Rhenium-188 Skin Cancer Therapy (SCT) European Subanalysis: Two-year efficacy and safety from a prospective multicentre phase IV study

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Conflict of Interest

Siroos Mirzaei reports speaking and lecture fees and travel reimbursement by OncoBeta
Nicola Mulholland reports travel reimbursement by OncoBeta
Julia Tietze reports speaking and lecture fees and travel reimbursement by OncoBeta
Gerhard Dahlhoff and Carmen Felpeto-Santero are OncoBeta's employees

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The authors are PI or investigators of EPIC skin study.

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Australia: Siddhartha Baxi, Giuseppe Cardaci, Angela Hong.
United Kingdom: Nicola Mulholland, Saqib Bashir.
Germany: Julia Tietze, Martin Heuschkel.
Austria: Siroos Mirzaei.
South Africa: Mike Sathekge, Kgomotso Mokoala.

Rhenium- Skin Cancer Therapy (Rhenium-SCT)

What is Rhenium-SCT?

A single-session, non-invasive radiation treatment that harnesses the beta particles from rhenium-188 decay (17hr half-life) to trigger tumour cell death.

1

How is it applied?

Dermatologists select patients and refer them to Nuclear Medicine who apply the treatment. Applied as a resin, it is administered over a film affixed to indicated BCC and SCC lesions, allowing for conformal treatment without the need for complex planning.

2

Mechanism of Action

The shallow penetration profile of rhenium-188 beta particles (2.12 MeV max; 92% penetration within 3mm of skin), allows for targeted treatment, whilst avoiding unnecessary exposure of healthy tissue.

3

Patient Experience

Treatment is painless and lasts from 45-180 minutes, depending on lesion depth. Patients can return to activities immediately. A delayed radiodermatitis occurs, characterised most commonly by erythema, pruritis and scabbing.

4







Common patients treated

- Cosmetic or functional considerations
- Comorbidities
- Unable to complete fractionated radiotherapy
- Multiple lesions
- Recurrent lesions
- Remote or rural patients
- Declines surgery

References: Baxi et al 2026 EANMI, doi:10.1016/j.eanmi.2026.100311; Sedda AF, et al. Dermatological high-dose-rate brachytherapy for the treatment of basal and squamous cell carcinoma. Clin Exp Dermatol. 2008;33(6):745-749. doi: 10.1111/j.1365-2230.2008.02852.x 2. Cipriani C, et al. Personalized irradiation therapy for NMSC by rhenium-188 skin cancer therapy: a long-term retrospective study. J Dermatolog Treat. 2020:1-7. doi: 10.1080/09546634.2020.1793890. 3. Castellucci P, et al. High dose brachytherapy with non sealed 188Re (rhenium) resin in patients with non-melanoma skin cancers (NMSCs): single center preliminary results. Eur J Nucl Med Mol Imaging. 2021;48(5):1511-1521. doi: 10.1007/s00259-020-05088-z. 4. Cipriani C, et al. Personalized high-dose-rate brachytherapy with non-sealed rhenium-188 in non-melanoma skin cancer. Int J Nucl Med. 2017;114–112.

Rhenium-SCT Multidisciplinary Treatment Pathway

A simple, efficient pathway from referral to follow-up

Dermatologist

1 Patient Selection



- **Refer + Biopsy**
- **Confirm suitability**
  - ✓ Histology
  - ✓ Lesion Depth
  - ✓ Surface area

Derm – Nuc Med / Rad Onc

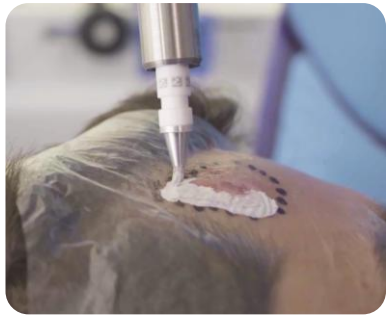
2 Lesion Planning



- **Schedule patients into treatment sessions** (Grouping by surface area)
- **Define lesion margins**
- **Generate treatment plans**

NucMed / RadOnc

3 Administer Treatment



- **Apply Rhenium-SCT** *(~20–30 min)*
- **Session-based delivery** *(usually 3-5 patients per session)*
- **Efficient outpatient workflow**

Technician

4 Post Treatment



- **Remove treatment and clean site**
- **Perform radiation check**
- **Dispose via waste management**

Dermatologist

5 Follow-Up



- **Provide aftercare instructions**
- **Review at 2-3 visits**
- **Monitor healing and response**

Initial Consult & Referral | **Rhenium-SCT Treatment Day** | **Follow-Up**

Rhenium-SCT Clinical Data Timeline

2008

1st Re-188 publication for NMSC.

Sedda *et al*.

2009-2020

Case series Re-188 study in SCC of the penis
Carrozzo *et al.*, 2013

Retrospective Re-188 study in superficial lesions
Cipriani *et al., 2017*

Retrospective Re-188 study of 50Gy to base of lesion
Cipriani *et al.,* 2020

2021

1st Prospective Re-SCT study

Castellucci *et al*.

2023

1st Dermatologist-led publication

Tietze *et al.*

2024

EPIC-Skin study 6 month
Baxi *et al.*

1st patient centred publication
Kronert *et al*.

