Mallia Aesthetics achieves key regulatory steps for novel sCD83-derived ingredient for hair growth

- **Safety assessment of cosmetic formulations using sCD83-based MAL-838 completed successfully**
- **INCI name assigned and listing in the European CosIng database obtained**
- **All upcoming 8T3 cosmetic products have been certified as microbiome-friendly**

Erlangen, Germany, August 20, 2025 - Mallia Aesthetics GmbH, a company focusing on the development and commercialization of cosmetic products to stimulate hair growth, today announced the successful completion of multiple important steps in the development and regulatory validation of MAL-838. MAL-838 builds the foundation for the company's upcoming hormone-free 8T3 product line targeting hair growth and is derived from the human soluble protein sCD83. Laboratory studies have shown that sCD83 is able to stimulate hair growth and induce signaling pathways for hair growth including in human tissue samples and induce new hair follicles in several model systems.

As part of Mallia Aesthetics' preparations for market launch in the fourth quarter of this year, a comprehensive safety assessment of the formulations of all planned 8T3 products has been successfully completed in accordance with the European Cosmetics Regulation EU 1223/2009. Extensive in vitro and in silico tests by an independent laboratory have demonstrated the safety of MAL-838 as a cosmetic ingredient. The safety reports now confirm that MAL-838 and the formulations of all planned 8T3 products can be used safely, which paves the way for commercialization of the cosmetics.

In parallel, MAL-838 has now been officially listed in the European CosIng database (Cosmetic Ingredients Database), the EU's authoritative registry of cosmetic ingredients, which further establishes its regulatory compliance and market readiness. The ingredient has also been assigned a dedicated INCI name: sh-Polypeptide-167. This internationally recognized designation is used on product labels and provides transparency for consumers through standardized labeling of all ingredients.

Mallia's 8T3 product formulations of MAL-838 have also been certified as microbiome-friendly following independent testing. This means that the 8T3 formulations do not disrupt the healthy skin microbiome unlike many other hair growth products that rely on solvents like ethanol or contain preservatives. With the 8T3 product line, Mallia Aesthetics aims to offer high-performing yet mild and skin-compatible solutions for hair growth.

"We're very happy to have successfully achieved these regulatory steps. With the safety evaluation completed, INCI registration and CosIng listing obtained, and the microbiome-friendliness validated, we have laid the foundation for a responsible and successful market entry with our 8T3 product line. Our goal is to deliver truly differentiated products in the hair growth market that are scientifically sound, safe, and aligned with current standards in skin health," said **Dr. Anne Asmuß, Managing Director of Mallia Aesthetics**.

About sCD83

Soluble CD83 (sCD83) is an immunomodulatory protein that is currently being developed for the topical treatment of hair loss (MAL-856) and stimulation of hair growth (MAL-838). The soluble CD83 protein was first identified in 2001 by Mallia co-founder Prof. Steinkasserer. It has anti-inflammatory properties via the induction of resolution of inflammation, which promotes wound healing and induces new hair growth.[1] In addition, sCD83 has been shown to activate regulatory T cells (Tregs)[2], which interact directly with hair follicles and can activate them.[3] Furthermore, sCD83 inhibits cell death of hair follicles and directly activates follicular stem cells, thereby stimulating new hair growth. This multimodal mode of action distinguishes sCD83 from other topically applied hair growth agents.

Topically applied, sCD83 can directly reach the hair follicles but does not penetrate through the skin and thus does not enter the bloodstream. The effect is localized, which is a major advantage over systemic treatment options, which can cause severe side effects.

About Mallia

Mallia Innovations GmbH, based in Erlangen, Germany, is the holding company strategically driving the proprietary development and commercialization of biopharmaceutical therapies and cosmetic applications of the immune modulatory sCD83 protein, targeting hair growth, hair loss and other dermatological indications, including wound healing.

Mallia Therapeutics GmbH focuses on the clinical development of novel therapies for patients suffering from androgenetic alopecia or alopecia areata, among other conditions. MAL-856 is based on the scientifically proven immune modulatory mode of action of sCD83, which has been investigated for close to 25 years by Mallia Co-founder Prof. Dr Alexander Steinkasserer.[4]

Mallia Aesthetics GmbH focuses on cosmetic applications for the stimulation of hair growth, which are also based on the scientifically validated sCD83 protein. The Company develops Innovative cosmetic products using MAL-838 that will be marketed to specialists and consumers.

For more information, visit www.mallia.com, follow us on LinkedIn.

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