

Rhenium-188 skin cancer therapy (SCT) European Subanalysis: Two-year efficacy and safety from a prospective multicentre phase IV study

Julia Tietze¹, Siroos Mirzaei², Nicola Mulholland³, Martin Heuschkel¹, Giuseppe Cardaci⁴, Angela Hong⁵, Mike Satheke⁶, Kgomotso Mokoala⁶, Siddhartha Baxi⁷, Gerhard Dahlhoff⁸

1. University Medical Center Rostock, Rostock, Germany. 2. Clinic Ottakring, Institute of Nuclear Medicine with PET-Center, Vienna, Austria. 3. Kings College Hospital NHS Foundation Trust, London, United Kingdom. 4. Hollywood Private Hospital, Perth, Australia. 5. GenesisCare, North Shore Health Hub, St Leonards, Australia. 6. University of Pretoria and Steve Biko Academic Hospital, Pretoria, South Africa. 7. GenesisCare, John Flynn Hospital, Tugun, Australia. 8. OncoBeta GmbH.

1 Background

Non-melanoma skin cancers (NMSC) are the most common malignancies worldwide. While surgical excision, including micrographic surgery, achieves clearance rates exceeding 95%, treatment may be associated with disfigurement, functional morbidity, or may not be appropriate in cases of multiple lesions, anatomically difficult locations, due to patient comorbidities or preference. Rhenium-188 skin-directed radioisotope therapy has been used clinically for NMSC since 2008, with retrospective series, pooled analyses, and prospective studies reporting high local control and favourable cosmetic outcomes. The present study built on these findings by evaluating efficacy, patient quality of life and safety in selected NMSC lesions.

2 Method

This prospective, multicentre, single-arm phase IV study enrolled 187 adults with 1-3 biopsy-proven NMSC lesions ≤3mm deep with ≤8cm² area. The European Continent sub-analysis included 85 82 patients (Austria: 30 patients, Germany: 29 patients, United Kingdom: 23 patients). Patients received a single outpatient treatment with rhenium-188 therapy delivering 50 Gy to the deepest point of the lesion. Clinical response was assessed using modified RECIST criteria. Secondary endpoints included quality of life, treatment comfort, cosmesis and safety.

3 Results

Demographics

Enrolled in Study

187 patients across Global
82 patients in Europe
30 patients in Austria
29 patients in Germany
23 patients in United Kingdom

Age Median

74.4 years (range: 31-95 years) in Europe
80.7 years (range: 55-95 years) in Austria
68.3 years (range: 31-88 years) in Germany
74.6 years (range: 45-92 years) in United Kingdom

BCC and/or SCC:

1-8cm²; ≤3mm deep

Tumours

in intent to treat population

225 tumours RECIST
96 tumours Europe
34 tumours Austria
36 tumours Germany
26 tumours United Kingdom

Fitzpatrick Type

I (23%); II (56.7%); III (18%); IV (1.7%); V (0%); VI (0.6%) across Global
I (11.9%); II (70.1%); III (17.9%); IV (0%); V (0%); VI (0%) in Europe
I (83.3%); II (16.7%); III (0%); IV (0%); V (0%); VI (0%) in Austria
I (6.9%); II (75.9%); III (17.2%); IV (0%); V (0%); VI (0%) in Germany
I (13.0%); II (87.0%); III (0%); IV (0%); V (0%); VI (0%) in United Kingdom

Lesion Characteristics

Rhenium-SCT single-session 50Gy treatment to depth of tumour

Nose: 25.1%; 21.7% Scalp: 9.1%; 10.9%
Forehead: 8.6%; 17.4%
Cheek: 7.4%; 9.8% Ear: 8.2%; 8.7%
Perioral: 4.5%; 7.6%
Neck: 4.1%; 3.3% Upper Limb: 10.7%; 4.3%
Torso: 11.1%; 9.8% Lower limb: 10.7%; 6.5%

■ Global ■ Europe

24 Month Outcomes

Table 1 - Primary Outcome: Best Overall Response (BOR): The primary outcome was the number and percentage of lesions achieving complete clinical response (CR) during the study using Modified Visual RECIST. For each lesion with at least one post-baseline Modified Visual RECIST (vRECIST) assessment, the Best Overall Response (BOR) was defined as the highest response observed according to the following ordering: CR, partial response (PR), stable disease (SD), progressive disease (PD). Recurrence was documented as a lesion having achieved a CR or PR at an earlier time, followed by a PD recorded in the electronic case report form (eCRF) in a later assessment, which was defined by the protocol as modified vRECIST with a 20% increase of sum of longest diameter of the target lesion.