2025

EPIC-Skin study 12 month
Cardaci *et al.*

Retrospective **3-year Re-SCT outcomes**
Castellucci *et al.*

Prospective difficult-to-treat BCC
Chessa *et al.*

Review GEC-ESTRO BRAPHYQS
Lozares *et al*

Meta-analysis Re-188 studies
Sadeghpour *et al*

2026

EPIC-Skin study 24 month: Efficacy. Safety, Cosmesis and Patient reported outcomes
Baxi *et al.*

Review Re-188 in NMSC. Castellucci *et al*

Continuing education Re-188 in NMSC
Martinez-Albero *et al.*

European Subanalysis EPIC-Skin study 24month

Expanding published reports and studies that support routine clinical implementation
Manuscript in preparation

Sedda et al. Clin Exp Dermatol. 2008;33:745–749. Cipriani et al. J Dermatol Treat. 2022;33:969–975. Castellucci et al. Eur J Nucl Med Mol Imaging. 2021;48:1511–1521. Tietze et al. Clin Nucl Med. 2023;48:869–876. Baxi et al. J Nucl Med. 2024;65:1450–1455. Cardaci et al. Adv Radiat Oncol. 2025;10:101802. Krönert et al Healthcare 2024, 12, 921. Chessa et al. Dermatol Pract Concept. 2025;15:4993. Castellucci et al. J Nucl Med. 2025;00:1–6. Lozares et al. Clin Transl Radiat Oncol. 2025 Jun 8;53:100991. doi: 10.1016/j.ctro.2025.100991. Sadeghpour et al. Front Med. 2025;12:1707729. E. Martínez Albero et al Rhenium-188 resin therapy for non-melanoma skin cancer, Revista Española de Medicina Nuclear e Imagen Molecular (English Edition) 2026. Castellucci P et al. Epidermal radionuclide therapy with rhenium-188 in non-melanoma skin cancer: a short narrative review. Front Med (Lausanne). 2026 Jun 3;13:1850326. doi: 10.3389/fmed.2026.1850326. Baxi et al 2026 EANMI, doi:10.1016/j.eanmi.2026.100311. *Abbreviations: NMSC: non-melanoma skin cancer; Re-SCT: Rhenium Skin Cancer Therapy; PROs: patient-reported outcomes; GEC: Groupe Européen de Curiethérapie; ESTRO: European Society for Therapeutic Radiology and Oncology; BRAPHYQS: BRAchytherapy PHYsics Quality Assurance System. ; BCC: Basal cell carcinoma.*

EPIC-Skin International Prospective Study

A global, multicenter, single-arm, Phase 4 post-marketing clinical study

- **Non-inferiority study**
- **Head-to-head comparison inappropriate** (multiple clinical scenarios, no single treatment modality; **radiotherapy is heterogeneous**, with no single standard comparator modality).

7 sites; 5 countries

(Austria, Germany, UK, Australia, South Africa)

Time Points: 0, 6-, 12-, 24-month

Stage I / II, BCC / SCC;

- De novo / Recurrent
- 1 - 3 lesions;
- Up to 8cm^2 area; ≤ 3mm deep

→ Patients deemed **unsuitable for surgery**

Efficacy, cosmesis, toxicity, Safety, QoL, PROs

The study design was **informed by multiple formative datasets** and **prospectively** structured to assess:

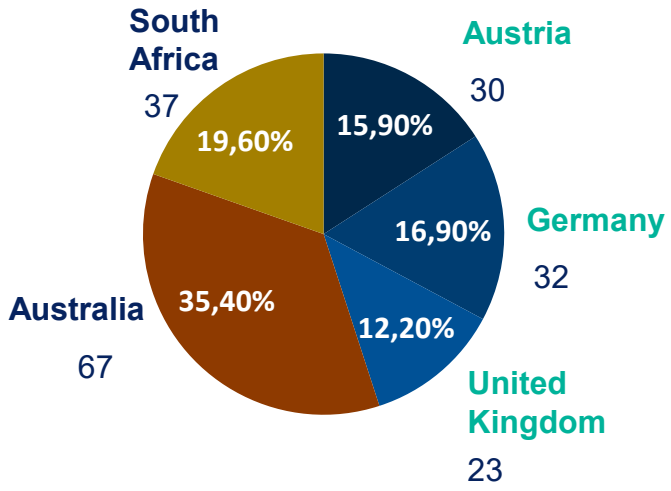
- Durability
- Safety
- Cosmesis
- Patient experience

Rhenium-Skin Cancer Therapy (SCT) for the Treatment of Non-Melanoma Skin Cancer. (EPIC-Skin); ClinicalTrials.gov ID NCT05135052

Abbreviations: Re-SCT: Rhenium Skin Cancer Therapy; PROs: patient-reported outcomes; BCC: Basal cell carcinoma; SCC: Squamous cell carcinoma; QoL: quality of life

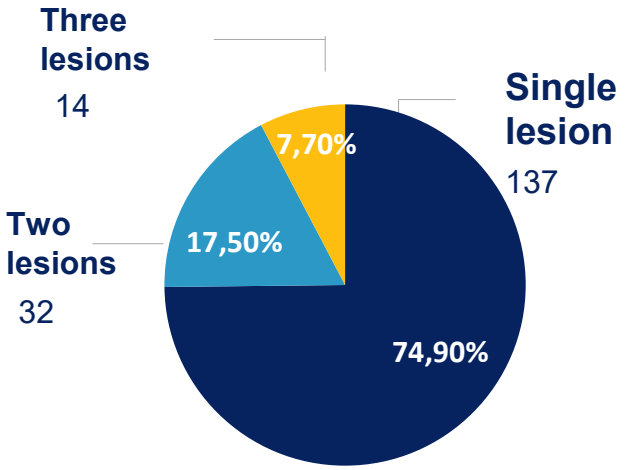
Patient Demographics and Baseline Characteristics (FAS)

