A-368 - Intralesional L19IL2/L19TNF in high-risk lacSCC patients: results from the Phase II DUNCAN Trial Exploratory Cohort [Abstract]

T. Eigentler, A. Cozzio, S. Haferkamp, P. Rutkowski, J. Hassel, U. Leiter, K. Kähler, Julia Welzel, E. Ramelyte, T. Amaral, L. Flatz

Angaben zur Veröffentlichung / Publication details:

Eigentler, T., A. Cozzio, S. Haferkamp, P. Rutkowski, J. Hassel, U. Leiter, K. Kähler, et al. 2026. "A-368 - Intralesional L19IL2/L19TNF in high-risk lacSCC patients: results from the Phase II DUNCAN Trial Exploratory Cohort [Abstract]." *EJC Skin Cancer* 4 (Supplement 1): 101010. https://doi.org/10.1016/j.ejcskn.2026.101010.

A-187

Interest of an anti-hair loss serum containing Silybum marianum extract, manganese pyrrolidone carboxylic acid (PCA), and a Lespedeza capitata extract in the management of post-cancer treatment alopecia: an international real-world study

V. Mengeaud [1], A. Stennevin [2], A. Brocario [1], E. Mantel [1], B.M. Piraccini [3]

[1] *Pierre Fabre Dermo-Cosmetics and Personal Care, Medical Direction Ducray, Lavaur, France*
[2] *Pierre Fabre Dermo-Cosmetics and Personal Care, Medical Direction Eau Thermale Avène, Lavaur, France*
[3] *Private Dermatology Practice, Bologna, Italy*

Background: Alopecia induced by cancer treatments is one of the side effects most feared by patients, profoundly affecting self-esteem, body image and quality of life, even after treatment has ended. Although reversible, hair regrowth is often slow, and may occasionally be incomplete or with hair poor in quality. In this context, the management of post-cancer treatment alopecia appears to be a major challenge in oncodermatology and supportive care, justifying the evaluation of new topical strategies aimed at promoting faster, denser and better-quality regrowth.

This study evaluates the efficacy and tolerance of an anti-hair loss serum on four types of alopecia, including post-cancer treatment alopecia.

Methods: This international, open label, real-world, prospective and multicentric study was conducted in 13 countries. Adult subjects with post-cancer treatment alopecia were included and followed for 3 months. The serum containing Silybum marianum extract, manganese PCA, and Lespedeza capitata extract was applied once daily to the scalp, in monotherapy, in combination, or after other treatments, including drugs and emerging therapies (such as platelet-rich plasma (PRP), mesotherapy.), according to usual practice of dermatologists.

Efficacy was measured using a Numeric Rating Scale (NRS) that evaluated hair aspects according to dermatologist and subject assessment. Tolerance was assessed on a 4-point scale. Changes from baseline were analyzed for all endpoints.

Results: 28 subjects (5 men and 23 women, phototypes I to V) with post-cancer treatment alopecia were included, of whom 75% had chemotherapy-induced alopecia. Two-thirds of this group (n = 19, 67.9%) used the serum as monotherapy. Dermatologists perceived a 63% improvement in hair density ($p < 0.001$) and a 72% improvement in hair volume ($p < 0.001$) after 3 months from baseline. A significant improvement was also perceived by treated subjects, who reported a 90% increase in hair growth ($p < 0.001$), a 75% increase in hair density ($p < 0.001$), an 88% increase in hair volume ($p < 0.001$), and 100% increases in hair strength ($p < 0.001$) and hair thickness ($p < 0.001$) from baseline to 3 months. Tolerance was rated by dermatologists as good to very good in 96.4% of subjects.

Conclusions: This anti-hair loss serum is an effective and well-tolerated option and could be used as supportive care for managing post-cancer treatment alopecia.

https://doi.org/10.1016/j.ejcskn.2026.101009

A-368

Intralesional L19IL2/L19TNF in high-risk lacSCC patients: results from the Phase II DUNCAN Trial Exploratory Cohort

T. Eigentler [1], A. Cozzio [2], S. Haferkamp [3], P. Rutkowski [4], J. Hassel [5], U. Leiter [6], K. Kähler [7], J. Welzel [8], E. Ramelyte [9], T. Amaral [10], L. Flatz [6]

[1] *Hauttumorzentrum Charite - Klinik für Dermatologie, Venerologie und Allergologie, Berlin, Germany*
[2] *Kantonhospital St. Gallen, St. Gallen, Switzerland*
[3] *University Hospital Haale/Saale, Halle/Saale, Germany*
[4] *Maria Sklodowska-Curie National Research Institute of Oncology Warsaw Poland, Warsaw, Poland*
[5] *NCT Heidelberg, Heidelberg, Germany*
[6] *University Hospital of Tuebingen, Tuebingen, Germany*
[7] *University Hospital Schleswig-Holstein, Kiel, Germany*
[8] *University Hospital Augsburg, Augsburg, Germany*
[9] *University Hospital Zurich, Zurich, Switzerland*
[10] *Institut Strauss, Straßburg, France*

Background: Cutaneous squamous cell carcinoma (cSCC) accounts for around 20% of all skin cancers. Although surgery is curative for most patients, some present with or progress to locally advanced disease that is no longer amenable to resection (lacSCC). For these patients, surgery or radiotherapy may not be appropriate and systemic checkpoint blockade may be ineffective or poorly tolerated. Daromun, a combination of two targeted immunocytokines (L19IL2 and L19TNF), that have already demonstrated efficacy and a well manageable safety profile in the treatment of locally advanced melanoma and locally advanced Basal Cell Carcinoma (laBCC), could provide an effective and well-tolerated treatment option.

Methods: In the phase II DUNCAN single-arm trial, patients with high-risk laBCC or lacSCC, who were ineligible for or refusing surgery/RT, were treated with up to four weekly intratumoral administrations of Daromun (a maximum 13 million IU of L19IL2 and 0.4 mg of L19TNF), across all injectable lesions. Here we report the results for the lacSCC exploratory cohort (n = 20) including pathological complete response (pCR), the best objective response rate (BORR per RECIST v1.1) and safety.

Results: Overall, 21 were enrolled in the lacSCC exploratory cohort. Median follow-up at data cut-off (16 June 2025) was 32 weeks. Within the lacSCC exploratory cohort, 20 patients received treatment and ten of them (50%) achieved pathological pCR. Among patients with pCR, 9/10 (90%) remained recurrence-free at the injected lesions after a median follow-up of 36 weeks; one patient died from non-cancer causes without evidence of recurrence. Sixteen patients were evaluable for the BORR by RECIST v1.1: 8/16 (50%) responded, including 7 complete responses (43.8%) and 1 partial response (6.3%). After a median follow-up of 25 weeks, only 1/8 responders (13%) had progressed. Daromun was well tolerated and treatment-related adverse events (TRAEs) were transient. The most frequent grade 1–2 TRAEs (>10% of patients) were injection-site reactions (44.9%), chills (33.7%), pyrexia (32.6%), influenza-like illness (16.8%), fatigue (11.2%) and injection-site pain (10.1%). No grade ≥4 or serious TRAEs were reported.

Conclusions: In this exploratory clinical trial intralesional Daromun showed promising activity (50% pCR; 50% BORR) with durable local control and a favourable safety profile, consistent with the laBCC cohort. Daromun may represent a promising local treatment option for patients with lacSCC who have limited alternatives, warranting further investigation in larger clinical trials.

https://doi.org/10.1016/j.ejcskn.2026.101010