EraGen Biosciences Announces Luminex License and Distribution Agreement EraGen expands the potential of MultiCode®-PLx Systems by Expanding a Partnership with Luminex Corporation

(April 26, 2005 – Madison, Wisconsin) EraGen Biosciences, a rapidly growing molecular diagnostics company driving early, accurate diagnosis for disease, announced today it has signed an expanded licensing and distribution agreement with Luminex Corporation (Nasdaq: LMNX), Austin, Texas.

"Our MultiCode-PLx product-line, built on the Luminex® 100 System, a laser-based fluorescent analytical test system, is one of the premier methods for the multiplexed detection of nucleic acids for clinical and research diagnostics. Our technology, in conjunction with the Luminex xMAP® technology creates the fastest and easiest way for CLIA laboratories, hospitals and universities to do automated, multiplexed detection in a one-well assay," said Irene Hrusovsky, President and CEO of EraGen Biosciences.

Under the terms of the agreement, EraGen has the rights to distribute and sell Luminex 100 Systems and kits that include non-standard nucleic acid bases, proprietary to EraGen, designed for selected in vitro clinical diagnostic purposes.

"We believe the combination of EraGen's proprietary chemistry and Luminex's xMAP multiplex technology will be highly competitive in the diagnostics market place, particularly against monoplex alternatives," said Greg Gosch, Luminex Vice President of Marketing. "We look forward to continuing to work with Eragen, a Gold sponsor at Luminex's annual Planet xMAP users meeting this week in Austin, on commercialization of their upcoming product lines."

The EraGen MultiCode-PLx System is a bead-based nucleic acid detection method that uses PCR in combination with target-specific primers to detect multiple targets in one well. The EraGen test delivers accurate results in hours eliminating tedious steps verses other methods which can take a week or more.

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Gross Deletion Detection Now Available with The Ambry Test for Cystic Fibrosis

IRVINE, CA (May 20, 2005) – AMBRY GENETICS, a worldwide leader in genetic testing, announced it has introduced a valuable enhancement to its Cystic Fibrosis molecular testing menu. **The Ambry Test: CF AMPLIFIED** can now detect gross deletions, increasing the detection rates of genetic abnormalities that can cause CF. Gross deletions for CF have been commercially undetectable until now.

"This is the next obvious step in improving the molecular diagnosis of CF—but no one had been able to bring it to market," said Charles Dunlop, Chief Executive Officer of Ambry Genetics. "I am proud that our research department has made us the first company to provide the clinical market with this breakthrough technology and offer health care professionals a higher level of resolution in their diagnosis," continued Dunlop.

The Ambry Test™: CF and **The Ambry Test: CF AMPLIFIED** combine scanning and sequencing technologies to analyze a gene's entire coding region plus surrounding critical introns. The tests provide the most comprehensive analysis of the CFTR gene currently available, scanning for the more than 1,300 known mutations rather than simply identifying 25 to 100 specific mutations. Gross deletion testing can aid in those cases when full gene sequence analysis has not resulted in a conclusive diagnosis. "We have gone beyond the single nucleotide with the addition of our gross deletion detection assay," states Anja Kammesheidt, Chief Scientific Officer of Ambry Genetics. "In our ongoing efforts to advance our specialized genetic tests, this type of analysis will help to close the diagnostic gap in many difficult unresolved cases."

Gross deletions comprise a significant percentage of mutations causing CF. Since Ambry Genetics' new deletion assay may solve more patient dilemmas by providing a complete explanation, Ambry Genetics is offering to retest individuals, when appropriate, at a reduced cost. From now through the end of August, patients who have previously had their DNA analyzed by the Ambry Test: CF can be tested for gross deletions for $250. Clients who have submitted DNA within the past thirty days do not have to submit another sample. Samples sent prior to the past thirty days do require another sample submission. Ambry Genetics provides free sample submission kits including free shipping, the convenience of medical insurance billing and institutional billing. Medicaid is accepted from several states.

CF affects approximately one in every 3,000 individuals in the United States, making it one of the most common inherited disorders.

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EraGen Biosciences and Bayer HealthCare LLC, Diagnostics Division, Announce Agreements for New Cystic Fibrosis (CF) Assay

(May 18, 2005 – Madison, Wisconsin) – EraGen Biosciences, a rapidly growing molecular diagnostics company and Bayer HealthCare LLC, Diagnostics Division, a member of the Bayer Group (NYSE:BAY) announced today that EraGen has licensed its patented MultiCode-PLx® System to Bayer HealthCare in an exclusive worldwide agreement for Cystic Fibrosis. Bayer

HealthCare will provide laboratories with a rapid, easy-to-use Cystic Fibrosis assay capable of being automated for mutation carrier screening, as well as for neonatal and newborn testing.

