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ASX and Media Release

21 November 2022

SDI receives US FDA approval for new amalgam replacement product

MELBOURNE, Australia - SDI Limited (ASX: SDI), a leading dental technology company that conducts research and development, manufacturing, and distribution of specialty dental materials, is pleased to announce regulatory approval has been received from US Food and Drug Administration (FDA) for SDI's amalgam replacement product 'Stela'.

Stela is a newly developed and innovative product that meets market demand for a highly durable tooth coloured amalgam alternative. For decades, dentists have used amalgam, silver in colour, for fillings due to its unmatched durability, low cost, and ease to place. Changing consumer preference for tooth-coloured fillings presented the industry with the challenge and opportunity to develop a product that has the matched durability of amalgam, but tooth coloured. Stela meets this demand.

Commenting on the Stela product, SDI's Chief Executive Office, Samantha Cheetham said:

"The world is rapidly moving away from amalgam and that is why we mobilised our 50 years of amalgam knowledge behind developing Stela. Stela truly is the new amalgam alternative. The benefits of Amalgam are its strength, low cost, and ease of use by dentists, with no etching, layering, or light cure. That is the basis of Stela. Further many products claim to be an amalgam alternative, but fail comparisons based on strength, marginal sealing, and depth of cure. Stela has been formulated specifically as a posterior restorative, with the advantage of having a lifelike aesthetic result."

Stela technology is the result of a strong partnership between SDI's scientists, with 50 years of experience developing dental materials, and aeronautical engineers from the University of New South Wales (UNSW), University of Wollongong and University of Sydney, world leading Australian universities. Stela was developed over a 5-year time frame via a rigorous and scientifically proven process and supported by government via grants.

Exporting to over 100 countries globally, SDI operates in highly regulated regions requiring regulatory approval prior to product launch. Receiving FDA approval for Stela is a major milestone in the process of launching the amalgam replacement product into the US, with this region representing 23.2% of total sales in FY22.

Over the next 4-6 months, SDI will be working with US dentists, key dental opinion leaders and distributors to educate and market the Stela product before a formal launch in the US anticipated in Q1FY24. The FDA approval allows dentists and opinion leaders to properly test the product on the oral environment, an essential part of the education process.

Stela will form part of SDI's aesthetic reporting segment, as it is not only an alternative to amalgam but also an alternative to the boarder aesthetic solutions, due to its tooth-coloured appeal.

SDI is currently seeking approval from other regulatory authorities, including Therapeutic Goods Administrator (TGA) in Australia. The FDA approval is a landmark approval and SDI expects approvals in other regions to follow.



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Chief Executive Officer Samantha Cheetham added on the regulatory approval:

"We are thrilled to have received FDA approval in the United States for our newly developed and innovative product Stela. I would like to thank our talented R&D team and partners at the University of New South Wales, University of Wollongong and University of Sydney who collaboratively have created a break through and innovative product not matched by any other product in the market."

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

Please contact Adrian Mulcahy if you have any queries.

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About SDI Limited

Founded in 1972 and publicly listed on the Australian Securities Exchange in 1985, SDI Limited is a leading dental technology company that conducts research and development, manufacturing, and marketing of specialist dental materials. SDI's products combine innovation and excellence to provide the ideal restorative materials for the dental profession.

All of SDI's products are manufactured in Victoria, Australia. SDI's products are distributed through distributors and retailers in over 100 countries throughout the world. SDI has offices and warehouses in Australia, USA, Germany, and Brazil.