

## Gyros introduces new application to monitor anti-drug antibodies during development of biotherapeutics

### Automated, drug-tolerant immunoassay increases workflow efficiency

**October 11, 2011, Uppsala, Sweden:** Gyros AB, a leader in utilization of microfluidic technologies to miniaturize and automate immunoassays, announced today the launch of a new Gyrolab™ application to increase efficiency when looking for anti-drug antibodies (ADA) during the development of biotherapeutics.

The application incorporates essential sample pretreatment steps, used to improve the drug tolerance of an ADA assay (the assay's ability to detect ADAs in the presence of free drug), into an automated, nanoliter-scale assay workflow. Overall run times are reduced and technical performance improved compared to alternative techniques.

The new Gyrolab ADA assay format performed well when used with customer samples at beta-test sites, producing results that were within the current recommendations for sensitivity in the presence of high free drug concentrations.

The application comprises a new Gyrolab ADA CD, Rexpip ADA buffer and dedicated, 21 CFR Part 11 compliant, Gyrolab ADA Software that guides the user through the standard ADA analysis workflow from assay development and validation to screening and confirmatory analysis. Drug tolerance is achieved by subjecting samples to an acidic incubation step to dissociate any drug-ADA complexes. Samples are then neutralized and assay reagents added prior to measurement. Automation together with full control over assay-specific incubation times ensures consistent performance and facilitates assay validation. All products are optimized for use with the company's Gyrolab workstation.

Erik Walldén, CEO at Gyros, explained further, "We have worked closely with key players in the biopharmaceutical industry to incorporate this proven, accepted sample pretreatment step into our automated, nanoliter-scale assay format and to ensure that the Gyrolab ADA Software module supports the entire workflow through to data evaluation." Mr. Walldén continued, "With the launch of the Gyrolab ADA solution we have expanded the utility of the Gyros immunoassay platform that is already proven to increase workflow efficiency for applications such as pharmacokinetic and pharmacodynamic studies, biomarker monitoring and impurity testing. This unique solution offers Gyrolab workstation users an efficient alternative to existing assay formats for a critical application and supports our long term objective of setting the industry standard for immunoassays within the time-critical workflows of the biopharmaceutical industry."

### About anti-drug antibodies (ADA)

Biotherapeutic drugs have relatively long half-lives and may be dosed at high levels. This can lead to an immunogenic response in the form of ADAs that bind to the circulating drug thereby reducing efficacy or risking patient safety. Consequently, it is a regulatory requirement to monitor for ADAs in preclinical and clinical studies as well as during post-market surveillance. However, a general problem when trying to detect ADAs in serum is that they bind readily to free drug. This masks their presence when using conventional immunoassay techniques, increasing the risk of false negatives and missing possible biological side effects.

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**Notes to editors:**

**About Gyros ([www.gyros.com](http://www.gyros.com))**

Gyros AB is the world leader in utilization of microfluidic technologies to miniaturize and automate immunoassays. The Gyros™ immunoassay platform increases productivity and efficiency during development of biotherapeutics and vaccines, saving time and labor. Major biopharmaceutical companies and their service providers utilize the Gyros platform to boost time-critical workflows and meet increasing regulatory demands.

Spanning the entire spectrum of immunoassays, the platform cuts the time to result significantly. Faster development times, and unattended running of assays at nanoliter scale, save labor and sample. The ease of assay transfer between sites and from development to regulated environments is unsurpassed in the industry.

The company has around 60 employees, based at its headquarters in Uppsala, Sweden and at regional sales and support offices in the USA and Europe, and a growing network of distributors.

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