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News

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FOR IMMEDIATE RELEASE

ESA Biosciences to Launch CLIA-Waived LeadCare II at American Academy of Pediatrics Meeting, October 7-10, Booth 1062

Point-of-Care Device is an Important New Tool in Preventing Lead Poisoning – the #1 Environmental Threat to Children

CHELMSFORD, Mass., October 3, 2006 – ESA Biosciences, Inc., a Magellan Biosciences company, will launch LeadCare® II – the world's only CLIA-waived point-of-care blood-lead-testing system – in booth 1062 at the American Academy of Pediatrics national conference, October 7-10, in Atlanta, Georgia. Waived status greatly expands the potential sites where lead testing can be performed to more than 115,000 point-of-care locations nationwide, according to U.S. Food and Drug Administration (FDA) estimates. These locations can include all physicians' offices, as well as community health centers, WIC centers (Women, Infant, and Children program) and mobile clinics, health fairs, or home visits – giving healthcare providers a valuable new tool to better reach those children and adults most at risk for lead poisoning. ESA developed LeadCare II with partial funding from the Centers for Disease Control and Prevention (CDC).

The FDA announced the CLIA waiver September 18, 2006, at a press briefing held at the headquarters of the U.S. Department of Health and Human Services (HHS) in Washington, D.C. Admiral John O. Agwunobi, MD, the U.S. Assistant Secretary for Health; Andrew C. von Eschenbach, MD, Acting Commissioner of the FDA; and Jon L. Gant, Director of the Office of Healthy Homes and Lead Hazard Control of the U.S. Department of Housing and Urban Development (HUD), all spoke of LeadCare II as a vital tool to bring lead testing to community settings, a key strategy in achieving President Bush's public health goal of eliminating lead poisoning in children by 2010. Also participating in the briefing were Daniel G. Schultz, MD, Director of the FDA's Center for Devices and Radiological Health (CDRH), Steven I. Gutman, MD, Director of the Office of In Vitro Diagnostic Device Evaluation and Safety, and Carol Benson, MD, Associate Director, Division of Chemistry and Toxicology Devices. As part of the presentation, Ann Chappie, Medical Technologist and the CDRH's primary reviewer for LeadCare II, demonstrated the analyzer's ease of use by performing a lead test on Dr. von Eschenbach. His blood-lead level was within normal range.

Describing LeadCare II as "…a truly innovative application of technology to an entirely important public health challenge," Dr. Agwunobi, a pediatrician who worked in inner city hospitals, described the difficulties in reaching at-risk populations: "I saw children come in to be tested … only to find that their results of lead in their blood were higher than they were supposed to be. They'd leave, not knowing the results for those tests, because it typically took days, weeks, perhaps longer, for the results to come in. Now we have a test that we can take to those children. Now we have a test that we can get results while they are there with us and quickly do follow-up testing if their screening indicates that something is wrong. We don't have to wait until the lead level in a child's blood is such that it is affecting their brain's development before we intervene."

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. LeadCare II removes all the complications formerly associated with blood-lead testing – waiting days for expensive lab results, or spending precious time trying to contact patients for critical follow-up care. LeadCare II delivers quantitative blood-lead results, equivalent to those reported by reference laboratories, with only *two drops* of blood in just *three minutes*.

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"This waiver is a significant development in the world of blood-lead testing, and we expect that it will greatly expand the effectiveness and scope of lead-poisoning-prevention programs worldwide," said Walter DiGiusto, ESA Biosciences president. "In this country, public health departments and community-outreach programs are shouldering an ever-increasing burden in the battle against childhood lead poisoning. Reaching at-risk children even once to collect a blood sample is challenging enough. Reaching them a second time to initiate treatment can sometimes be impossible. Studies show that 50 percent of Medicaid children will move four times before their second birthday. LeadCare II enables physicians and outreach workers to test, treat if necessary, and educate – instantly, on the spot, and all in one visit. This approach is the most-effective way to stem the adverse effects of lead exposure and prevent permanent damage."

LeadCare II is far simpler to administer than traditional blood-lead tests. It requires only a finger-stick sample, can be combined with other routine waived blood tests, and saves administrative time spent on paper work, tracking, and follow-up. Further, since LeadCare II qualifies for reimbursement as a quantitative blood-lead test and the cost per test is typically about half of the cost of sending a lead test to an outside laboratory, it frees valuable resources to enable individual physicians and lead-poisoning-prevention programs 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.

LeadCare II is an improved, waived version of ESA's original LeadCare system, the most-widely used blood-lead-testing system by pediatricians, family practitioners, public health, and military clinics worldwide.

For more information on LeadCare II, please contact Robb Morse at (978) 250-7072, e-mail LeadCareinfo@esainc.com, or visit www.waivedleadcare.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. Founded in 1968, ESA is a wholly owned subsidiary of Magellan Biosciences, Inc.

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.

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