

ASX ANNOUNCEMENT

CELLMID'S FGF5 INHIBITOR CLINICAL STUDY PUBLISHED

- **New publication for Cellmid's FGF5 inhibitors in peer reviewed journal**
- **Formulations with lead compound showed efficacy in reducing hair loss in blind placebo controlled clinical study**
- **Manuscript on the *in vitro* screening approach and results of compound discovery by Cellmid's Japanese scientists**

SYDNEY: Thursday, 2 March 2017, Cellmid Limited (ASX: CDY) is pleased to advise that a manuscript describing the screening approach and clinical study carried out by Cellmid's wholly owned subsidiary, Advangen Limited, has been published in the journal *Clinical, Cosmetic, and Investigational Dermatology* **10**: 71-85. 27 Feb 2017.

The paper, titled "*Promotion of Anagen, increased Hair Density and Reduction of Hair Fall in a Clinical Setting Following Identification of FGF5 Inhibiting Compounds via a Novel Two Stage Process*", describes the development and screening programme behind the Company's FGF5 inhibitory technology and the discovery of novel, single molecule FGF5 inhibitors.

The paper also describes the results of the blinded, placebo controlled clinical study of topical formulations containing the lead inhibitor in men and women. The paper can be accessed via the Journal website.

Few effective treatments exist for hair loss in both men and women, and the current market contains numerous products with unknown mechanisms of action, and/or cosmetic claims not verified by scientific data. In contrast, Advangen's technology is based around the inhibition of FGF5, an important molecule in the hair cycle that signals hair follicles to stop producing hair and rest.

FGF5 has no other known function: animals and humans carrying mutations in the FGF5 gene have long, thick hair, but are otherwise healthy. Advangen has extensively screened botanical extracts, and more recently individual compounds, for FGF5 inhibitory activity using robust cell based assays.

The peer-reviewed publication of these data represents an important step for the Company's subsidiary, Advangen, and strengthens the position in the market of its products as effective hair loss treatments based on validated scientific rationale.

The lead compound identified through the screening method, named MTP3, has been shown to be almost seven times more effective in inhibiting FGF5 than previous extracts and is now included in all évolis® branded products. The data generated through the compound screening is also the subject of a patent application, currently under examination.

“The identification of single molecule inhibitors rather than whole botanical extracts represents a significant improvement in the precision of the Company's évolis® hair loss treatments, and resulted from a substantial body of work by our dedicated Japanese research team”, said the study's lead author Dr Dominic Burg. “The compelling clinical results highlight the utility of évolis® products against pattern hair loss in both men and women” he added.

Detail of the Study and results

The manuscript describes Advangen's development of a novel two-stage *in vitro* cell-based platform for the discovery and validation of a number of single molecule compounds of botanical origin as FGF5 inhibitors. The sole use of *in vitro* methods for discovery and validation is a critical strategy, as animal testing methods would restrict the marketing of products tested in that manner in some regions including the European Union.

Advangen's scientists discovered potent FGF5 inhibitory activity amongst select members of the monoterpene family with the lead molecule MTP3 nearly seven times more potent than the company's previously published inhibitors ($p=0.0024$).

As part of the study, formulations containing the lead molecule were delivered to AMA laboratories U.S.A, an independent contract research organisation. The new formulations underwent safety testing via a repeated insult patch test on 50 individuals. No adverse events or reactions were recorded. A protocol for a single blind, placebo controlled clinical study of men and women with mild to moderate hair loss was developed and test participants were recruited.


A panel of 32 healthy individuals with hair loss (Male: Hamilton Norwood scale 2 to 4, and Women: Ludwig scale i2 to ii2) were randomised into 3 age and sex matched groups: Placebo, and two formulations with differing concentrations of novel active. Participants were assessed over 16 weeks of treatment by measuring hair fall, anagen-telogen ratio (the ratio of hairs in growth phase compared to those in rest phase), expert visual grading, and a subset was examined by high resolution matched photography.

Both formulations showed significant improvements over baseline and compared to placebo. The best performing formulation was able to increase the number of follicles in the growth phase ($p=0.002$), reduce hair loss ($p=0.007$), improve the appearance on visual grading ($p=0.004$), and displayed a continued increase in hair density on digitally matched photography over the 16-week study period. The Placebo group did not show any improvement, and had a trend for worsening hair-fall over 16 weeks.

End

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Cellmid Limited (ASX: CDY)



Cellmid is an Australian life sciences company with lead programs in multiple disease indications. The Company, through its wholly owned subsidiaries, Lyramid, Kinera and Advangen, develops and markets innovative novel therapies and diagnostic tests for fibrotic diseases, cancer, ischemic diseases of the heart and hair loss. Cellmid holds the largest and most comprehensive portfolio of intellectual property relating to the novel targets midkine (MK) and FGF5 globally. Intellectual property pertaining to this novel target is being exploited through wholly owned subsidiaries Lyramid and Kinera. Advangen, Cellmid's consumer health business, sells its FGF5 inhibitor hair growth products in Australia and Japan, and currently expanding distribution in other territories. For further information, please see www.cellmid.com.au and www.evolisproducts.com.au.

Advangen Limited - Cellmid's Consumer Health Division

In 2013 Cellmid acquired Advangen Inc. (Japan), the owner of a range of FGF5 hair growth technologies and became the only company globally with an FGF5 inhibitor hair growth product range on the market. Cellmid has continued innovation and product development and filed a number of new patent applications covering several hair growth agents including midkine and a group of novel FGF5 inhibitors. In addition to distribution in Australia and Japan the Company is actively expanding into other markets such as the USA, Asia and Europe

Investment in life sciences companies

There are a number of inherent risks associated with the research, development and commercialisation of pharmaceutical products. Investment in companies specialising in these activities carry specific risks which are different to those associated with trading and manufacturing businesses. As such, these companies should be regarded as highly speculative. Cellmid recommends that investors seek professional advice before making an investment in its shares.