12-Month Interim Analysis:

EPIC-Skin: Efficacy, Safety, and Patient Reported Outcomes of Rhenium-Skin Cancer Therapy for Non-Melanoma Skin Cancer

A phase IV, multi-centre, international, open label, single arm study.
Cardaci G, *et al. Adv Radiat Oncol*. 2025;10(7):101802.[1]

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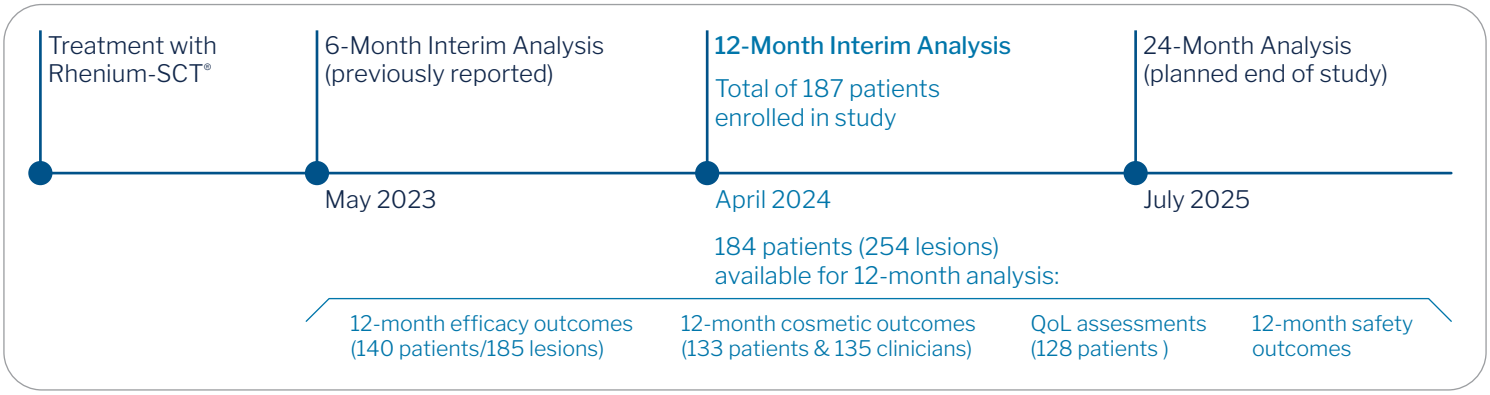
Non-invasive rhenium-188 therapy for non-melanoma skin cancer (NMSC): Planned 12-month interim reporting of ongoing EPIC-Skin Study

The objectives of this on-going prospective, multicentre, single-arm, international, phase IV study are to assess efficacy, safety, and patient-reported outcomes of Rhenium-SCT® as a treatment for NMSC.

The study also aims to demonstrate non-inferiority to historical values for complete response (CR) rates following surgery or radiotherapy (91% basal cell carcinoma (BCC) and 79% for squamous cell carcinoma (SCC) at 5 years).

A total of 187 adult patients with histological confirmed stage I or II NMSC are enrolled in the study. At the time of this 12-month interim reporting: enrolment data was available for 184 patients (254 lesions), efficacy data for 140 patients (185 lesions) and 128 patients with baseline, 6-month and 12-month quality of life (QoL) assessments.

Study centres participating in the initiative are located in Australia, Austria, Germany, United Kingdom and South Africa.



Methods & Materials:

- Rhenium-SCT® was administered on day 0 as a single 50-Gy dose treatment by topical application of rhenium-188 as a resin applied to adhesive foil affixed to target lesion
- Primary endpoint was the proportion of lesions achieving a complete response (CR) during the study. CR was assessed at 6, 12 and 24 months, using modified Response Evaluation Criteria in Solid Tumour (RECIST) criteria
- Secondary endpoints included patient-reported changes in QoL using the Skin Cancer Index (SCI) score, treatment comfort, cosmesis (using Cosmetic Outcome Visual Analogue Scale (VAS), by both patient and clinician), treatment-emergent adverse events (TEAEs) and CTCAE toxicity

Key Clinical Outcomes at 12 Months:

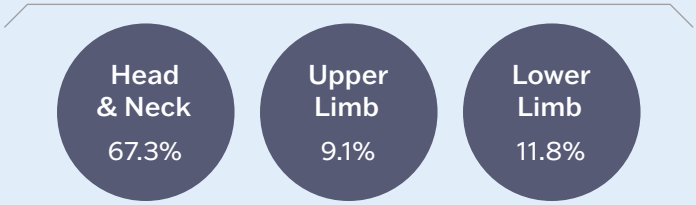
- **Efficacy**: Complete response rate, 94.1%; Partial response rate, 3.2%
- **Quality of Life**: Patient-reported QoL improved by an adjusted mean of 10.55 points from baseline
- **Treatment Comfort**: No reported treatment pain or discomfort
- **Cosmetic Evaluations**: Favourable cosmesis outcomes reported by both patients and clinicians
- **Adverse Events**: Most commonly reported 12-month CTCAE toxicity was hypopigmentation (60.4%; grade 1); No CTCAE toxicities greater than grade 2

