MAGELLAN BIOSCIENCES

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News

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Magellan Biosciences Subsidiary Receives CLIA Waiver from FDA for LeadCare II

CHELMSFORD, Mass., September 18, 2006 – Magellan Biosciences, Inc. announced that the U.S. Food and Drug Administration (FDA) has granted a CLIA waiver for the new LeadCare® II blood-lead testing system developed and marketed by the company's subsidiary, ESA Biosciences. LeadCare II will be the focus of a press briefing at 1 pm this afternoon, to be held at the U.S. Department of Health and Human Services headquarters in Washington, D.C. ESA plans to launch LeadCare II at the American Academy of Pediatrics national conference, October 7-10, in Atlanta, Georgia.

The device, which improves on ESA's original LeadCare – now the most widely used blood-lead testing system in the world – is a key element of Magellan's strategy to expand its offerings to the global point-of-care clinical-diagnostic market. Waived status significantly expands the potential sites where lead testing can be performed – for example, in all physician's offices, as well as community health centers, mobile clinics, health fairs, work sites, or home visits – giving healthcare providers a valuable new tool to reach those children and adults most at risk for lead poisoning.

In order for a test to be granted a CLIA (Clinical Laboratory Improvement Amendments) waiver, it must pass rigorous federal standards for simplicity, accuracy, and ease of use so that any healthcare professional can perform the test without special training or advanced certification. According to Magellan's President and CEO, Robert J. Rosenthal, ESA developed the device for the thousands of health centers worldwide that are looking to improve their patients' health outcomes by performing rapid tests on site rather than sending samples to an outside lab. "Experience with our previous point-of-care device demonstrates that this strategy works: educating parents on the dangers of lead at the same time they see their child's lead-levels come up on the screen has had a dramatic effect in reducing future lead exposure. Parents understand the implications and take action. Further, in cases where clinics have used LeadCare to identify children with significantly elevated lead levels, they have taken the children directly to the hospital for follow-up, allowing life-saving treatment to start in a matter of hours, rather than days or weeks."

Dr. Rosenthal continued, "Our company mission is to improve outcomes for our customers by delivering high-quality products that provide better, faster, more-accurate results. Our plan is to use the LeadCare II platform to develop additional point-of-care tests."

Developed with funding from the CDC, LeadCare II removes the complications formerly associated with blood-lead testing. LeadCare II delivers quantitative blood-lead results, equivalent to those reported by reference laboratories, with only two drops of blood in just three minutes so providers no longer have to wait days for expensive lab results, or spend time trying to contact patients for critical follow-up care. It requires only a finger-stick sample and can be combined with other routine waived blood tests. Further, since LeadCare II qualifies for reimbursement as a quantitative blood-lead test and the cost per test is actually less than one would pay an outside laboratory, it is an attractive option for individual physicians and lead-poisoning-prevention programs; it frees valuable resources to enable them to screen more at-risk children.

Why blood-lead testing is necessary
Even with a considerable reduction in the number of children suffering from lead poisoning over the past 30 years, lead poisoning remains the number one environmental threat to children, according to the CDC, yet it is entirely preventable. The key is early detection through screening and immediate intervention when testing identifies elevated blood-lead levels. According to HUD, 25 percent of American homes still contain a significant amount of lead-paint hazards, the primary source of exposure. While a blood-lead test is federally mandated for all children enrolled in Medicaid at one and two years of age, estimates are that fewer than 25 percent of these children are being tested. Because most pediatricians, public health clinics, and others serving at-risk children lack the certification for moderately complex tests required by federal law, they must send samples to reference labs off site, wait for results, and risk losing track of the child when treatment is needed. The CLIA-waived LeadCare II system is designed to remedy this problem.

About Magellan Biosciences
Magellan serves the worldwide clinical-diagnostics market with rapid point-of-care analyzers and automated systems for near-patient testing. Scientists use our discovery systems and sensors for cutting-edge research to develop a new understanding of health and illness – from disease pathology to biomarker identification. We design all of our systems, sensors, and consumables to deliver better, more-reliable results. And better results help drive improved health outcomes: earlier, more-accurate diagnoses; breakthroughs that can lead to novel treatments, new cures – innovations to enhance life. A privately held company, Magellan serves customers through wholly owned subsidiaries: ESA Biosciences, Dynex Technologies, and TekCel. For more information, visit www.magellanbio.com.

About ESA Biosciences
ESA Biosciences, Inc. enables answers to pressing applications challenges by applying its expertise in specialty detection and electrochemistry, combined with components, kits, and reagents, for analytical laboratories, commercial diagnostics laboratories, and the clinical point-of-care setting. ESA is a wholly owned subsidiary of Magellan Biosciences, Inc.

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