Number patient /country



189 participants

Number lesions / patient



183 participants with recorded details of 243 lesions

Lesion characteristics

2.27cm²
Mean Lesion Area

1.40 mm
Mean Lesion Depth

Baxi S, Cardaci G, Hong A, Mulholland N, Mokoala K *et al*. 188Rhenium skin cancer therapy: Two–year efficacy, safety and patient reported outcomes from the prospective, multicentre, phase IV, EPIC-Skin study in non-melanoma skin cancer. EANM Innovation, 5 (2026): 100311, ISSN 3051-2913. https://doi.org/10.1016/j.eanmi.2026.100311.

GLOBAL

Patient Demographics and Lesions Characteristics

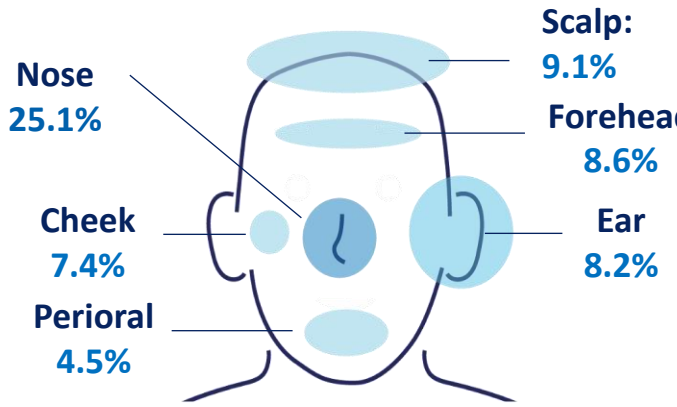
71.5 years
Median age (range 27-95)

80%
Fitzpatrick Type I or II

Fitzpatrick Type

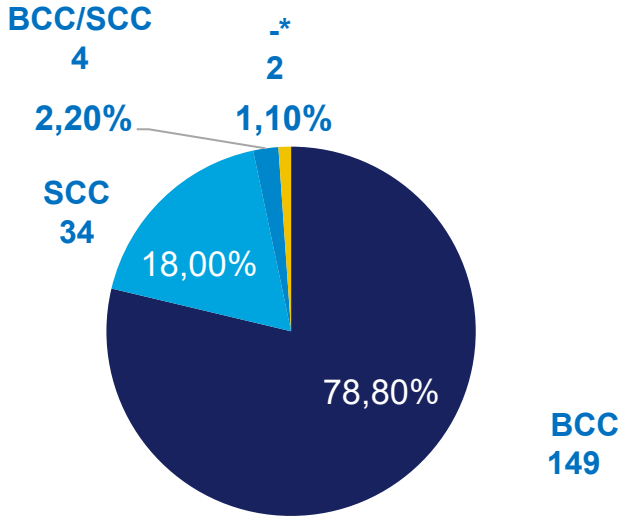
I (23%); II (56.7%); III (18%); IV (1.7%); V (0%); VI (0.6%)

Lesions Location



Neck: 4.1%
Torso: 11.1%
Upper Limb: 10.7%
Lower limb: 10.7%

Histology



Number and percentage of each lesion histological

Baxi S, Cardaci G, Hong A, Mulholland N, Mokoala K *et al*. 188Rhenium skin cancer therapy: Two–year efficacy, safety and patient reported outcomes from the prospective, multicentre, phase IV, EPIC-Skin study in non-melanoma skin cancer. EANM Innovation, 5 (2026): 100311, ISSN 3051-2913. https://doi.org/10.1016/j.eanmi.2026.100311.

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Patient Demographics and Lesions Characteristics

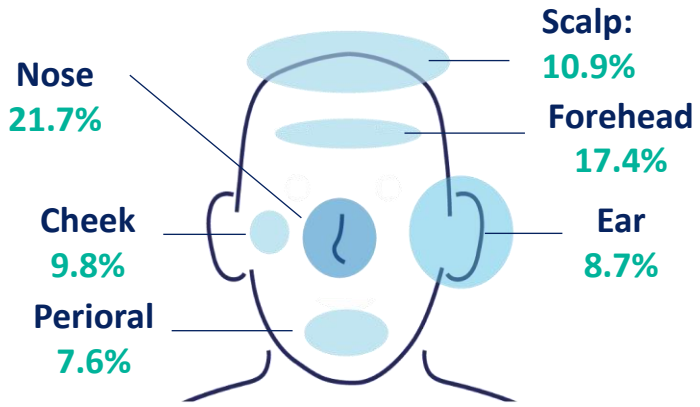
76.5 years
Median age (range 31-95)

