26 March 2024

Osteopore advances next-generation bone scaffold clinical trials in Australia

Highlights

- **Recruitment for the cranial reconstruction trial has been completed with patient outcomes demonstrating excellent vascularity and bone regeneration**
- **Recruitment for the long bone reconstruction trial has now closed with indications of strong patient outcomes**
- **The clinical team seeks to publish a manuscript in an international peer-reviewed medical journal to share the exciting results of the clinical trials**
- **Osteopore is well-placed to offer surgeons in Australia a Therapeutic Goods Administration (TGA) compliant custom-made medical device**

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 provide an interim update on the Company-sponsored single-arm feasibility clinical trials in Brisbane, Australia[1] – announced on 26 August 2021 – relating to cranial and long bone reconstruction using polycaprolactone-tricalcium phosphate, customised scaffolds.

According to the study protocols, each study aimed to recruit between 5 to 10 patients. The key primary endpoints include the formation of regenerate bone that is sufficient to protect the brain (cranial reconstruction) and enable weight-bearing (long bone reconstruction).

[1] ASX announcement "Osteopore Sponsors Australian Patient Trials", 26 August 2021.

Recruitment for the cranial reconstruction trial is now complete with nine patients participating. Three patients have reached the post-surgery milestone of 24 months, with one at 18 months, and the remaining patients between 1 and 9 months.

Treatment outcomes have demonstrated that Osteopore's custom-made device is capable of restoring vascularity within the scaffold while directing bone regeneration – when combined with the surgical technique of Regenerative Matching Axial Vascularisation (RMAV).

The RMAV technique involves performing a vascularised free tissue transfer using a bioresorbable, 3D-printed scaffold to promote and support bone regeneration. This is a technique developed by Principal Investigator (PI) Dr. Michael Wagels, who is a distinguished member of Osteopore's Scientific & Clinical Advisory Panel[2].

The long bone reconstruction trial has closed for recruitment with two patients participating. The patients are due to complete their post-surgery follow-up in June 2024 and December 2024 respectively.

Both patients are progressing well in their post-surgery recovery. However, due to the stagnant recruitment process and the considerable duration of the study, the Company has reached a consensus with Dr. Wagels that the clinical trial shall cease recruitment.

Dr. Wagels and his clinical team are seeking to publish in an international peer-reviewed medical journal to share the exciting results of the clinical trials. The interim success of our clinical trials provides Osteopore with stronger assurance relating to the clinical outcomes of these challenging bone reconstruction segments.

Together with the patient outcomes achieved across five previous "first-in-human" cases – including two shin bones, one mid-face, two lower jaws and one skull – the Company strengthened its clinical databank with prospective and retrospective data. It is now in a stronger position to offer its custom-made medical device in Australia as per the TGA's specific guidelines in the document "Custom-made medical devices (V4.1 October 2022) [3]".

The definition of a custom-made medical device is one that is personalised for a specific patient, for the sole use by a particular health professional, and manufactured in accordance with a written request by the requesting health professional. Osteopore shall work towards making its custom-made device available on the Australian Register of Therapeutic Goods (ARTG) should the demand for this product exceed the current threshold of five cases annually.

[2] ASX announcement "Osteopore Advisory Panel of Distinguished Industry Leaders", 27 February 2023.

[3] https://www.tga.gov.au/sites/default/files/custom-made-medical-devices.pdf

Commenting on the Company's promising outcomes of the clinical trials, Osteopore CEO, Dr Lim Yujing, said:

"The clinical data from these trials has demonstrated that our products are safe and effective in treating complex bone defects. While cases such as these are less common, the impact on patient quality-of-life is substantial.

We are keen to help these patients with solutions like this custom-made device, which helps to augment clinical outcomes and, in some cases, transform patient lives. It is a privilege for us to support patients and surgeons in their times of need." said Dr Lim.

Leveraging on this, the Company is concurrently pursuing a custom-made device designation with the European Authorities to gain market access in Europe, which does not have the limit of five cases annually as per the TGA. More updates shall be made available in the near-term.

ENDS

This announcement dated 26 March 2024 has been authorised for release to the ASX by the Board of Osteopore Limited.

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About Osteopore Limited

Osteopore Limited is a Singapore-founded regenerative medicine company and a global leader in 3D-printed biomimetic and bioresorbable implants. The Company seeks to commercialise products that stimulate natural bone healing across multiple segments.

Osteopore creates patented scaffolds using 3D-printed biomimetic and bioresorbable materials to guide and nurture bone-forming cells.

Through our proprietary manufacturing process – which uses a naturally dissolving polymer – our patented scaffolds enable bone tissue growth, significantly reducing the post-surgery complications commonly associated with permanent bone implants.

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