



Asuragen Launches CE Marked IVD AmplideX™ Fragile X Test in Europe Asuragen Establishes International Distributor Network for its Molecular Diagnostics Products

Austin, Texas – March 23, 2011 – Asuragen, Inc. announced that they have achieved CE-marking and commercial launch in Europe of the [AmplideX™ FMR1 PCR Kit](#) for the detection of CGG repeats in the fragile X mental retardation (*FMR1*) gene. The AmplideX FMR1 PCR Kit is widely available through Asuragen's recently established network of [distributors](#) in Europe. The AmplideX™ FMR1 PCR Kit is used as an aid in the diagnosis of fragile X syndrome and associated disorders, such as fragile X-associated primary ovarian insufficiency (FXPOI) and fragile X-associated tremor/ataxia syndrome (FXTAS). The Kit provides a high throughput PCR and CE analysis workflow that can accurately resolve sample zygosity and reproducibly detect the full range of full mutation alleles in a single reaction. These assay capabilities reduce the need for Southern blot testing to 2% or less of all samples.

According to Dr. Sara Seneca from the University of Brussels, Belgium, "This new technology has distinct advantages over existing methodologies and was easy to adopt for routine use in our clinical lab". Dr. David Barton from the National Centre for Medical Genetics in Dublin, Ireland, also commented that "We have gained substantial efficiencies since adopting the AmplideX Kit for our Fragile X testing".

"As we expand our molecular diagnostic portfolio for oncology and genetics with the launch of our proprietary CE-marked AmplideX FMR1 PCR Kit, we have put in place an experienced and effective network of European distributors already dominant in the molecular diagnostic testing arena." said President, Rollie Carlson Ph.D, "Our distribution partners will also serve a critical role in accelerating clinical validation and CE-marking of our portfolio of molecular diagnostic products."

About Fragile X Syndrome

Fragile X is a trinucleotide repeat disease caused predominantly by the expansion of CGG sequences in the 5' region of the fragile X mental retardation 1 (*FMR1*) gene. The specific number of CGG repeats is associated with a constellation of disorders that can affect patients both young and old. For example, individuals with full mutations (>200 CGG repeats), often present classic fragile X syndrome (FXS), characterized by mental retardation, autistic-like behaviors, and emotional and psychiatric challenges. FXS is the most common known genetic cause of autism and is one of the most frequent referrals for testing as recommended in the recent European Molecular Genetic Quality Network (EMQN) and the UK Clinical Molecular Genetics Society's guidelines. According to the EMQN, fragile X syndrome is the most common cause of inherited mental retardation with an estimated incidence of 1 in 4000-9000 males and 1 in 7000-15,000 females. Two additional and more recently characterized *FMR1* disorders are fragile X-associated tremor/ataxia syndrome (FXTAS), which is primarily associated with parkinsonism and dementia in male premutation carriers over the age of 50, and fragile X primary ovarian insufficiency (FXPOI), a leading cause of ovarian dysfunction in women. Nearly all cases of FXS, FXTAS, and FXPOI are caused by CGG repeat expansion in *FMR1*. Thus, quantifying the number of CGG repeats is an important goal.

About Asuragen

Asuragen is a fully integrated diagnostic development company and pharmaceutical services provider. The Company's diagnostic product portfolio consists of the first-ever validated microRNA diagnostic assay for pancreatic cancer, quantitative RNA tests for leukemia gene translocations, innovative genetic testing solutions for the fragile X mental retardation (*FMR1*) gene, Signature® Oncology products for the qualitative detection of gene translocations and mutations in a variety of hematological and solid tumors, RNA stabilization technologies, and industry-leading controls and standards engineered using its patented Armored RNA® technology. Asuragen is empowered with a high level of scientific expertise and assay development capabilities, CLIA and GLP testing services, and an established cGMP manufacturing facility, which allow it to span the spectrum of discovery, testing, production and commercialization for companion diagnostics. For more information, visit www.asuragen.com.

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