6 Month Interim Analysis:

EPIC-Skin: Efficacy of Personalised Irradiation with Rhenium-Skin Cancer Therapy (SCT) for the treatment of non-melanoma skin cancer

A phase IV, multi-centre, international, open label, single arm study.
Baxi, S *et al. Journal of Nuclear Medicine*, July 2024.[8]

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The EPIC-Skin study aims to further evaluate the efficacy of Rhenium-SCT® as well as identifying and evaluating patient reported outcomes, such as quality of life, treatment comfort and cosmetic outcomes.

The study has enrolled 182 adult patients with a confirmed histologically of stage I or II non-melanoma skin cancer. Patients are participating for 12 months, with a follow up period to 24 months. At the time of this 6-month interim data analysis, 182 patient records have been treated and evaluated. A total of 126 patients have completed the treatment-related questionnaire.

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

Timings: Recruitment commenced in September 2022, and remained open to suitable patients for 12-months. Enrolled patients then followed treatment guidelines and study protocol for aftercare and will be monitored during a 24 month follow-up.

Interim Data: As per the study Statistical Analysis Plan and protocol, an interim analysis was planned once 50% of subjects completed the six month follow-up visit.

The purpose of this interim analysis is to provide an early indication of effects of treatment on patient reported outcomes, namely the Skin Cancer Index quality of life tool and the subject's reported comfort of treatment. In addition, this analysis summarises the tumour response assessments for subjects that have completed the six month follow-up. As this is an interim analysis, subjects are at various points through the study.

182 records provided for interim analysis:

144 (79.1%)	**32** (17.6%)	**4** (2.2%)	**2** (1.1%)
were basal cell carcinomas (SCC)	were squamous cell carcinomas (SCC)	were patients with both BCC and SCC	had not yet been classified

Demography of subjects: The median age of subjects was 72 years, with a range of 27 years to 95 years. Over half of subjects (56.5%) were aged 70 years or higher, and 53.7% of subjects were male. Ethnicity was recorded for 177 subjects, of whom 175 were white, and two were black/African American.

Location of treated tumour: 176 subjects with information on the tumour location were included in the 6-month interim analysis dataset, 125 had a single lesion recorded (71.0%), 34 had two lesions (19.3%), and 17 had three lesions (9.7%).

Comfort of treatment:

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

Efficacy assessment:

103 of 106 tumours assessed at 6-months were classified as complete response, with the remaining 3 classified as partial response, **demonstrating 97.2% complete response.**

Adverse events (AEs):

There were 40 AEs reported in 29 subjects (15.9% of subjects reporting at least one AE). **There have been no adverse events leading to study withdrawal.**

Rhenium-SCT®
A painless* and non-invasive† treatment for non-melanoma skin cancer[1-3]

*No reported pain during procedure.[1,2]
†A procedure is considered non-invasive when no cut or break in the skin is created.[4]

Precise[1,5]
Accurate dosing.
Spares healthy tissue.

Non-invasive[2]
A procedure is considered non-invasive when no break or cut in the skin is created.[4]

Painless[1,2]
No pain reported during procedure.

Simple, easy[2]
Able to adapt to skin surfaces.[1,3]

Single-session[1,2,5]
Complete tumour regression in 98.5% of lesions treated.[5]

Short duration of treatment[7]
Treatment time is generally 45 to 180 minutes.

Aesthetic/functional[2,3,6]
No disfiguring scarring.
Retained functionality in high-risk and difficult to treat areas.

Certified medical device
ARTG number 400142.
SAHPRA approved.
CE certified.

Simple steps for single-session treatment[1-3,7]

Step 1
The referring physician identifies the lesion and marks the area to be treated.

Step 2
The treating physician covers the area with a clear plastic film before applying the Rhenium-SCT paste.

Step 3
After a calculated period of time, the film is removed and the waste is disposed of.

For more information on Rhenium-SCT, scan this QR code or visit www.oncobeta.com

References: 1. Cipriani C, *et al. J Dermatol Treat*. 2022;33(2):969–975. Epub 22 Jul 2020. **2.** Castellucci P, *et al. Eur J Nucl Med Mol Imaging*. 2021;48(5):1511–1521. **3.** Cipriani C, *et al. Int J Nucl Med*. 2017 Jul;114–122. **4.** Australian Therapeutic Goods Administration. ARTG Public summary 400142. **5.** Cipriani C, *et al. In Therapeutic Nuclear Medicine*. 2014. RP Baum (Ed), New York: Springer. **6.** Sedda AF, *et al. Clin Exp Dermatol*. 2008;33(6):745–749. **7.** Data on file. OncoBeta® Garching, Germany. **8.** Baxi S, *et al. J Nucl Med*. 2024;00:1–6. DOI: 10.2967/jnumed.124.267988.

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epidermal radioisotope therapy