Patient Demographics at 12-month Follow-up (non-missing demographic responses)

	Overall	BCC	SCC	BCC/SCC
Number of Patients	184	147	33	4
Mean Age (years)	70.3	69.7	72.6	74.8
Female (%)	46.7	49.7	33.3	50

NMSC Tumour Characteristics at 12-month Follow-up

Lesion location (n=254; all treated patients)



Number of lesions per patient (n=184)

Safety Outcomes

Rhenium-SCT® was broadly well-tolerated, with most TEAEs occurring during the acute phase of treatment and resolved rapidly. 129 patients CTCAE toxicity outcomes were available for the 12-month interim assessment:

- Most commonly reported CTCAE toxicity was grade 1 hypopigmentation (60.5%)
- No reported toxicities greater than grade 2 were reported at 12 months
- Incidence of Grade 3 toxicity was 6.9% (5/9 only at Day 14) and Grade 4 toxicity was 1.5% (only at Day 14). No grade 3/4 toxicities at 12-months

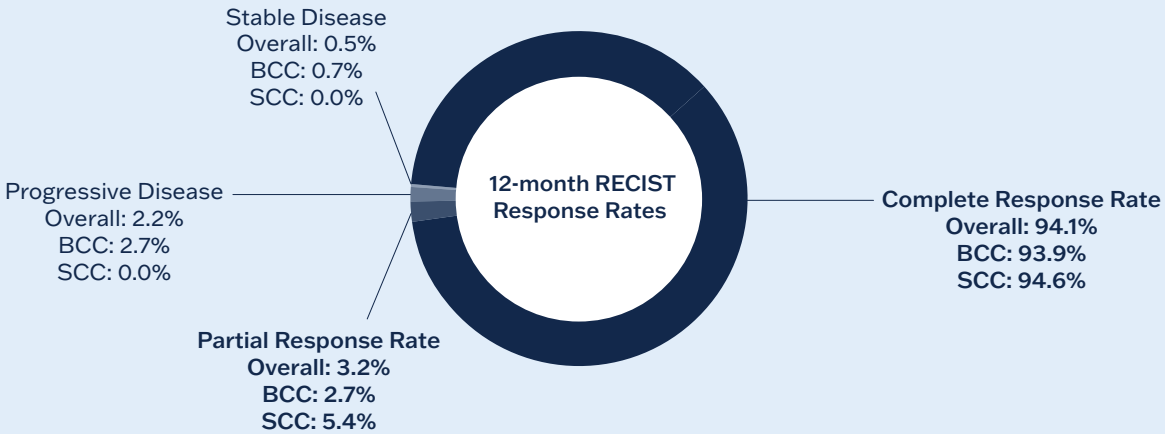
CTCAE Toxicity	Grade 1	Grade 2
Hypopigmentation	60.5%	0.8%
Ulceration	3.1%	2.3%
Induration	11.6%	2.3%
Telangiectasia	10.1%	0.0%

Study withdrawals and deaths:

- 3 patients withdrew from the study due to AEs, but none were related to treatment
- 4 deaths were reported during the study, none of which were related to treatment

Key Efficacy Findings at 12 Months

140 patients (185 lesions) had data available for efficacy analysis. The remaining 44 patients (23.9%) were either lost to follow-up or had not yet reached their 12-month time point.