82%
Fitzpatrick Type I or II

Fitzpatrick Type

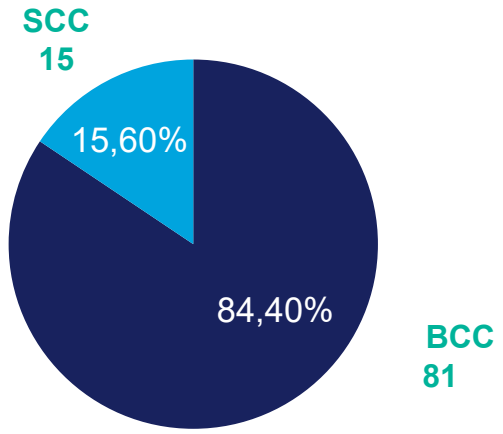
I (11.9%); II (70.1%); III (17.9%); IV (0%); V (0%); VI (0%)

Lesions Location



Neck: 3.3%
Torso: 9.8%
Upper Limb: 4.3%
Lower limb: 6.5%

Histology



Number and percentage of each lesion histological with RECIST

Bashir S, Mulholland N, Heraghty N, Emmert S, Tietze, *et al.* European Sub-Analysis of EPIC Skin Study: Rhenium SCT for Non-Melanoma Skin Cancer. *Manuscript in preparation*

GLOBAL

EPIC-Skin 24-month outcomes

Efficacy, 24 months

Overall, 214 of 225 tumours assessed over 24-months were classified as complete response (CR), with a further 7 classified as a partial response.

BOR	All Sites All Tumours	All Sites BCC	All Sites SCC
CR	214/225 (**95.1%**)	171/179 (**95.5%**)	43/46 (**93.5%**)
PR	7/225 (3.1%)	5/179 (2.8%)	2/46 (4.3%)
SD	2/225 (0.9%)	2/179 (1.1%)	0/46 (0.0%)
PD	2/225 (0.9%)	1/179 (0.6%)	1/46 (2.2%)
Relapse (PD from CR or PR)	5/221 (**2.3%**)	4/176 (**2.3%**)	1/45 (**2,2%**)



Efficacy, 24 months

CR

95%

Relapse rate 2.3%

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EPIC-Skin 24-month outcomes

Efficacy, 24 months

Overall, 95 of 96 tumours assessed over 24-months were classified as complete response (CR)

BOR	EU Continent All Tumours	EU Continent BCC	EU Continent SCC	Austria Site	Germany Site	UK Site
CR	95/96 (**99.0%**)	81/81 (**100.0%**)	14/15 (**93.3%**)	34/34 (100.0%)	35/36 (97.2%)	26/26 (100.0%)
PR	0/96 (0.0%)	0/81 (0.0%)	0/15 (0.0%)	0/34 (0.0%)	0/36 (0.0%)	0/26 (0.0%)
SD	0/96 (0.0%)	0/81 (0.0%)	0/15 (0.0%)	0/34 (0.0%)	0/36 (0.0%)	0/26 (0.0%)
PD	1/96 (1.0%)	0/81 (0.0%)	1/15 (6.7%)	0/34 (0.0%)	1/36 (2.8%)	0/26 (0.0%)
Relapse (PD from CR or PR)	5/95 (**5.3%**)	4/81 (**4.9%**)	1/14 (**7.1%**)	0/34 (0.0%)	5/35 (14.3%)	0/26 (0.0%)

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Efficacy, 24 months

CR

99%

Relapse rate 5.3%

GLOBAL

EPIC-Skin 24-month outcomes

Healing Trajectory

BCC, nose bridge (2.25 cm², 1 mm deep)



