



NEW DATA SUPPORT ROLE OF PROMETHEUS LABORATORIES' NOVEL ASSAY IN OPTIMIZING IBD TREATMENT MANAGEMENT

- Antibody-to-infliximab levels highly predictive of disease activity, regardless of drug concentration levels -
- Data provide further evidence for standardized, combined, antibody-to-infliximab and serum infliximab level monitoring among IBD patients on infliximab -
- Oral presentation one of 13 Prometheus abstracts at Digestive Disease Week 2012 -

San Diego, May 22, 2012 – Prometheus Laboratories Inc., a specialty pharmaceutical and diagnostic company, announced today the thirteen abstracts relating to its proprietary diagnostic platform presented at Digestive Disease Week (DDW) 2012.

The abstracts (see full list below) highlight Prometheus's innovative technologies aimed at helping healthcare providers personalize patient care with the goal of ultimately helping to improve patient outcomes. Topics span across a wide spectrum of scientific and clinical research that offers novel solutions to current and future patient needs. "We are proud to continue to lead the way toward personalized medicine. We are committed to continue to advance our novel technology platforms and partner with the GI community to help bring valuable products to market with the goal of continuing to improve patient outcomes," said Joseph M. Limber, President and Chief Executive Officer of Prometheus.

In the Feagan et al abstract, antibody-to-infliximab (ATI) levels proved highly predictive of disease activity, as measured by median C-reactive protein (CRP) concentrations - regardless of serum infliximab (IFX) levels. Both ATI and IFX levels were measured using the novel Prometheus mobility shift assay among more than 1,487 samples from 532 participants in four prospective Crohn's disease randomized controlled trials. CRP concentrations were higher among ATI positive patients with IFX levels < 3 µg/ml (8.4 vs. 5.65; $p < 0.001$) as well as IFX levels ≥ 3 µg/ml (9.9 vs. 1.5; $p < 0.01$), as compared to ATI negative patients.

The development of these antibodies can shorten the duration of clinical response to IFX and decrease the likelihood of an IBD patient remaining in remission.

"Knowing exactly what factors contribute to a patient's loss of response to a biologic therapy is ideal for accurately and efficiently determining an appropriate course of action to restore treatment response," said Brian Feagan, M.D., Director, Robarts Clinical Trials, Robarts Research Institute. "Our data suggest that antibodies-to-infliximab are highly predictive of disease activity and may help establish a new standard of care that includes combined IFX-ATI monitoring for IBD patients treated with biologics."

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Oral presentations:

- Novel infliximab (IFX) and antibody-to-infliximab (ATI) assays are predictive of disease activity in patients with Crohn's disease (CD), presentation #565 in Research Forum by Brian G. Feagan et al on May 20 (4:30-4:45 p.m. PDT)
- Antibodies to infliximab can either be persistent or transient: a retrospective case-control study in IBD patients treated with infliximab maintenance therapy, presentation #563 in Research Forum by Niels Vande Casteele et al on May 20 (4:00-4:15 p.m. PDT)
- Combined serologic, genetic, and inflammatory markers can accurately differentiate non-IBD, Crohn's disease, and ulcerative colitis patients, presentation #166 in Research Forum by Scott E. Plevy et al on May 19 (3:30-3:45 p.m. PDT)
- Blood microRNA (miRNA) Expression Patterns Can Identify Inflammatory Bowel Disease (IBD) Patients with Dysplasia and Cancer, presentation #108 in Research Forum by Francis A. Farraye et al on May 19 (10:30-10:45 a.m. PDT)

Poster presentations:

- New assay to detect infliximab levels and anti-infliximab antibodies from a single serum sample is useful in measuring efficacy of treatment with infliximab in children with IBD (#Sa2037), May 19
- Accelerated clearance of serum infliximab therapy for acute ulcerative colitis is associated with treatment failure (#Sa2031), May 19
- Association of serum infliximab and antibodies to infliximab to long term clinical outcome in acute ulcerative colitis (#Sa2047), May 19
- Comparison of homogeneous mobility shift assay and solid phase ELISA for the measurement of drug and anti-drug antibody (ADA) levels in serum from patients treated with anti-TNF biologics (#Su1928), May 20
- Alosetron treatment reduced health care utilization and improved symptoms more effectively than traditional therapy in women with severe IBS-D (#Tu1386), May 22
- Real-world use of alosetron: results of a multi-center observational study (#Tu1393), May 22
- Evaluation of phosphorylation signatures in suspected pancreatic cancer using endoscopic ultrasound-guided fine needle (EUS-FNA) aspirates: a feasibility study (#Su1909), May 20
- Comparison of phosphorylation signatures in patients with suspected pancreatic cancer undergoing endoscopic ultrasound-fine needle (EUS-FNA) with and without malignant cytology: a pilot study (#Sa1520), May 19
- Psychological variables add incremental value to biological markers in differentiating IBS from healthy volunteers (#Tu1392), May 22

About IBD

IBD, including Crohn's disease and ulcerative colitis, is a chronic inflammatory condition of the intestinal tract. Symptoms of the disease may include diarrhea, abdominal pain, fever and rectal bleeding. Patients may require long-term medical care, including hospitalizations, surgeries and therapeutics. The condition can be difficult to diagnose and manage clinically while consuming a substantial amount of healthcare resources in terms of physician time, procedures and medications. The Crohn's and Colitis Foundation of America estimates that approximately 1.4 million Americans suffer from IBD.

About IBS

According to the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), about 20% of the U.S. adult population has symptoms of IBS, making it one of the most common disorders diagnosed by physicians. At least twice as many women as men are affected by IBS, a disorder characterized most commonly by cramping, abdominal pain, bloating, constipation and diarrhea. Although it significantly impairs health-related quality of life, many people suffer from IBS for years before being properly diagnosed and treated. The NIDDK also estimates that up to 70% of people suffering from IBS are not receiving medical care for their symptoms, due in part to the current difficulties of diagnosing IBS.

About Prometheus

Prometheus Laboratories Inc. is committed to improving lives through the development and commercialization of novel pharmaceutical and diagnostic products that enable physicians to provide greater individualized patient care. Prometheus is a leader in applying the principles of personalized medicine to the diagnosis and treatment of gastrointestinal diseases and is applying these principles to oncology. Its strategy includes the marketing and delivery of pharmaceutical products complemented by proprietary diagnostic testing services. By integrating therapeutics and diagnostics, Prometheus believes it can provide physicians with more targeted solutions to optimize care for their patients. Prometheus became part of Nestlé Health Science in July 2011. Prometheus' corporate offices are located in San Diego, California. For more information about Prometheus, please visit www.prometheuslabs.com.

About Nestlé Health Science

Nestlé Health Science, a fully-owned subsidiary of Nestlé S.A., has been operational since January 1, 2011 and has worldwide headquarters in Lutry, Switzerland. Nestlé Health Science offers nutritional solutions for people with specific dietary needs related to illnesses, disease states or the special challenges of different life stages. For more information about Nestlé Health Science, please visit www.nestlehealthscience.com.

About Digestive Disease Week

DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 19 - 22, 2012, at the San Diego Convention Center. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit www.ddw.org.

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