Axiostat becomes the first wound dressing from India to get US FDA clearance

Bengaluru, 28th February 2018: Giving a fillip to the Government's 'Make in India' initiative, Axiostat has become the first Indian wound care product to receive 510(K) FDA clearance in the US for its pioneering haemostatic dressing. Axiostat, a 100% chitosan haemostatic dressing to stop external bleeding, was earlier approved with CE mark in Europe. The FDA clearance now allows Axiostat to be marketed in the US as over-the-counter (OTC) product for control of bleeding.

Axiostat Chitosan Hemostatic Dressing is a patented product that has prevented countless deaths due to bleeding in battlefields, hospitals, and on roadsides, worldwide. The innovative first-aid dressing stops uncontrollable bleeding within just two-three minutes of its application. Axiostat has become the de-facto product of Indian armed forces, since its life-saving quality came to the fore during a surgical strike.

Commenting on the FDA approval, **Leo Mavely, CEO of Axio Biosolutions,** said, "The FDA clearance of Axiostat in the US is a major milestone in our journey so far. This is a validation of the performance, safety and efficacy of Axiostat in bleeding control. We developed Axiostat to be a world-class quality product and this clearance reiterates that. This is a 'proudly made in India' product for the global market. The achievement of US FDA 510(k) clearance represents a significant undertaking for us at Axio, and we could not have done it without the trust and support of our entire team as well as investors, who have always supported our vision and made this day possible."

Earlier this year, Axio Biosolutions had raised $7.4mn in a Series B funding round led by Ratan Tata's UC- RNT, along with existing investors Accel Partners and IDG Ventures India. As the first Indian company to launch an indigenously developed emergency haemostat for trauma care, Axio Biosolutions has been steadily disrupting the wound care market.

Axio Biosolutions has its corporate office in Bengaluru and Axiostat is currently manufactured at their GMP, ISO 13485-certified manufacturing facility in Gujarat. In the US, the product will be marketed by its subsidiary, Advamedica Inc headquartered in Boston.

About Axio Biosolutions

Axio was founded in 2008 by Leo Mavely, a bioengineer to develop novel biopolymer-platform-based products for wound care. Axio has the distinction of being the first company from India to design, develop and commercialize an Emergency Haemostat for Trauma care. Vision of Axio is to develop affordable, high-impact medical products that can solve unmet healthcare needs of emerging markets. Controlling life-threatening

bleeding continues to be the major cause of death from traumatic injuries. Axiostat® is its flagship product developed to reduce the mortality due to traumatic bleeding. Axio is a ISO 13485 certified company with an experienced team focused on bringing high-impact medical products to markets world-over. Axio is funded by marquee investors such as Accel, IDG Ventures and UC-RNT.

Axio is today a global name that uses innovative medical technology to create breakthrough products and save people's lives. Axiostat is regularly used by Indian Armed forces, BSF, NSG, and other para-military forces, as part of their defense kit, during their operations at the border and conflict zones such as North-East. Axio's customers also include numerous government hospitals and reputed private institutions such as AIIMS, Manipal, Apollo, Breach Candy and Fortis among others.

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