Polarean Receives Clearance for New MRI Chest Coil

Polarean (AIM: POLX) (the “Company”), a commercial-stage medical device leader in advanced MRI scanning of the lungs, announces it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the Company’s specialized MRI chest coil to now include Philips 3.0T MRI scanners for the visualization of the Xenon-129 (129Xe) nuclei.

The Polarean XENOVIEW™ 3.0T Chest Coil is a flexible, single channel, transmit-receive RF coil tuned to image 129Xe nuclei while a patient is positioned inside a multinuclei-capable MRI scanner. The XENOVIEW Chest Coil is indicated to be used in conjunction with compatible 3.0T MRI scanners and approved hyperpolarized 129Xe for oral inhalation for the evaluation of lung ventilation in adults and pediatric patients, aged 12 years and older. The addition of the new Philips configuration does not affect the intended use of the device; the safety and effectiveness has been confirmed with testing.

Christopher von Jako, CEO of Polarean, said: “Polarean continues to develop and launch new devices and accessories that empower sites to perform modern respiratory imaging, enabling as many clinicians as possible to use our technology for their patients. This FDA clearance also further supports our recently announced collaboration with Philips, by expanding our product line to be compatible with their advanced MRI systems.”

About Polarean (www.polarean.com)

The Company and its wholly owned subsidiary, Polarean, Inc. (together the "Group") are revenue-generating, medical imaging technology companies operating in the high-resolution medical imaging space. Polarean aspires to revolutionize pulmonary medicine by bringing the power and safety of MRI to the respiratory healthcare community in need of new solutions to evaluate lung ventilation, diagnose disease, characterize disease progression, and monitor response to treatment. By researching, developing, and commercializing novel imaging solutions with a non-invasive and radiation-free functional imaging platform. Polarean’s vision is to help address the global unmet medical needs of more than 500 million patients worldwide suffering with chronic respiratory disease. Polarean is a leader in the field of hyperpolarization science and has successfully developed the first and only hyperpolarized MRI contrast agent to be approved in the United States. The company also commercializes systems (such as the HPX hyperpolarization system), accessories (such as Xe-specific chest coils and phantoms) and FDA-cleared post-processing software (to support ventilation defect analysis), to support fully integrated modern respiratory imaging operations.
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POL-PR-2309