Prometheus Laboratories Announces Collaboration with Celltrion for Anser® Testing

Therapeutic Drug Monitoring Test Validated for Subcutaneous Infliximab

SAN DIEGO, August 26, 2025 /ACCESSWIRE/ — Prometheus Laboratories Inc. ("Prometheus"), a leader in precision healthcare, today announced a collaboration with Celltrion USA, Inc. (“Celltrion USA”) to validate and expand the upper limit of quantitation for Anser® IFX (infliximab) therapeutic drug monitoring (TDM) testing for patients receiving ZYMFENTRA® (infliximab-dyyb). ZYMFENTRA is the only FDA-approved subcutaneous infliximab (IFX) formulation for maintenance treatment in adults with moderately to severely active Crohn’s disease (CD) and ulcerative colitis (UC) following intravenous infliximab.[1]

When dosing is optimized, biologics such as IFX are highly effective for managing CD and UC. Anser IFX testing uses a drug-tolerant homogeneous mobility shift assay (HMSA) to provide clinicians treating these immune-mediated diseases with objective data on drug concentrations and the presence of anti-drug antibodies. This data can guide informed therapeutic decisions to support adequate drug exposure and persistent response, making it a valuable tool for optimizing treatment strategies.

“As pioneers in therapeutic drug monitoring, we’re pleased to extend the validation of our proprietary HMSA platform to subcutaneous infliximab dosing,” shared Patricia Vasquez, President at Prometheus. “This collaboration with Celltrion USA supports gastroenterologists in their efforts to better understand the exposure-response relationship to give patients an improved chance of sustaining disease control and response on this convenient form of at-home treatment for these debilitating diseases.”

Prometheus is the first specialty lab to validate TDM testing for both intravenous and subcutaneous infliximab, supporting the growing demand for at-home treatment options.

“At Celltrion, having developed the world's first biosimilar monoclonal antibody, we remain committed to advancing IBD care through a patient-centered approach, cutting-edge research, and continuous innovation,” stated Thomas Nusbickel, Chief Commercial Officer at Celltrion USA. “IBD patients value the convenience of self-administering their maintenance treatments at home with ZYMFENTRA. This collaboration with Prometheus will support their providers in ensuring optimal drug concentrations and disease monitoring.”

References

1. ZYMFENTRA Prescribing Information.

About Anser

Anser is a proprietary family of homogenous mobility shift assays used to optimize biologic and biosimilar therapy in autoimmune diseases. These tests simultaneously measure biologic drug and anti-drug antibody levels in serum, and are available for therapeutic drug monitoring of adalimumab, infliximab, ustekinumab, vedolizumab and risankizumab. Anser testing was first launched in 2012 and has been cited in over 100 peer-reviewed publications or abstracts. Nearly 480,000 Anser tests have been performed for more than 220,000 unique patients.

About Prometheus Laboratories
Prometheus Laboratories has been a leading specialty clinical laboratory for 30 years. Our robust portfolio of precision medicine tests improves the healthcare journey for individuals with immune-mediated and gastrointestinal diseases by empowering providers to diagnose, treat and help get their patients into remission faster with precision-guided care. For more information, visit the Prometheus website and follow us on LinkedIn or X (formerly Twitter).

About Celltrion USA
Celltrion USA is Celltrion's U.S. subsidiary established in 2018. Headquartered in New Jersey, Celltrion USA is committed to expanding access to innovative biologics to improve care for U.S. patients. Celltrion's portfolio includes FDA-approved biosimilar products in immunology, oncology, hematology, and endocrinology. Celltrion USA will continue to leverage Celltrion's unique heritage in biotechnology, supply chain excellence and best-in-class sales capabilities to improve access to high-quality biopharmaceuticals for U.S. patients. For more information, please visit www.celltrionusa.com and stay updated with our latest news and events on our social media: LinkedIn.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS and MALIGNANCY

SERIOUS INFECTIONS
Patients treated with TNF blockers, including ZYMFENTRA, are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids.

Discontinue ZYMFENTRA if a patient develops a serious infection or sepsis.

Reported infections include:

- Active tuberculosis, including reactivation of latent tuberculosis. Patients with tuberculosis have frequently presented with disseminated or extrapulmonary disease. Test patients for latent tuberculosis before ZYMFENTRA use and during therapy. Initiate treatment for latent infection prior to ZYMFENTRA use.
- Invasive fungal infections, including histoplasmosis, coccidioidomycosis, candidiasis, aspergillosis, blastomycosis, and pneumocystosis. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. Antigen and antibody testing for histoplasmosis may be negative in some patients with active infection. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections who develop severe systemic illness.
- Bacterial, viral and other infections due to opportunistic pathogens, including Legionella and Listeria.

