



## Fully recruited EPIC-Skin international study for the treatment of Non-Melanoma Skin Cancer

**Garching n. Munich, Germany** – OncoBeta® GmbH, a medical device company specialised in innovative epidermal radioisotope therapies, has confirmed the phase IV international multi-centre study designed to further evaluate the Complete Response Rate of patients with non-melanoma skin cancer after treatment with Rhenium-SCT® is now fully recruited.

The EPIC-Skin study (**E**fficacy of **P**ersonalised **I**rradiation with Rhenium-**S**CT for the treatment of non-melanoma **skin** cancer) is based on the proven effect of the  $\beta$ -emitter rhenium-188 in the treatment of basal cell (BCC) and squamous cell carcinomas (SCC)<sup>1,2</sup>. The study aims to further evaluate the efficacy of Rhenium-SCT® as well as important Patient Reported Outcome Measures such as quality of life, treatment comfort and cosmetic outcomes.

Patients treated had a confirmed histopathology of stage I or II non-melanoma skin cancer. With the latest treatment round complete, all patients are now in the follow-up phase, which monitors quality of life, treatment comfort and cosmetic outcomes over the next 24 months. An interim analysis is expected to be published in mid 2023.

Professor Mike Sathekge, an internationally acclaimed researcher and current Head of Nuclear Medicine at Steve Biko Academic Hospital in Pretoria, South Africa, treated his first patient enrolled in EPIC-Skin in November 2022, and the latest patient marks the final treatment in the study.

An international multi-centre trial, the EPIC-Skin study is being conducted across five countries and seven major cities including Rostock, Vienna, London, Pretoria, Gold Coast, Perth and Sydney with more than 180 patients taking part.

There are more than 7.7 million cases of NMSC each year, and incidence rates are increasing globally.<sup>3,4</sup> Traditional treatments for NMSCs predominantly involve surgery, which carries a risk of scarring or loss of function. Treatment with Rhenium-SCT employs a non-invasive superficial application of a paste containing  $\beta$ -emitting particles directly to the lesion, which eliminate cancer cells without the need for surgery.<sup>2,5,6</sup>

Dr. Gerhard Dahlhoff, Medical Director at OncoBeta® GmbH, stated: “We are excited to complete the final patient recruitment within EPIC-Skin as we will now start to receive data on the quality-of-life outcomes. With patients in study centres across Australia, Austria, Germany, United Kingdom and South Africa, we have a mix of patients, ethnicities, NMSC localisations and lesion characteristics which will enable us to even further evaluate the outcomes of treatment with Rhenium-SCT®.”

Shannon D. Brown III, CEO and Managing Director at OncoBeta® GmbH, said, “The patient journey is often a difficult one, so it is critical that the medical community continues to improve and develop new treatment options for patients with NMSCs. The EPIC-Skin clinical study has the potential to influence and change the way we evaluate and fit NMSC treatments to the individual needs and requirements of patients.”

ClinicalTrials.gov Identifier: NCT05135052

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## About the Rhenium-SCT® (Skin Cancer Therapy)

Non-melanoma skin cancer (NMSC) is the most common form of cancer in humans.<sup>4</sup> The most common cause of NMSC is sun exposure, while other predisposing factors include genetic skin conditions and immunosuppressive diseases or treatments.<sup>7</sup>

The Rhenium-SCT is a painless\*, single session†, non-invasive‡ therapy that provides aesthetic results, even in cases otherwise considered difficult to treat.<sup>2,5,6</sup> The Rhenium-SCT utilizes the radioisotope Rhenium-188 in an epidermal application with optimal properties for the treatment of NMSCs (non-melanoma skin cancers). The Rhenium-SCT is a precise, personalised<sup>1,2</sup> therapy that is only applied to the area needed to treat without affecting the healthy tissue. The specially designed device ensures the Rhenium-SCT compound never comes in direct contact with the patient's skin and the application is safe and simple for the applying physician. Most cases of NMSCs (Basal Cell Carcinomas and Squamous Cell Carcinomas) can be treated using the Rhenium-SCT in one single session.<sup>2,5,6†</sup> Scar-free healing of the treated lesion area and the regeneration of healthy tissue occurs usually within a few weeks after treatment.<sup>5</sup>

## About OncoBeta®

OncoBeta® with its headquarters located in Garching near Munich, Germany, is a privately held medical device company, specializing in the development and commercialization of state-of-the-art, innovative therapies. Since its foundation, OncoBeta® has concentrated its efforts on the development, regulatory approval(s) and commercialization of the epidermal radioisotope therapy Rhenium-SCT® (Skin Cancer Therapy), targeting non-melanoma skin cancers. OncoBeta® has perfected the customized application and device management system in conformity with all health, safety, and environmental protection regulatory standards.

Find out more about the Rhenium-SCT® at [www.oncobeta.com](http://www.oncobeta.com)

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## Forward-looking statements

This announcement includes forward-looking statements that involve risks, uncertainties and other factors, many of which are outside of OncoBeta's control and which could cause actual results to differ materially from the results discussed in the forward-looking statements. Forward-looking statements include statements concerning OncoBeta's plans, objectives, goals, future events, performance and/or other information that is not historical information. All such forward-looking statements are expressly qualified by these cautionary statements and any other cautionary statements which may accompany the forward-looking statements. OncoBeta® undertakes no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

\*No reported pain<sup>6</sup>

†Complete tumour regression in 98.5% of lesions treated.<sup>5</sup>

‡A procedure is considered non-invasive when no break or cut in the skin is created.<sup>8</sup>

## References

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