Patient-Reported SCI QoL Assessments

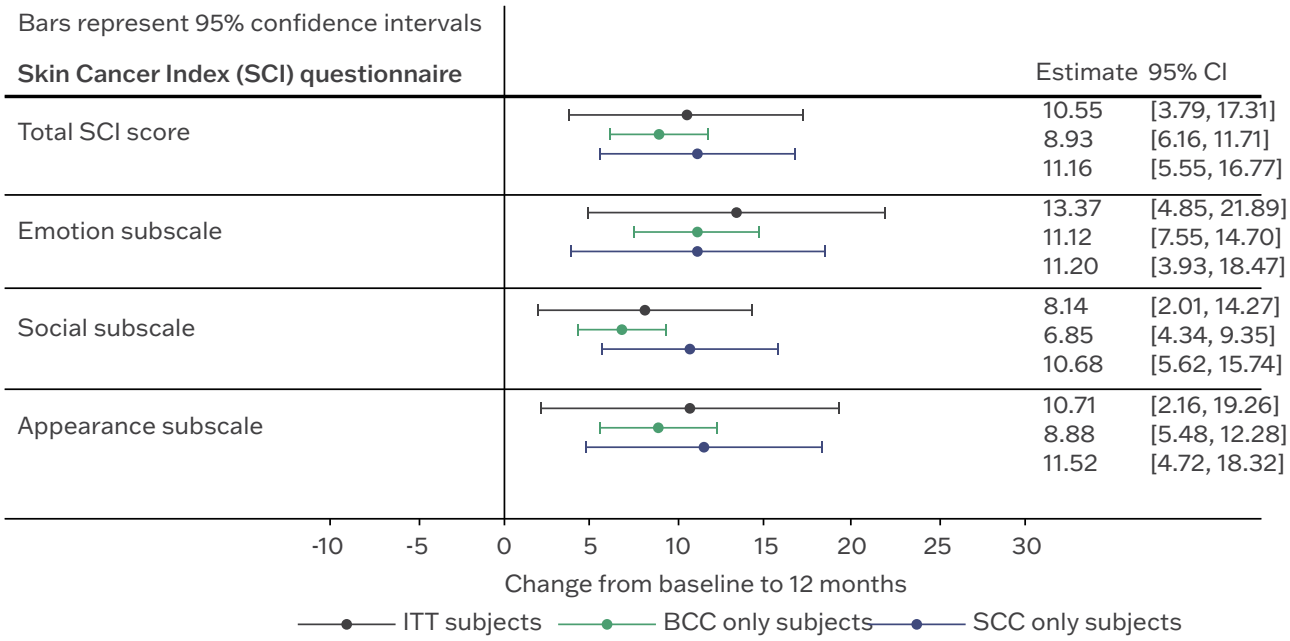
Consistent and continued improvements in QoL from baseline were seen, with all SCI subscales and total scores increasing:

- 128 patients had baseline, 6-month and 12-month SCI QoL assessments
- Total SCI QoL score and emotion subscale improved significantly from baseline (adjusted mean change 10.55 and 13.37 points, respectively)*
- Emotional, social, and appearance subscales also showed consistent improvement

**Significance determined by repeated measures model analysis of ITT subjects; baseline and age adjusted values*

Estimated Changes in SCI QoL Scores at 12-month Post-Treatment Follow-up

(A positive change indicates an improvement in score from baseline assessments performed before treatment)



Treatment Comfort

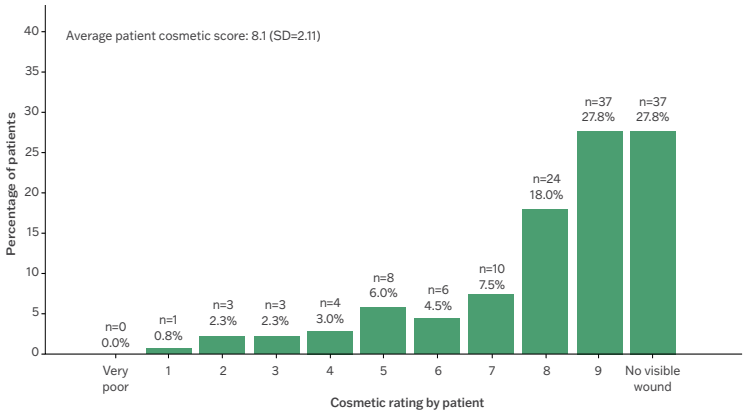
All patients reported no pain or discomfort during the procedure (46/184 patients missing data)

Cosmetic VAS Assessments

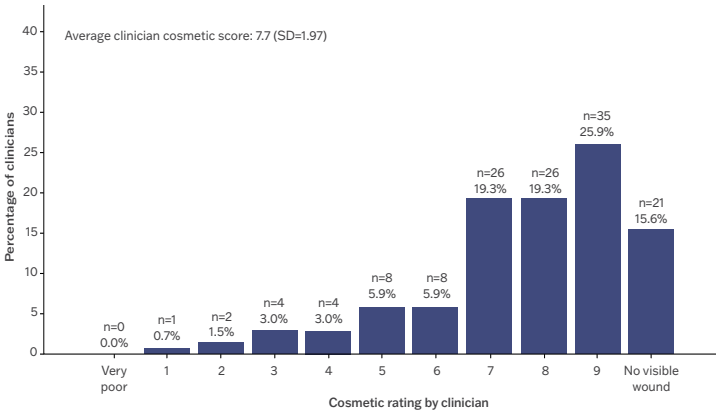
- Assessment data available for 133 patients and 135 clinicians
- Patients rated their results highly with the mean cosmetic VAS score: 8.1 (0 = very poor appearance to 10 = no visible wound)
- Patient assessments were slightly higher than clinician assessments (8.1 vs 7.7, respectively)