Toxicity

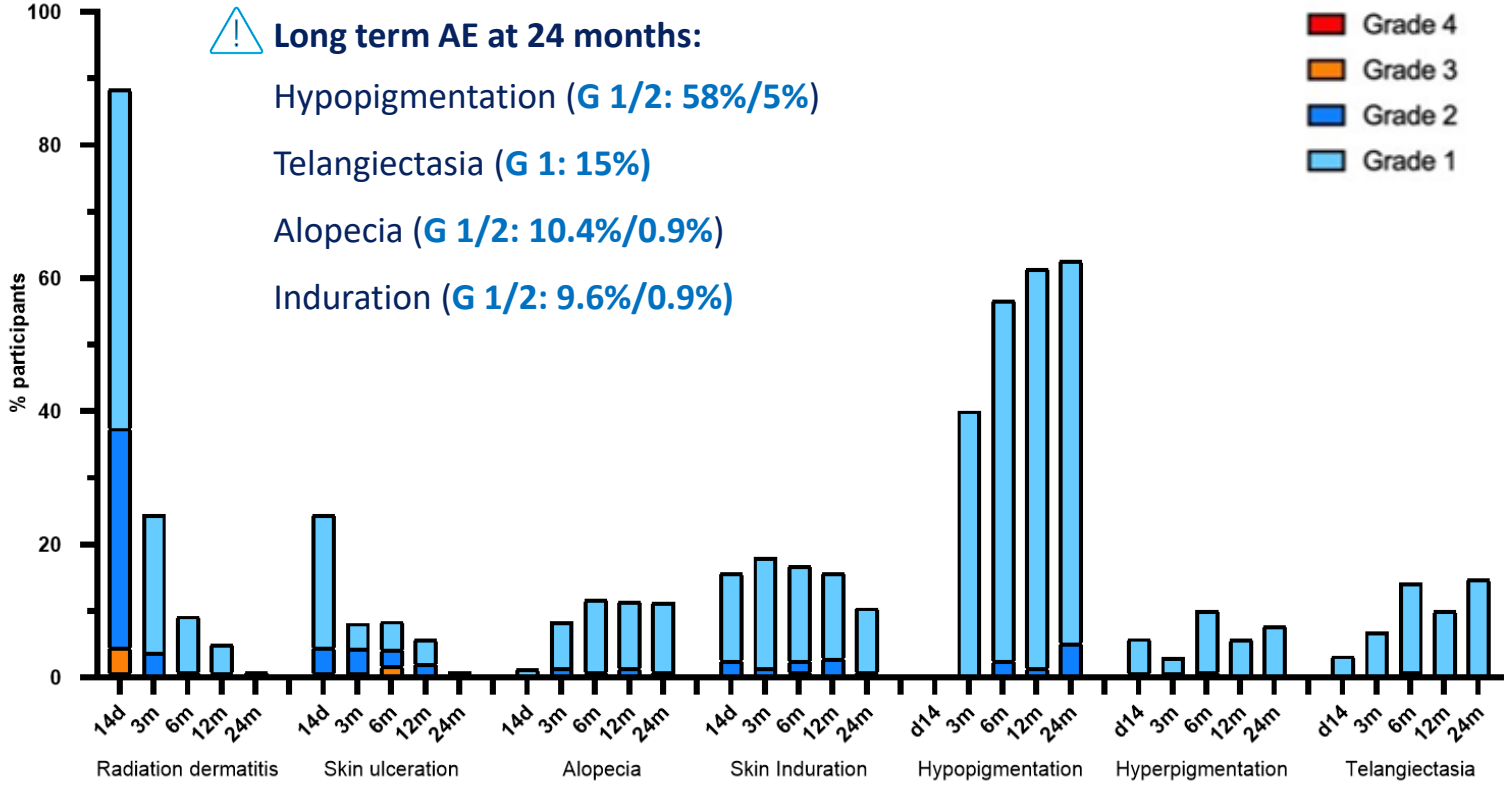
⚠ **Long term AE at 24 months:**

Hypopigmentation (**G 1/2: 58%/5%**)

Telangiectasia (**G 1: 15%**)

Alopecia (**G 1/2: 10.4%/0.9%**)

Induration (**G 1/2: 9.6%/0.9%**)



For each event type (radiation dermatitis, skin ulceration, alopecia, skin induration, hypopigmentation, hyperpigmentation, telangiectasia), only participants experiencing the event are graphed. Assessment for these events were undertaken at day 14, 3-month, 6-month, 12-month and 24-month visits. All percentages are based on the number of participants that were examined at the visit. For alopecia, hypopigmentation, hyperpigmentation and telangiectasia endpoints, CTCAEv5 are Grade 0-2 only. For skin induration, it is grade 0-3 only.

Abbreviations: CTCAE: Common Terminology Criteria for Adverse Events; 14d: day 14, 3m: 3-month, 6m: 6-month, 12m: 12-month and 24m: 24-month. Note: For hypopigmentation, CTCAE v5.0 Grade 2 is defined by extent of involvement, including ≥10% body surface area. As all treated lesions were ≤8 cm², Grade 2 hypopigmentation in this study reflects investigator assessment of pigment-loss intensity within the treated area.

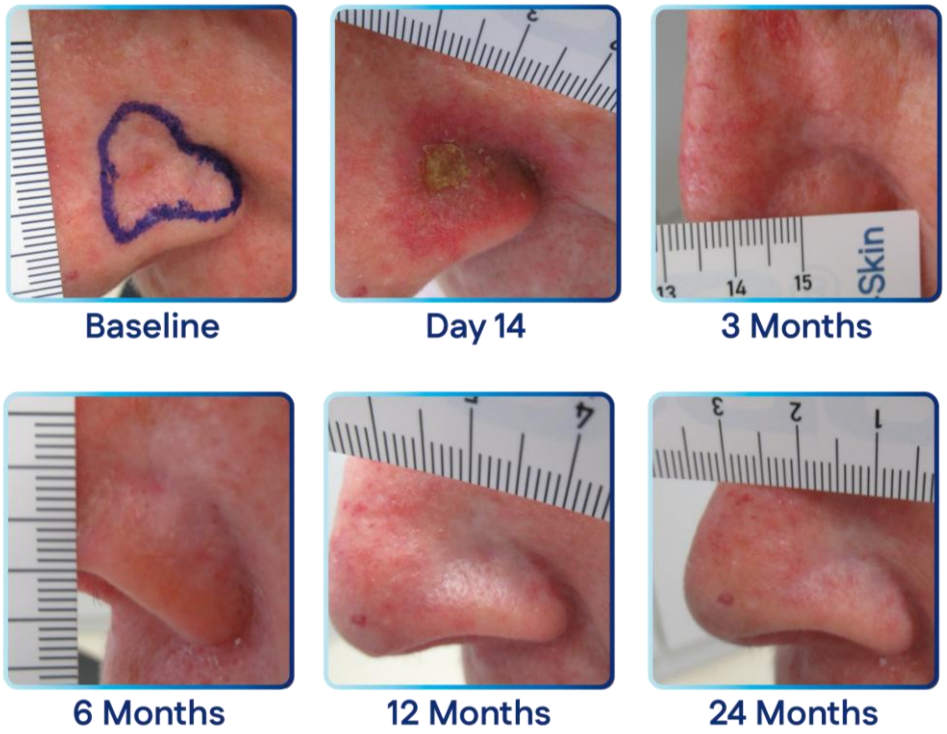
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EPIC-Skin 24-month outcomes

