



PROMETHEUS[®]
Therapeutics & Diagnostics

For the person in every patient

PROMETHEUS LAUNCHES NEW ADALIMUMAB DRUG AND ANTIBODY LEVELS MONITORING TEST

– PROMETHEUS[®] Anser[™] ADA designed to help identify potential causes for loss of treatment response among IBD patients using adalimumab –

San Diego, April 30, 2013 – Prometheus Laboratories Inc., a specialty pharmaceutical and diagnostic company, announced today the US market launch of its proprietary new test, PROMETHEUS[®] Anser[™] ADA. This novel test measures drug (adalimumab) and drug antibody levels in one serum sample in inflammatory bowel disease (IBD) patients using adalimumab (ADA) – helping physicians identify potential causes for loss of treatment response and thus help guide patient management decisions. PROMETHEUS Anser ADA, which utilizes Prometheus’ proprietary homogenous mobility shift assay, follows the July 2012 introduction of PROMETHEUS Anser IFX to further expand the line of tests that target biologic agents being used to treat a variety of autoimmune diseases.

The Crohn’s and Colitis Foundation of America estimates that approximately 1.4 million Americans suffer from IBD. Many of these patients will use a biologic treatment like adalimumab to manage and control the symptoms of their disease. Over time, however, these biologic agents may lose their effectiveness, resulting in increased disease activity and high discontinuation rates. This loss of treatment response is typically the result of: (1) insufficient drug levels, or (2) the development of antibodies to the biologic agent itself.

Recent clinical studies suggest that as many as 44 percent of IBD patients who have lost response to adalimumab have antibodies to the drug.¹ If a patient loses treatment response to ADA, the most common first step for physicians is dose escalation, however depending on the mechanism of the loss of response, this may result in exposure of the patient to unneeded high drug doses and unnecessary expense.

“PROMETHEUS Anser ADA marks the latest milestone in our ongoing commitment to developing diagnostics to help guide personalized treatment decisions for gastroenterologists, patients and healthcare providers,” said Anthony Yost, Chief Commercial Officer of Prometheus. “As the gastrointestinal healthcare community continues to further understand the long-term use of biologic agents in treating diseases like IBD, the need for comprehensive diagnostic tests like PROMETHEUS Anser ADA and PROMETHEUS Anser IFX becomes more critical, as does the value these novel assays offer in terms of time and expense saved when response to adalimumab or infliximab is lost.”

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.

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About Adalimumab

Adalimumab is a fully human monoclonal antibody and belongs to a class of drugs called Tumor Necrosis Factor (TNF) blockers. TNF blockers suppress the immune system by blocking the activity of TNF, a substance in the body that can cause inflammation and lead to autoimmune diseases. In addition to being approved for Crohn's disease and ulcerative colitis, adalimumab is also approved for the treatment of other autoimmune diseases such as rheumatoid arthritis, psoriatic arthritis (joint pain associated with psoriasis), and ankylosing spondylitis (arthritis affecting the joints in the spine and the pelvis). The drugs in this class include Humira[®] (adalimumab), Remicade[®] (infliximab), Enbrel[®] (etanercept), Cimzia[®] (certolizumab pegol) and Simponi[®] (golimumab).

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References

1. Shui-Long Wang, et al., Monitoring of adalimumab and antibodies-to-adalimumab levels in patient serum by the homogeneous mobility shift assay. *Journal of Pharmaceutical and Biomedical Analysis* 78– 79 (2013) 39– 44

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.

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