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Breakthrough clinical trial launched at Princess Alexandra Hospital to rebuild jawbones

Highlights

- **Osteopore launches a clinical trial with Princess Alexandra Hospital for maxillomandibular reconstruction in at least 10 adult patients.**
- **The single-arm feasibility trial will be conducted in Australia, with patient recruitment anticipated by 2028.**
- **Follow-up with these patients is expected to be 36 months post-surgery.**
- **This trial seeks to determine the safety and tolerability of polycaprolactone-tricalcium phosphate scaffolds with a vascularised corticoperiosteal tissue transfer.**

Australian-Singaporean regenerative medicine company **Osteopore Limited** (**ASX: OSX**; **Osteopore** or **the Company**) – a global leader in 3D-printed biomimetic and bioresorbable implants – is delighted to announce a clinical trial in collaboration with Princess Alexandra Hospital (PA Hospital) for maxillomandibular reconstruction in at least 10 adult patients.

The single-arm feasibility trial will be conducted in Australia, with the completion of patient recruitment anticipated by 2028, and patient follow-up expected to be 36 months post-surgery.

The trial seeks to determine the safety and tolerability of polycaprolactone-tricalcium phosphate (PCL-TCP) scaffolds with a vascularised corticoperiosteal tissue transfer.

This technique – also known as regenerative matching axial vascularisation (RMAV) – was developed by Principal Investigator Dr. Michael Wagels, a plastic and reconstructive surgeon based at PA Hospital. RMAV had been successfully applied with the Company's PCL-TCP scaffolds in previously conducted cranial and long-bone reconstruction trials [1].

The loss of bone in the maxilla or mandible can significantly impact function and appearance, affecting basic abilities such as breathing, chewing, swallowing and speaking. These bones also play a key role in facial aesthetics, which is closely linked to psychosocial well-being.

Currently, autologous free tissue transfer is considered a state-of-the-art treatment. But, it comes with intrinsic donor site morbidity, limited adaptability for complex defects, a shortage of available donor site bone, and insufficient bone height for effective dental rehabilitation.

The Human Research and Ethics Committee (HREC) at Metro South Health has provided clearance, while Research Governance Office (RGO) clearance is expected to follow suit.

Commenting on the clinical trial at Princess Alexandra Hospital, CEO Dr Yujing Lim, said:

"We are delighted to grow our clinical collaboration with Princess Alexandra Hospital and Dr. Wagels.

"Focusing on regenerative medicine, we are committed to identifying key clinical applications for our technology, while continuously advancing product development.

"This collaboration leverages our strengths in technology and product development, alongside precise clinical needs identification.

"Our previous collaboration with the Hospital contributed to our recent European market approvals, and we look forward to creating more collaborations of this nature," said Dr Lim.

[1] ASX announcement "Osteopore progresses Australian bone scaffold trials", 26 March 2024.

Commenting on the clinical trial with Osteopore, plastic and reconstructive surgeon Dr. Michael Wagels said:

"The overarching goal of this project is to lay the foundation for future research, which refines the approach to maxillomandibular reconstruction in a way that minimises patient morbidity and mortality by using modern advances in tissue engineering.

"A robust body of evidence, as well as our in-human series, has suggested that the RMAV technique facilitates bone regeneration and is preliminarily safe and well-tolerated.

"We aim to further the use of RMAV through this feasibility study for maxillomandibular reconstruction, and hope that it lays the foundation for future randomised clinical trials in which RMAV is compared to the current gold standard," said Dr. Wagels.

ENDS

This announcement has been authorised for release to the ASX by the Board of Osteopore Limited.

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About Osteopore Limited

Osteopore Ltd. is a global medical technology company founded in Singapore and listed in Australia that commercialises products designed to enable natural bone healing across multiple therapeutic areas. Osteopore's patented technology fabricates specific micro-structured scaffolds for bone regeneration through 3D printing and bioresorbable material.

Osteopore's patent-protected scaffolds are manufactured using a proprietary manufacturing technique with a polymer that naturally dissolves over time to only allow natural and healthy bone tissue, significantly reducing the post-surgery complications commonly associated with permanent bone implants. Our 3D printing technology is unique to Osteopore.

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