OncoBeta Presents Two-Year EPIC Skin Study Results at ACRO 2026

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Positive final two-year outcomes were announced by OncoBeta from the completed Phase IV EPIC Skin study at the American College of Radiation Oncology (ACRO) 2026 Annual Meeting, delivered during a scientific breakfast symposium.

The data were presented by A/Prof Siddhartha Baxi (Radiation Oncologist) and provide a 24-month view of durable clinical response, tolerability, cosmetic outcomes, and patient-reported experience following a single treatment session with Rhenium-188 Skin Cancer Therapy (Rhenium-SCT®) for non-melanoma skin cancer (NMSC).

Top-line findings from EPIC Skin study showed:

Efficacy:

- Rhenium-SCT achieved a **94.7% complete response rate at 24 months** after a single session in evaluable lesions in the primary intent to treat analysis, demonstrating non-inferiority to historical complete response rates for NMSC. Rhenium-SCT achieved high response rates in both **basal cell carcinoma (93.9%)** and **squamous cell carcinoma (97.5%)**.

Safety:

- The study also reported a tolerability profile consistent with prior analyses, with **no treatment-emergent, treatment-related adverse events leading to study withdrawal**. Adverse events in participants were generally mild to moderate. The most common early adverse events occurring in ≥5% of participants at 14 days post treatment were radiation dermatitis, skin ulceration, skin induration and hyperpigmentation. Twelve Grade 3/4 events occurred at earlier time points, but none persisted past 6 months. The most common 24-month CTCAE graded Adverse Events of Interest were hypopigmentation (Grades 1/2: 58%/5%); telangiectasia (Grade 1: 15%); alopecia (Grades 1/2: 10.4%/0.9%) and induration (Grades 1/2: 9.6%/0.9%).

Patient Reported Outcomes:

- All average scores showed an increase in Skin-directed Quality of Life from baseline using the Skin Cancer Index (SCI). Patients and Clinicians reported favourable cosmesis outcomes, (patient mean score 8.5/10 on a visual analogue scale; clinician mean score 7.9/10) that remained stable over 24m. 100% of patients reported no pain or discomfort during the treatment session.

Gerhard Dahlhoff, OncoBeta CMO and EPIC Study Director, commented:

“Two-year follow-up is an important bar for non-melanoma skin cancer therapies. EPIC Skin is a strong international, multicentre, multidisciplinary clinical collaboration, providing a robust 24-month view of favourable, durable clinical response alongside patient-reported experience and cosmetic outcomes. These data strengthen the evidence base for Rhenium-SCT and support ongoing scientific engagement with the clinical community.”

Cody Allison, OncoBeta (MedTech) CEO, said:

"EPIC Skin's final 24-month outcomes are a compelling validation of durable response and a favourable patient experience with Rhenium-SCT, and we're pleased to share these results with the clinical community. These reinforce the patient-centred outcomes we believe matter in everyday care. We look forward to continued scientific engagement as we advance our clinical and access plans across markets where the therapy is authorised."

Non-melanoma skin cancer (NMSC)

Non-melanoma skin cancer (NMSC) is the world's most common malignancy and a growing burden on patients and health systems. In the United States alone, an estimated ~5.4 million basal and squamous cell skin cancers are diagnosed each year[1], and in Australia >1.1 million Medicare services are delivered annually for non-melanoma skin cancers[2].

While surgery remains highly effective for many lesions, a meaningful proportion of patients face trade-offs that go beyond simple clearance - tumours in cosmetically or functionally sensitive areas, multiple or recurrent lesions, frailty or comorbidities, anticoagulation, access constraints, or a preference to avoid surgery and associated repairs. In that context, treatments that can deliver durable local control while preserving tolerability and cosmetic outcomes have the potential to reduce treatment burden, improve the patient experience, and meaningfully reshape care pathways.

About the EPIC Skin Study

EPIC Skin is a Phase IV, prospective, multicentre, international, open-label, single-arm clinical study evaluating Rhenium-188 Skin Cancer Therapy (Rhenium-SCT®) in patients with non-melanoma skin cancer, including basal cell carcinoma and squamous cell carcinoma.

The study inclusion criteria were patients with 1-3 basal cell carcinoma (BCC)/squamous cell carcinoma (SCC) lesions < 3 mm deep (punch or excisional biopsy verified) and 1 – 8 cm^2 (~3 cm diameter). 189 patients with 254 lesions were enrolled.

The primary endpoint of the study is complete remission at 24 months as assessed by investigator evaluation using Modified Visual RECIST criteria. Secondary and exploratory endpoints include safety and tolerability, cosmesis, and patient-reported quality of life outcomes. The study was powered on a minimum of 120 evaluable subjects (assuming one lesion per subject), providing at least 80% power to conclude non-inferiority using a one-sided alpha of 0.025.

Based on 171 lesions with 24-month follow-up, the study met its primary objective of demonstrating non-inferiority to historical complete response rates following surgery and or radiotherapy. The observed CR rate of 94.7% with a 95% CI lower bound of 90.2% exceeded the pre-specified non-inferiority 85% margin.

Interim analyses from the EPIC Skin study have previously been published, including six-month and twelve-month outcomes[3,4]:

- **Six-month interim analysis:** Effectiveness and Patient Experiences of Rhenium Skin Cancer Therapy for Nonmelanoma Skin Cancer: Interim Results from the EPIC-Skin Study | Journal of Nuclear Medicine
- **Twelve-month interim analysis:** Efficacy, Safety, and Patient Reported Outcomes of Rhenium-Skin Cancer Therapy for Non-Melanoma Skin Cancer: 1-Year Results from the EPIC-Skin Study - Advances in Radiation Oncology

Presentation access
The ACRO 2026 presentation materials are available at:
https://www.oncobeta.com/fileadmin/user_upload/brochures/Acro2026.pdf

Important Information
Globally Rhenium-SCT is MDR-approved in EU (MDR 796214 R000), an AEMPS approved Class IIb Medical Device in Spain (PD/2022/6247(D)), ARTG-registered in Australia (ARTG Number 400142), A HSA-approved medical device in Singapore (Product Number: MDPR251103W0003), SAHPRA authorised in South Africa (00003410MD_v1) and Medsafe in New Zealand (230302-WAND-70RGWT).[5]

Rhenium-SCT® is not approved or cleared by the U.S. Food and Drug Administration. Data presented are for scientific and educational purposes only and do not constitute promotional claims.

Forward-Looking Statements
This press release contains forward-looking statements that involve risks and uncertainties. Actual results may differ materially from those expressed or implied. OncoBeta undertakes no obligation to update forward-looking statements except as required by law.

References

1. Rogers HW, Weinstock MA, Feldman SR, Coldiron BM. Incidence estimate of Non-melanoma skin Cancer (Keratinocyte Carcinomas) in the U.S. Population, 2012. JAMA Dermatology. 2015;151(10):1081–6.
2. Pandeya N, Olsen CM, Whiteman DC. The incidence and multiplicity rates of keratinocyte cancers in Australia. Med J Aust. 2017 Oct 16;207(8):339-343. doi: 10.5694/mja17.00284. PMID: 29020905.
3. *Baxi et al. J Nucl Med. 2024;65:1450-1455. DOI: https://doi.org/10.2967/jnumed.124.267988*
4. *Cardaci et al. Adv Radiat Oncol.2025;10:101802. DOI: https://doi.org/10.1016/j.adro.2025.101802*
5. Rhenium SCT IFU: Instructions for Use.

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