "Company"), the rapidly growing specialty pharmaceutical company, today announces that its US Atopiclair™ licensee Chester Valley Pharmaceuticals Inc ("CVP") has enlarged its sales force to sell Atopiclair™, Sinclair's product for the treatment of atopic and contact dermatitis. CVP has also entered into a US marketing co-operation agreement with Lupin Pharmaceutical Inc ("Lupin") to target the paediatric atopic dermatitis market.

Sinclair announces today that it has also in-licensed from a US inventor, Dr Mark Bogart, the rights to patents for a new product to treat onychomycosis, a treatment refractory chronic fungal infection that causes the toenails to thicken, discolour, disfigure, and split.

#### **Atopiclair™**

CVP Inc launched Atopiclair™ in June 2005. They have now increased their sales force from 28 to 40 sales representatives and entered a marketing co-operation agreement with Lupin, whose 41 strong sales force started promotion of Atopiclair™ to paediatricians and some general practitioners on 6 March. Both Lupin and CVP are planning to further increase the size of their sales forces during 2006.

Dr. Michael Flynn, CEO of Sinclair said: " We believe that Atopiclair™, an effective steroid-free product for relieving the symptoms of atopic dermatitis, will find rapid acceptance amongst dermatologists, paediatricians and parents as a safer alternative to steroids and topical immuno modulating agents which together comprise a major part of the market for this disease. Data from clinical trials convincingly demonstrates that Atopiclair™ is effective in reducing the itch, the severity and the extent of atopic dermatitis and a positive double blind multicentre trial carried out in the US has been published this month. US sales of Atopiclair are increasing steadily and we are very pleased that CVP have entered these arrangements to more than double the sales team promoting Atopiclair™ which increases its interface with dermatologists and its access to paediatricians."

Bob Moccia, CEO of CVP commented: "Market feedback on Atopiclair™ has encouraged us not only to expand our own sales force, but also to exploit the potential of this product by entering this marketing co-operation agreement with Lupin Pharmaceuticals Inc. Their 41 strong and experienced workforce started selling Atopiclair™ this week and will expand our coverage into the paediatric market in the US. We believe that since Atopiclair contains no corticosteroids and the fact that two main competitive products have recently received "Black Box" notices from the FDA, Lupin's sales force will achieve significant penetration in the paediatric market."

#### **Onychomycosis**

Sinclair also today announced it has licensed the rights from Dr Mark Bogart, a US inventor, to develop and commercialise a new topical product to treat fungal infections of the nails - usually the toenails. The patents claim a method of treating onychomycosis using compositions consisting of carboxylic acids and alcohols. The IP includes a granted US patent and corresponding applications in Europe, Japan, Australia, and Canada.

Onychomycosis is difficult to treat and clinical clearance of the disease is poor with current treatments. The nails of people with onychomycosis are initially a cosmetic concern. Without treatment, however, the nails can become thick and disfigured. The product to be developed acts predominantly by dehydrating the environment surrounding the causative fungal infection. The preparation is applied topically and penetrates nails readily.

The organisms that usually cause onychomycosis are *Trichophyton rubrum* and *Trichophyton mentagrophytes*. They are dermatophytes (fungi that infect hair, skin, and nails) and feed on keratinized (nail) tissue. The infections they cause are normally confined to the nails, but occasionally spread to the surrounding skin. Preclinical studies have shown that the product kills the main causative agent *T. rubrum* on contact.

Dr Michael Flynn, CEO of Sinclair commented: "Sinclair has been evaluating and testing this promising dermatological product for more than a year and are pleased that we have now secured the rights to commercialise it. It sits well in our area of niche dermatological products and addresses a significant and common medical condition. The yet to be named product joins an already robust pipeline of products which we expect to commercialise over the next several years."

## **Market data**

### **ATOPIC DERMATITIS.**

Atopic dermatitis is one of the most common dermatological complaints and accounts for a large number of physician consultations. It is known from independent studies to affect approximately 20% of school-aged children. Independent studies also suggest that the prevalence in adults is 1-3%.

The sector of the dermatology market in which Atopioclair™ competes was worth US\$1.9 billion in 2004 having grown in the previous year by 11%.

### **ONYCHOMYCOSIS.**

Rates of onychomycosis vary with the population considered. A recent study<sup>5</sup> in a general U.S. population revealed a prevalence of 2 to 3%, in the UK 2-4% of adults suffer from onychomycosis<sup>1-4</sup>. Patients with diabetes commonly develop onychomycosis because blood circulation is poor in the extremities, and the body's ability to fight infections is compromised. Small cuts, infections, and foot injuries can have serious consequences for diabetics. Recent studies<sup>6</sup> have shown a higher rate of amputation in diabetics with onychomycosis compared to those without the infection.

Treatments currently available are either systemic which can have unwelcome side effects or topical. The combined systemic and topical US market in 2003 was US\$1,068 million of which US\$900 million was for prescription systemic products.

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