PROMETHEUS LABORATORIES PRESENTS NEW DATA ON GROWING IBD DIAGNOSTIC PORTFOLIO AT DIGESTIVE DISEASE WEEK 2013

- New data demonstrate a critical relationship between antibodies to adalimumab (ATA) and clinical response in IBD patients -

- Encouraging body of data further support standardized use of liquid phase assays in managing loss of treatment response among IBD patients using infliximab and adalimumab -

San Diego, May 22, 2013 – Prometheus Laboratories Inc., a specialty pharmaceutical and diagnostic company, announced today the eighteen abstracts relating to its proprietary diagnostic platform were presented at Digestive Disease Week (DDW) 2013.

The abstracts (see full list below) highlight Prometheus' 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 and include novel data regarding the newly available PROMETHEUS® Anser™ ADA test, which measures drug (adalimumab) and drug antibody levels among IBD patients who have lost response to adalimumab (ADA). "We are proud to expand our line of novel assays that target the biologic agents used to treat a variety of autoimmune diseases," said Tony Yost, Chief Commercial Officer of Prometheus. "Our commitment to advancing personalized medicine for gastroenterologists, patients and healthcare providers is ongoing and continues to be validated in the clinical setting."

In one abstract, Fernando S Velayos et al., report a novel correlation between antibodies to adalimumab (ATA) and elevated C-reactive protein (CRP) concentrations that suggests ATA may be a more critical variable than drug concentration levels in targeting clinical response. ATA and serum drug levels were measured using the PROMETHEUS® Anser™ ADA test among 54 IBD patients receiving adalimumab. Drug concentration was detected in 90.7% of the samples, and detectable ATA was present in 22.2%. Serum ADA concentrations of ≤ 5 mcg/ml were associated with an elevated CRP (p=0.001). Detectable ATA was also associated with an elevated CRP, independent of drug concentration (p=0.002).

"Our study showed that antibodies to adalimumab are more prevalent than has been reported in some clinical trials," said Fernando S Velayos, MD, MPH, associate professor in the Department of Medicine and Center for Crohn's and Colitis at the University of California, San Francisco. "A better understanding of and the ability to detect the presence of these antibodies enhances our ability to more efficiently manage the loss of treatment response in our IBD patients using adalimumab."

Oral presentations:

- Prevalence of antibodies to adalimumab (ATA) and significance of ATA/drug concentration on CRP and symptoms in unselected IBD patients (#490) in ROOM 109A, Fernando S Velayos et al, May 19 (4:00-4:15 pm EDT)

- Early trough levels and antidrug antibodies predict safety and success of restarting infliximab after a long drug holiday (#492) in ROOM 109A, Felip Baert et al, May 19 (4:30-5:30 pm EDT)

- Preoperative serum biologic levels do NOT impact postoperative outcomes in ulcerative colitis (#1010) in ROOM 109A, Cheryl Lau et al, May 21 (3:00-3:15 pm EDT)

- Higher preoperative serum biologic levels are associated with postoperative complications in CD patients (#1011) in ROOM 109A, Cheryl Lau et al, May 21 (3:15-3:30 pm EDT)
Serological and inflammatory IBD marker prevalence as function of age in a large cohort of patients presenting IBD-like gastrointestinal symptoms (#1029) in ROOM 109A, Scott Plevy et al, May 21 (4:30-4:45 pm EDT)

**Poster presentations:**

- Mechanisms of loss of response to adalimumab in Crohn's Disease (TU1148), May 21
- Serum adalimumab levels and antibodies correlate with endoscopic intestinal inflammation and inflammatory markers in patients with inflammatory bowel disease (TU1147), May 21
- Serum adalimumab and immunogenicity in IBD patients after 80mg bi-weekly maintenance therapy (TU1135), May 21
- Characterization of neutralizing anti-drug antibody response in patients with loss of response to anti-TNF therapy (SU1172), May 19
- Utility of homogenous mobility shift assay for the measurement of protein therapeutics in serum (SU1162), May 19
- Low dose infliximab for prevention of postoperative recurrence of Crohn's disease: long term follow-up and impact of infliximab trough levels and antibodies to infliximab (TU1155), May 21
- Secondary infliximab treatment failure in Crohn's disease: therapeutic implications of measuring drug and anti-drug antibodies by three different binding assays (TU1142), May 21
- A multi-center observational study in community gastroenterology practices evaluating the clinical usage of testing for serum levels of infliximab and antibodies to infliximab (SU1192), May 19
- Association of serum infliximab and antibodies to infliximab to long-term clinical outcomes and mucosal healing in Crohn's disease (TU1150), May 21
- Comparison of early measurement of infliximab and antibodies-to-infliximab serum levels with standard trough analysis (TU1164), May 21
- Serological and genetic markers as predictors of complicated disease in patients with Crohn's disease (MO1322), May 20
- Genetic variants and markers of inflammation help to identify IBD patients with low serology (SU1169), May 19
- Association of a panel of anti-microbial antibodies with disease behavior and responses to anti-TNF therapy in a cohort of patients with ulcerative colitis (MO1324), May 20

**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.

**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 wholly-owned subsidiary of Nestlé, intends to spearhead the development of science-based personalised nutritional solutions. Building on its core HealthCare Nutrition business, the company has ambitions to address chronic conditions in the area of Gastrointestinal Health, Metabolic Health and Brain Health. 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. Nestlé Health Science employs around 3,000 people worldwide and has its headquarters in Lutry, Switzerland. For more information, please visit www.nestlehealthscience.com.

About Digestive Disease Week
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 (AASLD), the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy (ASGE) and the Society for Surgery of the Alimentary Tract (SSAT), DDW takes place May 18 – 21, 2013, at the Orange County Convention Center, FL. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. More information can be found at www.ddw.org.

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