Patient & Clinician Assessment of Cosmetic Appearance of Wound

Patient-Reported



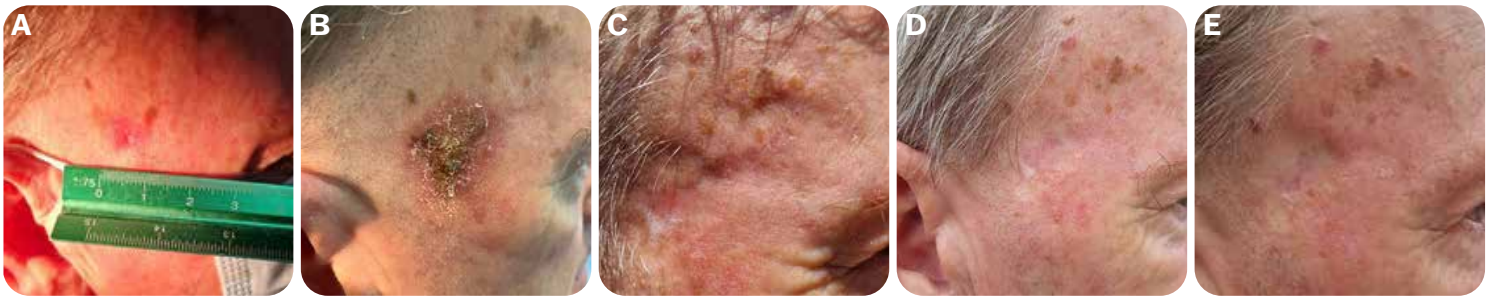
Clinician-Reported



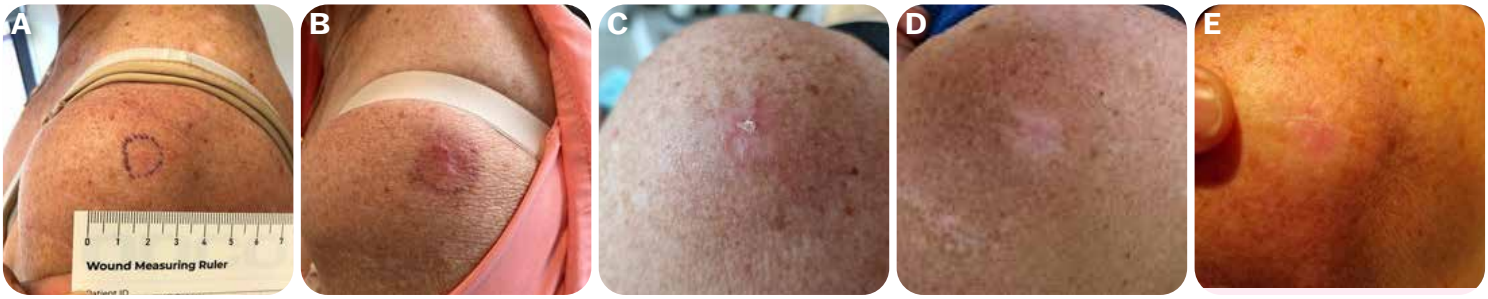
Conclusion: Rhenium-SCT® given as a single dose NMSC treatment sustained (to 12 months) high efficacy CR rates, improved QoL, and provided favourable cosmetic outcomes with minimal TEAEs.

This 12-month interim data strengthens the growing body of evidence supporting this non-invasive, targeted therapy for NMSC and supports the role of rhenium-188 as a treatment option alongside existing standards – giving a non-surgical alternative for patients with functional or cosmetic concerns or comorbidities.

Patient Photos: A) before treatment, B) 2-weeks after treatment, C) 3-months after treatment, D) 6-months after treatment, and E) 12-months after treatment with Rhenium-SCT.



67 year old male, diagnosed basal cell carcinoma on the temporal region.



67 year old female, diagnosed basal cell carcinoma on the shoulder.

66 year old female, diagnosed squamous cell carcinoma on the thenar web space (between the thumb and index finger).

Treatment Comfort

128 patients completed the treatment-related questions and of those 100% reported **NO pain or discomfort during treatment.**

Efficacy Assessment

174/185 tumours assessed as CR (94.1%) and 6 as Partial Response (3.2%) **– giving an overall response rate (ORR) of 97.3%.**

Adverse Events

142 TEAEs were reported in 61/187 patients (32.6% reporting at least one). **No TEAEs lead to study withdrawal.**

*Overall Response Rate (ORR) = Complete Response (CR) + Partial Response (PR).[2]

References: 1. Cardaci G, *et al. Adv Radiat Oncol.* 2025;10(7):101802. **2.** Villaruz LC, Socinski MA. *Clin Cancer Res.* 2013;19(10):2629–36.

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