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Xerion Limited, Australia

AMYCOT®: A novel bioactive extract from *Spirulina* with multi-functional properties shows clinical efficacy against onychomycosis and tinea infections; And its implications for other dermatological conditions

AMYCOT® is a bioactive extract derived from a strain of Spirulina *(Arthrospira maxima*), a *cyanobacterium*, which is commonly used as food supplement and has been consumed for centuries by the Aztecs in Mexico and tribes in Africa. AMYCOT® is produced through a proprietary process which enriches for the bioactive(s). The complex mixture contains a variety of molecules known to have anti-fungal activity as well as a unique activity targeting chitin, a cell wall component present in a broad range of fungi including yeasts. The fungicidal property of AMYCOT® is supported by electron microscopic studies showing rupture of test fungi after a few days as well as *in vitro* zone inhibition studies against a variety of dermatophytes and yeasts. Preclinical *in vitro* studies including use of an *in vitro* 3D human epidermis model have shown that AMYCOT® is non-toxic and non-allergenic with stimulation of skin cell growth properties. Furthermore, the bioactive extract demonstrates anti-inflammatory activity by reducing secretion of IL-1 alpha, a cytokine central to skin inflammation (unpublished results). Previous open-label studies by independent investigators demonstrated efficacy of AMYCOT® against a variety of dermatological fungal infections such as tinea and onychomycosis (2; unpublished results). To further confirm these studies, a single-center, randomised, double-blind, placebo-controlled clinical study was conducted in India. AMYCOT® was formulated as a lotion (8% AMYCOT®) to treat onychomycosis and as a cream (12% AMYCOT®) against tinea infections. The study's sample size was determined from a previous study on a cream and lotion that observed an 81% cure rate for the experimental drugs and an assigned 10% IGA response of 'cleared' or 'excellent' for the placebo group using a two-group Fisher's-exact test of equal proportions. Based on these assumptions, there is over 95% power to detect a significant difference between the treatment and placebo groups with 14 subjects per group (28 subjects overall) at 5% level of significance, and assuming a 20% dropout rate. From screening 50 potential patients, a total of 28 patients, 18 with tinea and 10 with onychomycosis were randomized in a ratio of 1:1 to treatment or placebo group. All were positive for all three parameters constituting mycological cure, which was assessed, was assessed by potassium hydroxide (KOH) smear, fungal culture and live spore count. Clinical cure was defined as Investigator global assessment (IGA) response of 'cleared' (100% improvement) or 'excellent' (>90% improvement). At the end of treatment, all three parameters were negative in the treatment arm, while KOH smear was positive in all subjects, and culture and live spore count were positive in six of them in the placebo arm. The treatments showed a significant improvement in all three parameters ($p<0.0001$, 0.019 and 0.019 respectively). At the end of the study, clinical cure was achieved in 11/14 of the tinea subjects and 5/5 of onychomycosis subjects in the treatment arms, while none in the placebo arm. No treatment-related adverse effects were observed in both groups. Additional examples on other subjects with onychomycosis and paronychia will be presented including the successful use of the bioactive extract against acne and pompholyx based on AMYCOT®'s anti-inflammatory and skin repair properties. nailKALM® (8% AMYCOT®) lotion and skinKALM® (12% AMYCOT®) are listed with the Australian TGA (Therapeutic Goods Administration).

Speaker Biography

Leodevico (Vic) Ilag is a Chief Scientific Officer and more than 20 years of biotech experience in the discovery and development of biologics and diagnostics serving in multiple senior executive roles in R&D and business development with several biotech companies in Australia and Europe.

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