



SPH.L

Licence Agreement with Medpharm Limited for Terbinafine Spray

Sinclair Pharma Plc ("Sinclair" or "the Company": SPH:L), the international specialty pharma company is pleased to announce the signing of a licence to the worldwide rights to develop a patented new spray presentation of the generic anti-fungal, terbinafine, for the treatment of Athlete's Foot (*Tineapedis*). Sinclair had previously entered an exclusive option for the technology and following completion of the recent fundraising has now exercised this option and signed a full licence. The product has completed European phase II non-inferiority studies with the brand leader for the indication (Lamisil® Once) as a comparator and has proven as efficacious in a 'once only' treatment of this common infection.

Terbinafine which is marketed by Novartis under the brand Lamisil® has proven to be the most effective treatment of Athlete's Foot which affects 70 % of the population at some point. At its peak worldwide sales of all forms of the anti-fungal, Lamisil®, achieved more than \$1 billion. Sinclair expects this to be a leading product for the Company's country operations in France, Germany, Italy and Spain, and an appealing product for partners worldwide with the potential to become Sinclair's leading product by revenue.

Medpharm Limited based in Guildford, close to Sinclair's own corporate office is a specialist contract formulation and development company for topical drugs and new innovative delivery systems. The company has patented and optimised the use of monophasic 'spray on patch' formulations of common APIs and this is their lead product.

After completing its review and strategic planning for US and European market entry, as well as preparation of pilot batches for a new US study, Sinclair will proceed with compiling a dossier for market authorisation applications in Europe and follow up the European study with a new study in the USA.

Sinclair now plans to submit its first MAA within the year with first European launch expected in H1 2012. In the USA, where Lamisil Once is not marketed, Sinclair will seek a major industrial partner for an expected 2014 launch.

Chris Spooner, Sinclair's CEO, commented: 'Terbinafine spray exactly fits Sinclair's strategy to deliver high-quality, value-added products with proven market potential. Athlete's Foot is a large and well understood market, with terbinafine the gold standard therapy. We believe a one-shot spray plaster presentation has clear advantages over current offerings and will prove a strong addition to both Sinclair's portfolio and those of our partners, having the potential to become easily Sinclair's biggest product.

The technology was licensed from Medpharm. This is a highly innovative partner with whom we very much look forward to further collaborations.'

Andrew Muddle, CEO of Medpharm added: 'We are very pleased to have Sinclair as a partner for this product. Sinclair has exhibited remarkable foresight, vision and enthusiasm for long term success



and we are pleased that they see MedSpray technology as part of that. Sinclair is committed to the global development and registration of the TerbinafineMedSpray and will go on to market and sell the product.

We see this as validation of the MedPharm business approach to develop our technologies, in this case MedSpray, with exemplary partners such as Sinclair.'

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Notes to Editors:

About Sinclair Pharma Plc www.sinclairpharma.com

Sinclair Pharma plc is an international specialty pharmaceutical company providing solutions to treat wounds, dermatological and oral diseases through advanced surface technology and innovative delivery systems. It has a growing sales and marketing operation that is present in France, Italy, Germany and Spain, and an extensive marketing partner network across selected developed & emerging markets.

About MedPharm Ltd www.medpharm.co.uk

MedPharm Ltd is an innovation-driven pharmaceutical development company committed to the identification, creation and development of unique therapeutic systems for topical use specialising in drug delivery to the skin, nail, mucous membranes, eye, nose and lung.

MedPharm offers a unique and highly specialised service in the area of pharmaceutical contract research and development. Capabilities comprise analytical, preformulation, formulation, in-vitro performance testing, GMP manufacture and preclinical and clinical evaluation.

The MedPharm team combines years of commercial experience in the pharmaceutical industry with the benefit of high-calibre scientists. MedPharm now has over 50 employees with in excess of 45 in R&D.

Tinea Pedis (Athletes Foot)

Athletes foot (tinea pedis) is a common foot infection caused by dermatophyte fungi on and in the epidermis of the skin of the feet causing flaking, itching and cracking of the infected area. It usually occurs between the toes but in severe cases can also affect the soles and the sides of the foot. If left untreated the condition can result in pain, swelling and inflammation of the affected area and can spread to other areas of the body, most commonly the nails of the feet (onychomycosis), the groin (jock itch) and the torso and limbs (tinea corporis). Treatment is by the application of topical antifungals, typically for a period of one to four weeks. Antifungals can be classified as fungicidal (kill fungi) such as allylaminesegterbinafine or fungistatic (inhibit the growth of fungi) such as azole compounds. Because of the long treatment duration time, non-compliance with treatment is an issue and may be one of the reasons why the condition has had a high rate of recurrence.

Terbinafine acts by preventing ergosterol biosynthesis via inhibiting the squaleneepoxidase which is a part of the fungal sterol synthesis pathway that creates the sterols needed for the fungal cell membrane