Life Technologies Receives FDA 510(k) Clearance for Diagnostic Use of Sanger Sequencing Platform and HLA Typing Kits

The Associated Press

Life Technologies Corporation (NASDAQ: LIFE) today announced that it has received U.S. Food and Drug Administration (FDA) 510(k) clearance for its 3500 Dx Genetic Analyzers and SeCore@ HLA typing kits. The development represents additional execution against the company's strategy to become a leader in the diagnostics market by offering both novel clinical assays and best-in-class molecular testing products.

"This successful application for our Sanger sequencer with HLA typing kits is further demonstration of Life Technologies' track record in obtaining FDA regulatory clearance for genetic analysis in the clinical market," said Greg Lucier, chairman and chief executive officer of Life Technologies. "We will continue to aggressively pursue a regulatory pathway for our leading technologies in the clinical space, including next-generation sequencing." The company's 7500 Fast Dx Real-time PCR system was cleared for diagnostic use with the Center for Disease Control's H1N1 assay in 2008. Life Technologies has also announced plans to submit its next-generation sequencing instrument, the Ion Torrent Personal Genome Machine (PGMT) for 510(k) clearance.

The Applied BiosystemsT 3500 Dx/3500xL Dx CS2 Genetic Analyzers, Invitrogen SeCore@ HLA Sequencing Kits, and uTYPE@ Dx HLA Sequence Analysis Software constitute the first 510(k)-cleared, sequence-based system for HLA typing in the United States. Tissue typing is an essential component of determining compatibility between donors and patients for organ and bone marrow transplantation. HLA typing on the 3500 Dx offers labs an optimized, streamlined workflow with higher resolution than other molecular HLA typing technologies such as sequence-specific oligonucleotide (SSO) methods.

"With clearance of this system, transplant patients can now have the confidence that their HLA tissue typing was performed utilizing a thoroughly tested, high resolution technique that has passed the strict test requirements of the FDA," said Ronnie Andrews, president of medical sciences at Life Technologies. "Precise HLA matching between donor and patient significantly improves overall transplant survival." The 3500 Dx is now the only 510(k)-cleared Sanger sequencer commercially available for the diagnostics market. Sanger, also known as capillary electrophoresis, sequencing is the technology that powered the Human Genome Project and remains the "gold-standard" for its accuracy, reliability and ease of use. It is expected that clearance will facilitate development of additional assays using the 3500 Dx and open up new partnerships with assay developers.

"Sanger sequencing remains the gold standard for providing the reliable results

clinical labs need, and 510(k) clearance of the 3500Dx will help to establish sequencing technology as a mainstay of the hospital lab," said Andrews. "The instrument was designed with the clinical laboratory in mind, featuring a novel design that incorporates the ability to track patient samples with radio frequency identification (RFID) tags, as well as redesigned data collection and analysis software." Products included in the current 510(k) clearance are the 3500 Dx/3500xL Dx Genetic Analyzers CS2; 3500 Dx Series Data Collection Software v1.0; SeCore@ HLA Sequencing Kits; and uTYPE@ Dx HLA Sequence Analysis Software. The 3500 Dx instrument is CE-marked for in vitro diagnostic use in Europe, has been approved by China's State Food and Drug Administration (SFDA) for diagnostic use in China, and is also available in Japan, Australia, India, New Zealand, Singapore, and Taiwan.

Additional products offered by Life Technologies for the diagnostics lab market include: the Applied Biosystems QuantStudioT Dx Real-Time PCR Instrument, which is CE-IVD marked for use in Europe and under review by FDA; the VeritiT Dx Thermal Cyclers; and the AcroMetrix@ line of quality controls for molecular diagnostic assays. In addition, the EZ ValidationT Online Tool is available for assisting in the validation and verification of molecular tests.

Life Technologies' next-generation sequencing platforms include the Ion Personal Genome Machine (PGMT) and Ion ProtonT. These instruments are currently marked for Research Use Only.

About Life Technologies
Life Technologies Corporation (NASDAQ: LIFE) is a global biotechnology company with customers in more than 160 countries using its innovative solutions to solve some of today's most difficult scientific challenges. Quality and innovation are accessible to every lab with its reliable and easy-to-use solutions spanning the biological spectrum, with more than 50,000 products for agricultural biotechnology, translational research, molecular medicine and diagnostics, stem cell-based therapies, forensics, food safety and animal health. Its systems, reagents and consumables represent some of the most cited brands in scientific research including: Ion TorrentT, Applied Biosystems@, InvitrogenT, Gibco@, Ambion@, Molecular Probes@ and Novex@. Life Technologies employs approximately 10,400 people and upholds its ongoing commitment to innovation with more than 4,000 patents and exclusive licenses. LIFE had sales of $3.8 billion in 2012. Visit us at our website: http://www.lifetechnologies.com.