Our Newsroom

At Accord BioPharma, we're never content with the status quo.

FDA Approves IMMGOLIS™ (golimumab-sldi) and IMMGOLIS INTRI™ (golimumab-sldi), First Biosimilars to Simponi® (golimumab) and Simponi Aria® (golimumab); Accord BioPharma to Lead U.S. Commercialization

May 18, 2026, 12:05 ET

- *FDA approval of IMMGOLIS and IMMGOLIS INTRI breaks new ground in patient access, marking the first biosimilar option to golimumab biologic therapy in the U.S.*
- *IMMGOLIS is approved for the treatment of adults with moderately to severely active rheumatoid arthritis (RA), in combination with methotrexate, and moderately to severely active ulcerative colitis (UC), while IMMGOLIS INTRI is approved for the treatment of adults with moderately to severely active RA in combination with methotrexate*
- *Accord BioPharma expands growing biosimilar portfolio as exclusive U.S. commercialization partner for IMMGOLIS and IMMGOLIS INTRI*

RALEIGH, N.C., May 18, 2026 /PRNewswire/ — Accord BioPharma, Inc., the U.S. specialty division of Intas Pharmaceuticals, Ltd. ("Intas Pharmaceuticals"), focused on the development of oncology, immunology and central nervous system (CNS) therapies, announced today that the U.S. Food and Drug Administration (FDA) has approved IMMGOLIS™ (golimumab-sldi), a biosimilar to Simponi® (golimumab), for the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate, and adult patients with moderately to severely active ulcerative colitis (UC). The FDA also approved IMMGOLIS INTRI™ (golimumab-sldi), a biosimilar to Simponi Aria® (golimumab), for the treatment of adults with moderately to severely active RA in combination with methotrexate. Simponi,

Janssen Biotech, Inc.
Exhibit 2050
Accord v. Janssen
IPR2026-00256, -00257, -00258, -00259
Ex. 2050-001

also approved IMMGOLIS INTRI™ (golimumab-sldi), a biosimilar to Simponi Aria® (golimumab), for the treatment of adults with moderately to severely active RA in combination with methotrexate. Simponi, Simponi Aria, IMMGOLIS, and IMMGOLIS INTRI each carry a Boxed Warning for Serious Infections and Malignancy; please see the Boxed Warnings for IMMGOLIS and IMMGOLIS INTRI below.[1,2]

IMMGOLIS and IMMGOLIS INTRI are the first FDA-approved golimumab biosimilars, and will be commercialized in the United States exclusively by Accord BioPharma. IMMGOLIS and IMMGOLIS INTRI were designated interchangeable by the FDA for rheumatoid arthritis and ulcerative colitis.

For the first time, patients with rheumatoid arthritis and ulcerative colitis will have an FDA-approved biosimilar option for both Simponi and Simponi Aria, a pivotal step toward broader access to biologic therapy. As the exclusive U.S. commercialization partner for IMMGOLIS and IMMGOLIS INTRI, Accord BioPharma plans to make these products available to patients and providers in Q4 2026.

"As the first golimumab biosimilars approved in the U.S., IMMGOLIS and IMMGOLIS INTRI represent a meaningful new option for people in the U.S. who are living with the chronic, debilitating autoimmune conditions associated with moderately to severely active rheumatoid arthritis or ulcerative colitis and need more affordable medication," said Chrys Kokino, President of Accord North America. "This approval answers a clear demand in the U.S. market and helps advance our ambitious goal to bring 20 biosimilars to market by the year 2030."

"Biosimilars are one of the most powerful tools we have to improve affordability and access across the U.S. healthcare system," said Binish Chudgar, Chairman and Managing Director of Intas Pharmaceuticals." With Accord BioPharma's deep expertise, dedicated team, and bold vision, the team is well positioned to bring this first-of-its-kind product to U.S. patients and providers later this year."

IMMGOLIS and IMMGOLIS INTRI were developed by Bio-Thera Solutions, which will maintain responsibility for manufacturing and product supply.

IMMGOLIS is not indicated for and should not be used or administered for the treatment of adult patients with active psoriatic arthritis (PsA) alone, or in combination with methotrexate; adult patients with active ankylosing spondylitis (AS); or pediatric patients weighing at least 15 kg with moderately to severely active ulcerative colitis (UC).

IMMGOLIS INTRI is not indicated for and should not be used or administered for the treatment of Active Psoriatic Arthritis (PsA) in patients 2 years of age and older; adult patients with active Ankylosing Spondylitis (AS); or Active polyarticular Juvenile Idiopathic Arthritis (pJIA) in patients 2 years of age and older.