Healing Trajectory

BCC, nose (2.6 cm², 1.3 mm deep)



Toxicity

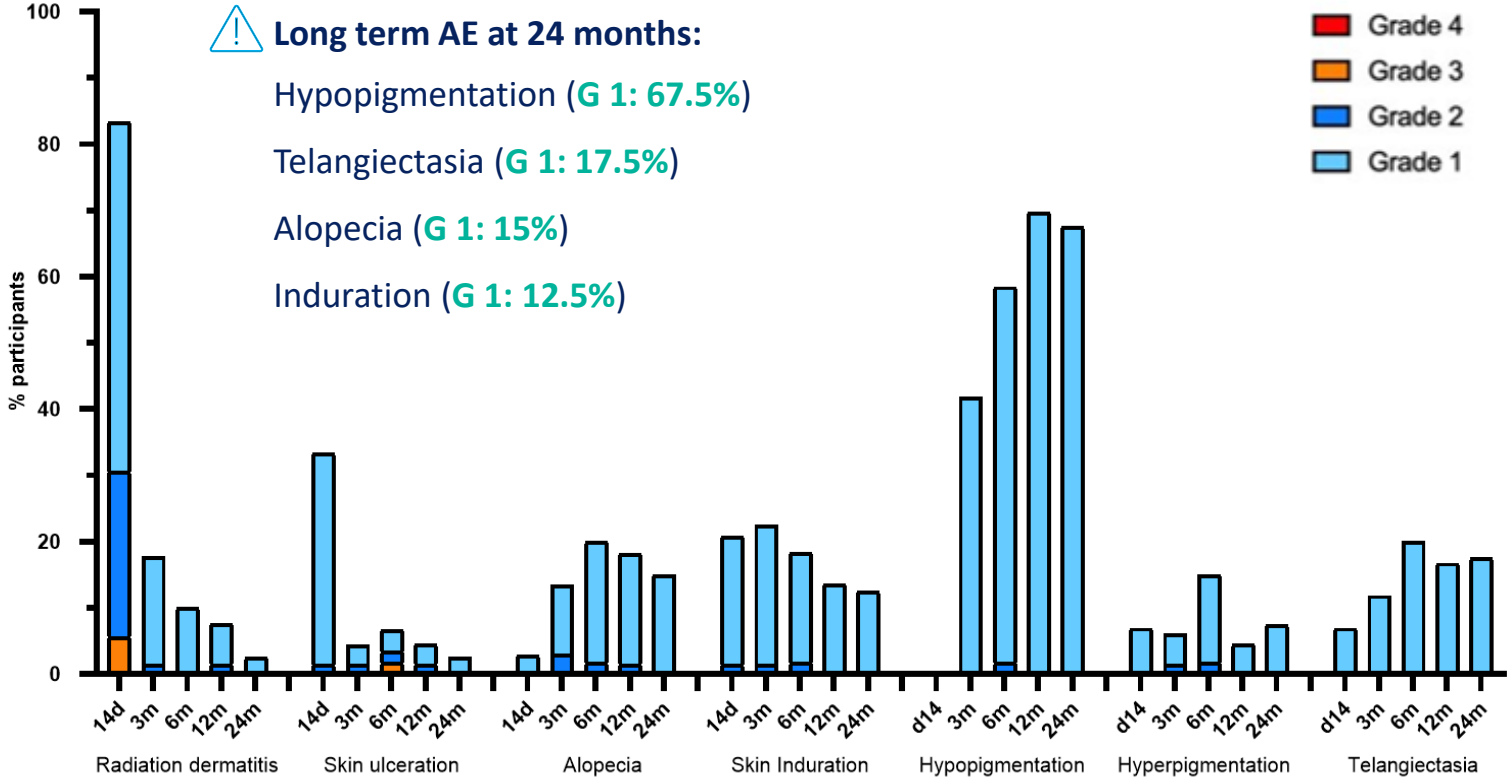
⚠ **Long term AE at 24 months:**

Hypopigmentation (**G 1: 67.5%**)

Telangiectasia (**G 1: 17.5%**)

Alopecia (**G 1: 15%**)

Induration (**G 1: 12.5%**)



For each event type (radiation dermatitis, skin ulceration, alopecia, skin induration, hypopigmentation, hyperpigmentation, telangiectasia), only participants experiencing the event are graphed. Assessment for these events were undertaken at day 14, 3-month, 6-month, 12-month and 24-month visits. All percentages are based on the number of participants that were examined at the visit. For alopecia, hypopigmentation, hyperpigmentation and telangiectasia endpoints, CTCAEv5 are Grade 0-2 only. For skin induration, it is grade 0-3 only.