(BOR)		All Study Sites	EU Continent Sites	EU Continent BCC	EU Continent SCC	Austria Sites	Germany Sites	UK Sites
CR	n/N	214/225	95/96	81/81	14/15	34/34	35/36	26/26
	Rate%	95.1%	99.0%	100.0%	93.3%	100.0%	97.2%	100.0%
PR	n/N	7/225	0/96	0/81	0/15	0/34	0/36	0/26
	Rate%	3.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
SD	n/N	2/225	0/96	0/81	0/15	0/34	0/36	0/26
	Rate%	0.9%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%
PD	n/N	2/225	1/96	0/81	1/15	0/34	1/36	0/26
	Rate%	0.9%	1.0%	0.0%	6.7%	0.0%	2.8%	0.0%
Relapse (PD from CR or PR)	n/N	5/221	5/96	4/81	1/15	0/34	5/35	0/26
	Rate%	2.3%	5.2%	4.9%	6.7%	0.0%	14.3%	0.0%

■ Global ■ Europe ■ Austria ■ Germany ■ United Kingdom * Global EPIC-Skin longitudinal response analyses are undergoing final harmonisation and validation ahead of manuscript submission.

Typical Healing Trajectory

BCC, nose, 2.6 cm², 1.3 mm deep

Baseline Day 14 3 Months 6 Months 12 Months 24 Months

SCC, chest, 3.2 cm², 0.3 mm

Baseline Day 14 3 Months 6 Months 12 Months 24 Months

Fig. 1. Example healing profiles in EPIC-Skin over 24m follow-up.

European Continent Real Experience beyond EPIC-Skin Study

United Kingdom Spain Switzerland Germany Austria Italy Greece

Fig. 3 Map representing real experience in regular clinical practice treating with Rhenium-SCT beyond EPIC-skin study, from 01.01.2023 to 01.09.2026

CTCAE Adverse Events of Special Interest

% participants

14d 3m 6m 12m 24m

Radiation dermatitis Skin ulceration Alopecia Skin Induration Hypopigmentation Hyperpigmentation Telangiectasia

Not present Grade 1 Grade 2 Grade 3

Grade 3 event (ulceration) occurred in 1 European patient (United Kingdom) at 6 months, but it did not persist to 12 months. No Grade 2 or 3 events at 24 months.

Fig.2CTCAEGradedAdverseEventsOfInterest. Foreacheventtype(radiationdermatitis,skinulceration,alopecia,skininduration,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.

4 Conclusion

Rhenium-188 therapy demonstrates durable efficacy at 24 months in appropriate NMSC lesions in the European continent population. Follow-up shows a stable safety profile, without evidence of accumulating late skin toxicity, supporting consideration of Rhenium-188 therapy as a non-surgical option for selected superficial NMSC in patients where surgery is either contraindicated or a suboptimal treatment choice.

These findings demonstrate the high clinical benefit of Rhenium-188 treatment and support the need for transparent discussion with patients regarding expected skin changes as part of shared decision-making when considering treatment options.

References: [1] Giuseppe Cardaci, MBBS, a Siddhartha Baxi, MBBS, b Saima Vohra, PhD, c Cody Allison, PhD, d Angela Hong, MBBS, e f Nicola Mulholland, MBBS, g Mike Satheke, MBChB, PhD, h Kgomotso Mokoala, MBChB, h Martin Heuschkel, Dr. med, j Julia Tietze, Dr. med, j Siroos Mirzaei, FANM, k and Gerhard Dahlhoff, Dr. med, l, (2025), Efficacy, Safety, and Patient Reported Outcomes of Rhenium-188 Skin Cancer Therapy for Non-Melanoma Skin Cancer: 1-Year Results from the EPIC-Skin Study, Advances in Radiation Oncology, 101802, Rhenium-188 Skin Cancer Therapy (SCT) for the Treatment of Non-Melanoma Skin Cancer, (EPIC-Skin); ClinicalTrials.gov ID NCT05135052

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