The agreement also provides Bayer HealthCare with additional rights enabling Bayer HealthCare to expand its presence in the genetics-based diagnostics testing market with a number of assays for other disease states.

Cystic Fibrosis and the Importance of Genetic Codes

Understanding variations in the human genetic code is vital to the development of new medical diagnostic and therapeutic products. Genetic tests look for abnormalities in a person's genes. According to the Cystic Fibrosis Foundation, Cystic Fibrosis is a genetic disease affecting about 30,000 children and adults in the United States with more than 1,000 new cases each year. It affects some 60,000 individuals worldwide.

Cystic Fibrosis is the most common inherited (autosomal recessive) disease in the Caucasian population. The disease is characterized by the body's production of abnormally thick, sticky mucus that clogs the lungs and leads to life-threatening lung infections. These thick secretions also obstruct the pancreas, preventing digestive enzymes from reaching the intestines to help break down and absorb food. Additional complications later in life include diabetes and osteoporosis. The median life expectancy of those individuals diagnosed with Cystic Fibrosis is the early-30's.

If a child inherits a defective gene from only one parent, the child will be an asymptomatic carrier of the disease gene. More than 10 million Americans, one in every 31, are asymptomatic carriers of the defective gene, according to the American College of Obstetricians and Gynecologists. If the child inherits two defective genes (one from each parent), then the child will have Cystic Fibrosis.

EraGen's MultiCode-PLx platform is an extremely cost-effective, high throughput genotyping system that simultaneously tests for predetermined mutations of the gene associated with Cystic Fibrosis, the cystic fibrosis transmembrane conductance regulator (CFTR) gene. Leveraging isobases, the test substantially reduces the time for cystic fibrosis multi-mutation analysis when compared to other testing systems currently available. The MultiCode-PLx System allows Bayer HealthCare' customers to enhance their level of Cystic Fibrosis clinical testing by reducing errors, providing faster turn around times and decreasing labor requirements.

"Current advancements in genetic and molecular diagnostics are transforming the realm of clinical laboratory medicine," stated Tony Bihl, President of Bayer HealthCare's Diagnostics Division. "Today's laboratories face mounting pressure to keep pace with escalating testing demands, while supporting the novel testing needs of the healthcare enterprise. Automated, genetic diagnostics assays, including Cystic Fibrosis, are vital for the laboratory to take advantage of clinical progress, while maintaining lab efficiencies and providing timely, reliable clinical information."

"We are excited to partner with Bayer HealthCare on the commercial expansion of our MultiCode product line. Bayer HealthCare previously licensed EraGen's technology for use in its FDA approved HIV, HCV, and Hepatitis B Versant® assays. These new agreements with Bayer HealthCare further validate our novel technology and acknowledge our ability to develop fast and effective molecular diagnostic products. Bayer HealthCare and EraGen–an emerging fast paced developer–are two companies bringing individual strengths together to better serve the clinical diagnostic market and improve patient outcomes," said Dr. Irene Hrusovsky, President and CEO of EraGen Biosciences.

"This new Cystic Fibrosis assay is only the first of a wide range of disease-specific MultiCode tests to come. This is a great day for EraGen," said Dr. James Prudent, Chief Scientific Officer, at EraGen.

References: Cystic fibrosis population carrier screening: 2004 revision of American College of Medical Genetics mutation panel, ACMG Cystic Fibrosis Carrier Screening Work Group in Genet. Med. September/October 2004, Vol. 6 No. 5: 387-391; updates 2001 guidelines. www.acmg.net; Cystic Fibrosis Foundation, www.cff.org, "Facts About Cystic Fibrosis"; www.marchofdimes.com; www.acog.com.

www.eragen.com
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The "New Products" page is designed to offer you news and information from businesses serving the genetics community. We welcome your submissions. All submissions are subject to review by the Editor. For more information, contact Al Lucchesi, National Accounts Manager, Lippincott Williams & Wilkins, 530 Walnut Street, Philadelphia, PA 19106; phone 215-521-8409; fax 215-521-8411; email alucches@lww.com.