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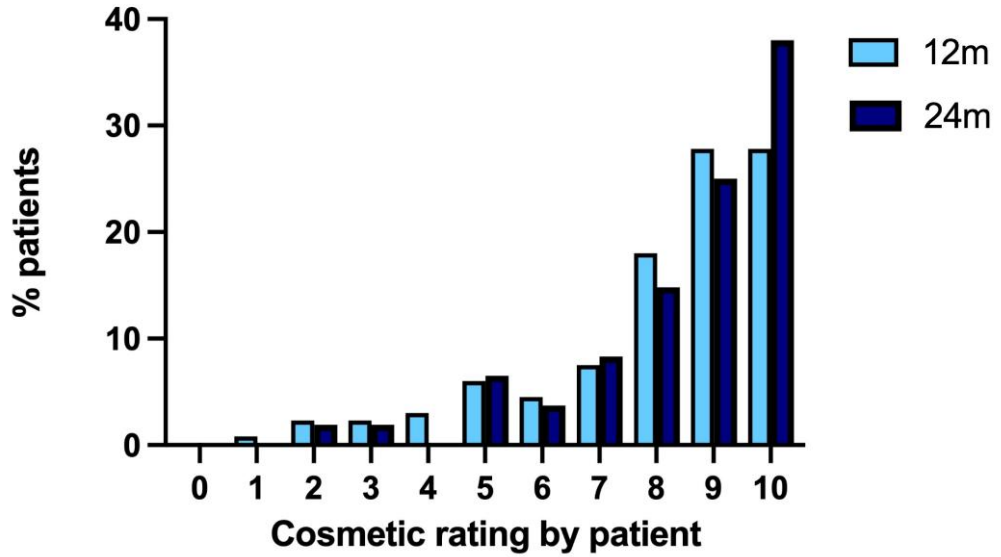
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EPIC-Skin 24-month outcomes

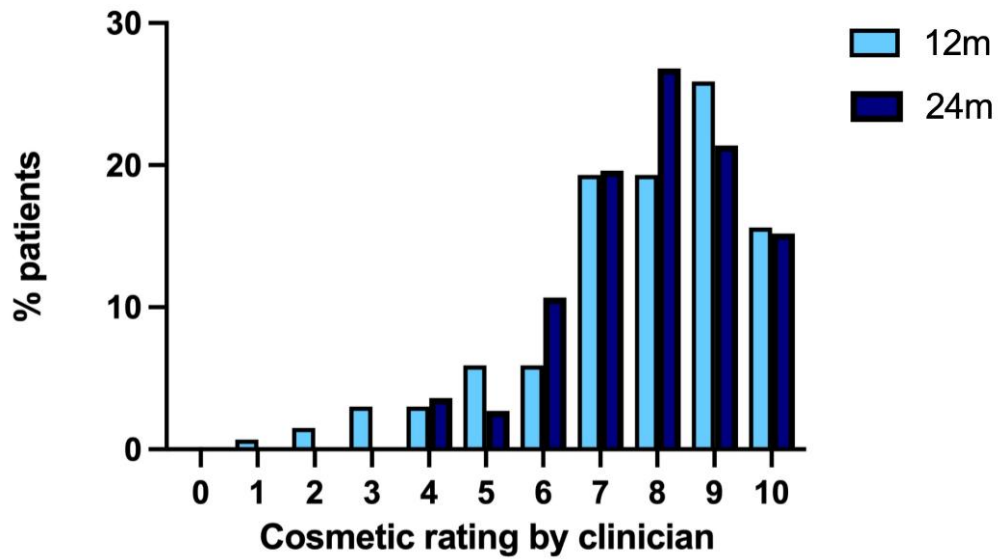
Cosmesis, 24 months

- Patient and clinician assessment of cosmesis remains stable over 24m

Patient-Rated: 8.5/10



Clinician-Rated: 7.9/10



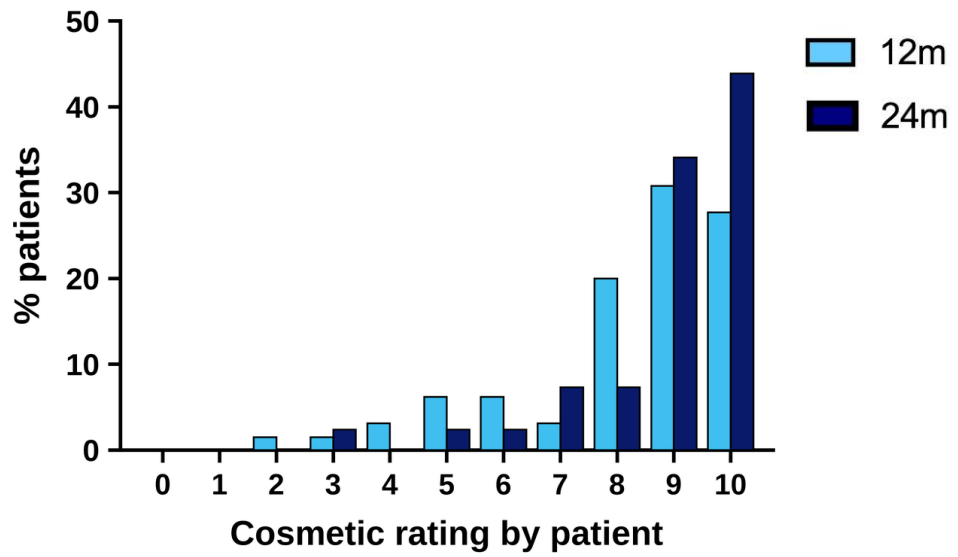
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EPIC-Skin 24-month outcomes

