

ASX RELEASE | OSTEOPORE LIMITED

OSTEOPORE RECEIVES AUSTRALIAN TGA APPROVAL

20 APRIL 2020: Osteopore Limited (ASX: OSX) (“Osteopore” or the “Company”), a medical device company commercialising a range of 3-D printed bioresorbable scaffolds for regenerative bone healing, is pleased to announce it has received Australian Therapeutics Goods Administration (“TGA”) approval for its craniofacial products, Osteomesh, Osteoplug, and Osteoplug-C.

Osteopore’s craniofacial products are used as bone void fillers for regeneration of natural bone. The products have broad application in neurological and craniofacial surgery; Osteomesh is able to treat orbital floor fractures; the Osteoplug is used for neurosurgical burr holes and other cranial defects, and the Osteoplug-C for neurosurgical burr holes and other cranial defects in conjunction with cerebral shunt operations. All three products have now been registered on the Australian Register of Therapeutic Goods (ARTG). Osteopore’s craniofacial products will also be included in the Prosthesis Listing in July 2020, after receiving acceptance for their application.

Obtaining TGA regulatory approval now allows Osteopore to make its products more broadly commercially available to doctors and hospitals across Australia, and the Company will continue ongoing discussions with potential distribution partners. Osteopore has already appointed an Australian based business development consultant to lead its distribution strategy and drive sales. Osteopore’s products have been previously successfully used in Australia, for customised implants used under Special Access Scheme, where the Osteopore scaffold technology is, in the view of the surgeon, the most applicable product to deliver the best patient outcome. Most notably, Osteopore’s technology was used in 2017 to enable the successful regeneration of a patient’s tibia after 36cm was removed due to infection, and this case received significant media coverage in late 2019 following the patient’s successful recovery.

Osteopore has already received regulatory clearance and approval in international markets including United States FDA and European CE Mark clearance, together with Singapore and other East Asian regulatory clearances.

Osteopore Global Regulatory Approval



Osteopore CEO Goh Khoon Seng said: “We are delighted to have now received TGA approval for Osteoplug and Osteomesh, and this has now opened up the Australian market to Osteopore. Australia is a key market for the global expansion of our business, and we are excited to be able to continue to build our revenue streams in this market”

This announcement has been approved for release by the Board of Osteopore.

For more information please contact:

Geoff Pocock

Executive Director

Osteopore Limited

+61 4 1219 4373

geoff_pocock@osteopore.com

About Osteopore Limited

Osteopore Ltd is an Australian and Singapore based medical technology company commercialising a range of bespoke products specifically engineered to facilitate 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 made from proprietary polymer formulations, that naturally dissolve overtime to leave only natural, healthy bone tissue, significantly reducing post-surgery complications that are commonly associated with permanent bone implants.

About Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, and is responsible for regulating therapeutic goods including prescription medicines, vaccines, sunscreens, vitamins and minerals, medical devices, blood and blood products. Almost any product for which therapeutic claims are made must be entered in the Australian Register of Therapeutic Goods (ARTG) before it can be supplied in Australia.

Forward Looking Statements

Statements contained in this release, particularly those regarding possible or assumed future performance, revenue, costs, dividends, production levels or rates, prices or potential growth of Osteopore Limited, are, or may be, forward looking statements. Such statements relate to future events and expectations and, as such, involve known and unknown risks and uncertainties. Actual results may differ materially from those expressed or implied by these forward-looking statements depending on a variety of factors.