Carefully consider the risks and benefits of treatment with ZYMFENTRA prior to initiating therapy in patients with chronic or recurrent infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with ZYMFENTRA, including the possible development of tuberculosis in patients who tested negative for latent tuberculosis infection prior to initiating therapy.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers, including infliximab products.

Postmarketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers, including infliximab products. These cases have had a very aggressive disease course and have been fatal. Almost all patients had received treatment with azathioprine or 6-mercaptopurine concomitantly with a TNF blocker at or prior to diagnosis. The majority of reported cases have occurred in patients with Crohn's disease or ulcerative colitis and most were in young adult males.

Contraindications

- ZYMFENTRA is contraindicated in patients with a history of a severe hypersensitivity reaction to infliximab-dyyb, other infliximab products, any of the inactive ingredients in ZYMFENTRA, or any murine proteins. Reactions have included anaphylaxis.

Warnings and Precautions

- ***Serious infections:*** Avoid in patients with active infection. If infection develops, conduct a prompt/complete diagnostic workup appropriate for immunocompromised patients and initiate antimicrobials. If systemic illness develops in patients who reside or travel to regions where mycoses are endemic, consider empiric antifungals.
- ***Malignancies:*** Malignancies, including lymphoma, were greater in TNF-blocker-treated patients. Consider the higher risk of hepatosplenic T-cell lymphoma (HSTCL) with combination therapy versus increased risk of immunogenicity and hypersensitivity reactions with monotherapy.
- ***Hepatitis B virus (HBV) reactivation:*** Test for HBV infection before starting treatment. Monitor HBV carriers during and several months after therapy for active HBV infection. If reactivation occurs, stop ZYMFENTRA and begin anti-viral therapy.
- ***Hepatotoxicity:*** Severe hepatic reactions, some fatal or necessitating liver transplantation have occurred in patients receiving infliximab products. Monitor hepatic enzymes and liver function tests every 3-4 months during treatment; investigate liver enzyme elevations and interrupt treatment if drug-induced liver injury is suspected. Instruct patients to seek immediate medical attention if symptoms develop.
- ***Congestive heart failure (CHF):*** New onset or worsening symptoms may occur. Avoid in patients with CHF. Monitor for new/worsening symptoms when administering ZYMFENTRA.
- ***Hematologic reactions:*** Advise patients to seek immediate medical attention if signs and symptoms of cytopenia develop; consider stopping if significant hematologic abnormalities develop.
- ***Hypersensitivity and other administration reactions:*** Serious hypersensitivity reactions, including anaphylaxis have occurred with intravenous formulations of infliximab; discontinue

ZYMFENTRA and start appropriate therapy.

- ***Neurologic reactions:*** Exacerbation or new onset CNS demyelinating disorders may occur; consider discontinuation of ZYMFENTRA.
- ***Risk of infection with concurrent administration of other biological products:*** Concurrent use with other immunosuppressive biologics may increase risk of infection.
- ***Risk of additive immunosuppressive effects from prior biological products:*** Consider the half-life and mode of action of prior biologics.
- ***Autoimmunity:*** Formation of autoantibodies and development of lupus-like syndrome may occur; discontinue ZYMFENTRA if symptoms develop.
- ***Vaccinations and use of live vaccines/therapeutic infectious agents:*** Prior to initiating ZYMFENTRA bring patients up to date with vaccinations. Live vaccines or therapeutic infectious agents should not be given with ZYMFENTRA. A 6-month waiting period following birth is recommended before the administration of live vaccines to infants exposed *in utero* to infliximab.

Common Adverse Reactions (≥3%)

- ***Ulcerative Colitis:*** COVID-19, anemia, arthralgia, injection site reaction, increased alanine aminotransferase, and abdominal pain.
- ***Crohn's Disease:*** COVID-19, headache, upper respiratory tract infection, injection site reaction, diarrhea, increased blood creatine phosphokinase, arthralgia, increased alanine aminotransferase, hypertension, urinary tract infection, neutropenia, dizziness, and leukopenia.

Drug Interactions

- Concurrent use with immunosuppressive biologics used to treat UC and CD is not recommended due to risk of infection.
- Formation of CYP450 enzymes may be suppressed by increased levels of cytokines during chronic inflammation. ZYMFENTRA could normalize the formation of CYP450 enzymes potentially resulting in decreased exposure of CYP450 substrates and requiring dose adjustments.

Please see full Prescribing Information, including **BOXED WARNING**.

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