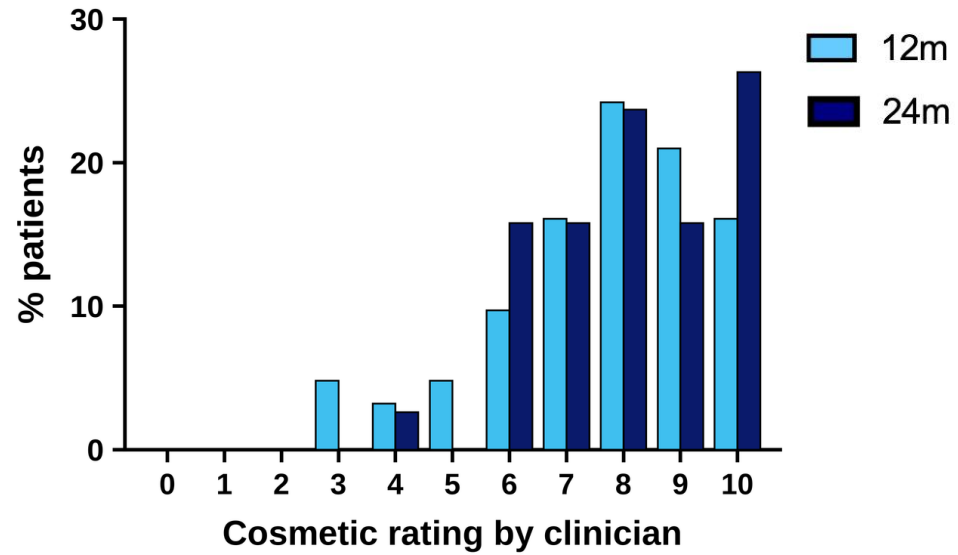
Cosmesis, 24 months

- Patient and clinician assessment of cosmesis remains stable over 24m

Patient-Rated: 8.5/10



Clinician-Rated: 8.0/10



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Map representing real experience (number of patients) in regular clinical practice treating with Rhenium-SCT beyond EPIC-skin study, from 01.01.2023 to 01.09.2026

EPIC-Skin: European Continent 24-Month Outcomes

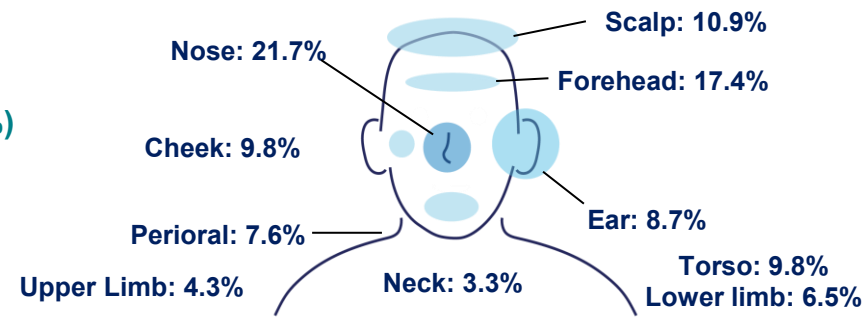
Prospective, international, multicentre, single-arm Phase IV study • 7 sites, 5 countries • ^{188}Re-SCT (Rhenium Skin Cancer Therapy) • NCT05135052

Single outpatient session	99.0%	5.3%
50 Gy ^{188}Re-SCT	complete response (95/96 lesions)	recurrence at 24 months

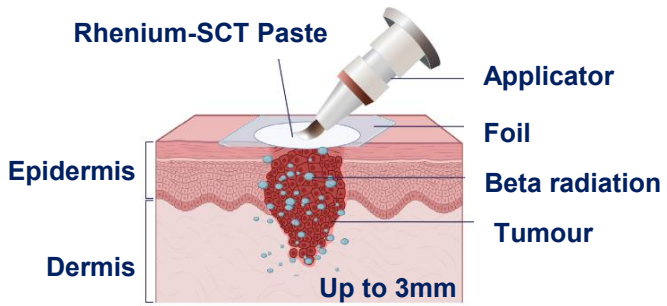
EPIC-Skin Phase IV Study

85 patients Median age 76.5 y (31–95 y)
with Biopsy-proven BCC (84.4%) & SCC (15.6%)
1–3 lesions/patient; ≤8 cm²; ≤3 mm deep
ITT: 96 lesions; 61 lesions at 24 m

Lesion Locations (79.4% head & neck)



Rhenium-SCT Single 50 Gy application



EFFICACY

99.0% CR • 1.0% PD
BCC 100% CR • SCC 93.3% CR
5.3% recurrence at 24 m

QUALITY OF LIFE

+7.92 point Skin Cancer Index vs baseline

COSMESIS & COMFORT

8.9/10 patient • **8.0/10** clinicians
100% no pain during treatment

SAFETY

Acute 14d: 83.4% radiation dermatitis (Gr3:5.6%/Gr4:0.0%);
Late 24m: No Gr3/4 toxicities; hypopigmentation 67.5%

Healing Trajectories

BCC, nose bridge (2.6 cm², 1.3 mm deep)



Baseline | Day 14 | 24 months

SCC chest (3.2 cm², 0.3mm deep)



Baseline | Day 14 | 24 months

J Tietze, S Mirzaei, N Mulholland, M Heuschkel, G Cardaci, A Hong, M Sathekge, K Mokoala, S Baxi, G Dahlhoff Rhenium-188 skin cancer therapy (SCT) European Subanalysis: Two-year efficacy and safety from a prospective multicentre phase IV study, presented at EADV2026

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