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Kane Biotech Receives ISO 13485:2016 MDSAP Quality Certification

Provides access to Canadian, Australian, New Zealand and Brazilian markets

WINNIPEG, Manitoba, July 17, 2024 (GLOBE NEWSWIRE) -- Kane Biotech Inc. (TSX-V:KNE; OTCQB:KNBIF) ("Kane Biotech" or "Kane") announces that it has received ISO 13485:2016 Medical Device Single Audit Program ("MDSAP") Quality Certification as a designer, developer and manufacturer of medical devices. This achievement speaks to Kane's demonstrated commitment to bringing quality products to market. These standards require the existence of a comprehensive quality management system with a focus on areas directly impacting patient safety, product performance and reliability.

Obtaining the ISO 13485:2016 MDSAP certification allows Kane to apply for regulatory approval of its revyve™ Antimicrobial Wound Gel in Canada, Australia, New Zealand and Brazil. MDSAP is an enhancement of Kane's previous quality certification which enabled Kane to receive US Food and Drug Administration 510(k) clearance for revyve™.

"This is yet another important milestone for Kane," said Marc Edwards, President and CEO of Kane Biotech. "There is a need to significantly improve the quality of products that are available to Canadian patients suffering from chronic wounds and today's announcement brings us one step closer to that end. It also opens the door to Kane expanding its certification and submitting other products for regulatory approval in order to build a comprehensive portfolio of advanced wound care products in these jurisdictions."

The MDSAP program was first introduced in 2016 and allows for an MDSAP-recognized auditing organization to conduct a single audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.

"Through these processes Kane has established a robust quality program associated with the medical device lifecycle to provide assurance consumers will receive safe and reliable products," said Lori Christofalos, Chief Quality Officer. "I would like to thank the team for all of their hard work as the challenges of preparing a first MDSAP audit are substantial but so are the long-term benefits. One audit allows Kane to meet the quality requirements of multiple regulators."

About Kane Biotech

Kane Biotech Inc. is a biotechnology company engaged in the research, development and commercialization of technologies and products that prevent and remove microbial biofilms. Kane has a portfolio of biotechnologies, intellectual property (67 patents and patents

pending, trade secrets and trademarks) and products developed by Kane's own biofilm research expertise and acquired from leading research institutions. DispersinB®, coactiv+™, coactiv+®, DermaKB™, DermaKB Biofilm™, and revyve™ are trademarks of Kane Biotech Inc. Kane is listed on the TSX Venture Exchange under the symbol “KNE” and on the OTCQB Venture Market under the symbol “KNBIF”.

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Source: Kane Biotech Inc.