

PORTLAND ORTHOPAEDICS

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Announcement

Portland Orthopaedics Lodges FDA Application to Implant New Primary Hip Replacements

First US patient with new M-Cor primary hip implant expected in first half 06

12 January 2006, Sydney: Sydney-based Portland Orthopaedics Limited (ASX: PLD) has lodged an application with the US Food and Drug Administration (FDA) for approval to market the company's new M-COR primary hip product range in patients in the US. Portland Orthopaedics received its first FDA approval for the DTC Hip in 2000 and in 2005 was granted FDA approval for use of its second product, the Equator Plus Cup.

The FDA Pre Market Approval (510k) approval process typically takes 90 days from lodgment and it is expected that the first M-COR primary hip implant on a US patient will take place shortly thereafter.

Portland is best known for its revision hip products used in patients typically with poor bone quality where the common styles of artificial hips are often unsatisfactory. Listed on 21 December 2005, Portland raised \$4.1 million in its initial public offering to expand its hip and knee replacements to offer a suite of products to surgeons.

The M-COR primary hip is fixed in the thigh bone (femur) with a traditional hammer and nail method that is very familiar to orthopaedic surgeons. In addition Portland's primary hip maintains the advantages of both modular design and a distinct neck component that improves the fit and adjustability which can increase longevity. Surgeons in the US are assisting Portland with design and the product instrumentation.

"This hybrid design includes some of the innovative features of Portland's revision hip while keeping the familiar interference fit method. This is a pragmatic business decision based on our four years of hip product distribution in the US," said Mr David Sekel, MD of Portland Orthopaedics.

"Portland will be equipped to service revision hip replacement surgery as well as mass market primary hip replacements. Importantly, this makes Portland much more attractive to hip and knee distributors as we will have a more complete suite to offer."

All Portland's products are designed and principally manufactured at its facility in Sydney.

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About Portland Orthopaedics: Listed on the ASX in December 2005, Portland (ASX: PLD) is a developer and manufacturer of specialist hip and knee joint replacements. Portland's first product, the DTC Hip, was conceived in 1991 as standard hip implants proved inadequate in cases with substantial bone loss especially where a hip implant had already been inserted. Portland's first hip implant was trialled in 1997 and so far more than 1,700 implants have been sold, the majority in the US and Australia.

Portland has regulatory approval to sell a range of primary, revision and tumour hip replacement products in the US, Europe, Australia, New Zealand and Israel.

Portland is expanding its business from a single product focus into a multi-product orthopaedics company. The Equator Plus cup and a second and complementary range of primary hip replacements are due for market launches in early 2006. A fourth product range of total knee replacement products is also due for release in early 2006. The core technologies are all patented and future applications include shoulders, ankles and other joints.
