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SOMNOMED RECEIVES FDA APPROVAL FOR NEW SMH BIOMATERIAL

US and Australian product sales expected in February/March

30 January 2008, Sydney: Leading maker and marketer of dental sleep devices, SomnoMed Limited (ASX: SOM) announced that its Swiss Joint Venture, SMH Biomaterial AG, has received US Food and Drug Administration (FDA) approval for a new polymer, the SMH BFlex soft material. The material can now be used to make dental sleep devices in the USA. More importantly, the company has the opportunity to market the material broadly in the USA to other dental and medical device companies.

In August 2007, SomnoMed acquired 50 percent of SMH Biomaterial AG, now a joint venture company with Mr Konrad Hofmann, the inventor of the polymer. The joint venture owns all intellectual property rights to the product, while SomnoMed is responsible for the global marketing and distribution to manufacturers of dental and medical devices around the world.

"This is a milestone development for SomnoMed" said Ralf Barschow, chief executive of SomnoMed Limited. "We are currently assessing various marketing and distribution options to introduce this novel material to the markets around the world. We have already been approached by large, reputable companies seeking a license, private label agreements or simply supply."

SomnoMed is assessing the global application and potential for SMH BFlex, especially outside the dental industry. "The global applications for SMH BFlex could be substantial and we will only make final decisions on how to distribute the material once thorough investigations are completed," said Barschow.

SomnoMed will use SMH BFlex as a new superior lining for its own SomnoMed MAS™, the dental device used to treat sleep apnoea and snoring. "The use of SMH BFlex in our SomnoMed and SomnoDent oral sleep devices will give us a competitive advantage. The new material is not only superior in terms of patient comfort but also in terms of longevity and product appearance."

"SMH BFlex does not react to bacteria the same way as other materials and as a result does not take on unpleasant odours over time. We believe the use of SMH BFlex in our devices will strengthen SomnoMed's claim for leadership in the dental sleep markets around the world," said Barschow.

The SomnoMed MAS™ device with the new SMH BFlex lining will be called SomnoDent Flex in Europe and SomnoMed Flex in the rest of the world. The product has been launched in Europe recently and will be launched in Australia/Asia in February and in the USA in March 2008.

The SomnoMed MAS™ is an oral appliance, which fits over the upper and lower teeth, much like a sports mouthguard. However, unlike a sports mouthguard, it is a custom-made, clinically-tested medical device that is highly effective (in most cases) in stopping snoring and treating obstructive sleep apnoea.

Sleep disorders are rapidly becoming a global epidemic and dentists are at the forefront of being able to screen and identify patients with obstructive sleep apnoea (OSA). OSA is thought to affect between 0.3 to 5 percent of people living in Western countries. The incidence of OSA is lower in women, with men affected 2-3 times more often.

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How the SomnoMed MAS™ works

The medical term for your lower jaw is 'mandible' and an oral appliance worn over the teeth is a 'splint', hence the name SomnoMed Mandibular Advancement Splint, or SomnoMed MAS™.
The SomnoMed MAS™ consists of two acrylic plates fitted over the upper and low teeth. A patented fin coupling mechanism on the lower arch accurately positions the lower jaw (mandible) a little forward of its natural position.
This positioning tightens the soft tissue at the back of the throat to stop it from collapsing – the cause of snoring (partial collapse) and sleep apnoea (full collapse). SomnoMed MAS™ allows the normal opening and closing of the mouth, allowing the user to yawn, speak and drink. The device will last 5 years and comes with a warranty.
The SomnoMed MAS™ is provided to patients through an integrated clinical protocol, involving dentists, primary care practitioners and sleep physicians. This pathway ensures that all patients are appropriately diagnosed and that only suitable patients are fitted with the device.