

WaveSense, Inc. Receives CE-IVD Marking Approval for Its Cell Enrichment Technology Platform

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IRVINE, Calif., Sept. 21, 2016 -- WaveSense, Inc. (www.wavesense.com) the leader in targeted cell isolation and enrichment from liquid biopsies, announced today that it has received CE-IVD marking approval for their suite of cell isolation and enrichment technologies. The approval includes the EpiSep® direct to slide enrichment technology as well as their proprietary paramagnetic bead technology for the selective isolation of cells expressing CD138. CE marking allows for marketing and sales of the products in the European Union and other countries. The WaveSense system, a growing pipeline of cell enrichment products, can be used for selective recovery/enrichment of cells expressing the CD138 cell surface antigen in biological fluids and tissue culture.

As molecular diagnostics become an integral part of the diagnosis and treatment of cancer there is growing concern that the correct cell type is being evaluated. This concern is most acute when a negative result is reported. The WaveSense cell enrichment platform is designed to address this issue and is in routine clinical use for multiple liquid biopsy applications, including one for the isolation and capture of positive CD138 cells. This is critical for identifying genomic and proteomic abnormalities in plasma cell neoplasms. A cell enrichment study led by Gary Lu, M.D., Department of Hematopathology, the University of Texas MD Anderson Cancer Center, showed that the median plasma cell percentage in non-enriched bone marrow specimens increased from 8% to 73% in enriched bone marrow specimens, implying a 9-fold increase in diagnostic sensitivity. (Arch Pathol Lab Med—Vol 137, May 2013).

“CE marking approval for the WaveSense product line, a FDA Class I technology, represents a significant milestone and accomplishment by all of the employees of WaveSense,” said CEO William Curtis, “The completion of the registration signifies that we are complying with the high standards of the EU governing authorities in the areas of quality, safety and performance.”

“The CD138 isolation and enrichment product for bone marrow is the company’s immediate commercialization focus in the EU,” added Curtis, who noted that the product is already in use by a growing number of prominent reference laboratories and cancer centers in the US and WaveSense can now replicate this acceptance in many European countries.

About WaveSense

WaveSense, based in Irvine, CA (www.wavesense.com) is the leader in targeted cell isolation and enrichment from liquid biopsies. The WaveSense In Vitro diagnostic (IVD) product line provides the most sensitive targeted cell enrichment solution, requiring only a small specimen to deliver the maximum number of pure target cells while simultaneously eliminating background cells. Without the need for expensive capital equipment, WaveSense technology enables enhanced patient diagnostic and management outcomes by optimizing the results of downstream diagnostic modalities including IHC, FISH, PCR, SNP, Gene Expression and NGS. The WaveSense platform fulfills the need to improve workflow, test sensitivity and test results while increasing revenue and reducing operational costs and complexity. WaveSense manufactures the only CE-IVD products for paramagnetic coupled antibody targeted cell enrichment.

For more information, visit www.wavesense.com or email: info@wavesense.com