IMPORTANT SAFETY INFORMATION

IMMGOLIS (golimumab-sldi) injection, for subcutaneous use
IMMGOLIS (golimumab-sldi) is a biosimilar* to SIMPONI® (golimumab)

IMMGOLIS INTRI (golimumab-sldi) injection, for intravenous use
IMMGOLIS INTRI (golimumab-sldi) is a biosimilar* to SIMPONI ARIA® (golimumab)

BOXED WARNING AND IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS INFECTIONS and MALIGNANCY

WARNING: SERIOUS INFECTIONS and MALIGNANCY

See full prescribing information for complete boxed warning

- **Serious infections leading to hospitalization or death including tuberculosis (TB), bacterial sepsis, invasive fungal (such as histoplasmosis), and other opportunistic infections have occurred in patients receiving golimumab products.**
- **Discontinue IMMGOLIS/IMMGOLIS INTRI if a patient develops a serious infection or sepsis.**
- **Perform test for latent TB; if positive, start treatment for TB prior to starting IMMGOLIS/IMMGOLIS INTRI.**
- **Monitor all patients for active TB during treatment, even if initial latent TB test is negative.**
- **Lymphoma and other malignancies, some fatal, have been reported in children. and adolescent patients treated with TNF blockers, of which IMMGOLIS/IMMGOLIS INTRI is a member.**

Serious Infections: Patients treated with golimumab products are at increased risk for developing serious infections involving various organ systems and sites that may lead to hospitalization or death. Discontinue IMMGOLIS/IMMGOLIS INTRI if a patient develops a serious infection.

Opportunistic infections due to bacterial, mycobacterial, invasive fungal, viral, or parasitic organisms including aspergillosis, blastomycosis, candidiasis, coccidioidomycosis, histoplasmosis, legionellosis, listeriosis, pneumocystosis, and tuberculosis have been reported with TNF-blockers, of which IMMGOLIS/IMMGOLIS INTRI is a member. Patients with histoplasmosis or other invasive fungal infections may present with disseminated, rather than localized, disease. The concomitant use of a TNF-blocker and abatacept or anakinra was associated with a higher risk of serious infections; therefore, the concomitant use of IMMGOLIS/IMMGOLIS INTRI and these biologic products is not recommended.

Treatment with IMMGOLIS/IMMGOLIS INTRI should not be initiated in patients with an active infection, including clinically important localized infections. Patients greater than 65 years of age, patients with co-morbid conditions and/or patients taking concomitant immunosuppressants such as corticosteroids or methotrexate may be at greater risk of infection.

Monitoring

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with IMMGOLIS/IMMGOLIS INTRI. Discontinue IMMGOLIS/IMMGOLIS INTRI if a patient develops a serious infection, an opportunistic infection, or sepsis. For a patient who develops a new infection during treatment with IMMGOLIS/IMMGOLIS INTRI, perform a prompt and complete diagnostic workup appropriate for an immunocompromised patient, initiate appropriate antimicrobial therapy, and closely monitor them.

Tuberculosis

Cases of reactivation of tuberculosis or new tuberculosis infections have been observed in patients receiving TNF-blockers, including patients who have previously received treatment for latent or active tuberculosis. Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating IMMGOLIS/IMMGOLIS INTRI and periodically during therapy. Consultation with a physician with expertise in the treatment of tuberculosis is recommended to aid in the decision whether initiating anti-tuberculosis therapy is appropriate for an individual patient.

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Invasive Fungal Infections

If patients develop a serious systemic illness and they reside or travel in regions where mycoses are endemic, consider invasive fungal infection in the differential diagnosis. Consider empiric anti-fungal therapy in patients at risk for invasive fungal infections and consultation with a physician with expertise in the diagnosis and treatment of invasive fungal infections.

Hepatitis B Reactivation

The use of TNF blockers, of which IMMGOLIS/IMMGOLIS INTRI is a member, has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic HBV carriers. In some instances, HBV reactivation occurring in conjunction with TNF-blocker therapy has been fatal. The majority of these reports have occurred in patients who received concomitant immunosuppressants.

All patients should be tested for HBV before initiating TNF-blocker therapy. For patients who test positive for hepatitis B surface antigen, consult a physician with expertise in the treatment of hepatitis B before initiating TNF-blocker therapy. Exercise caution when prescribing IMMGOLIS/IMMGOLIS INTRI for patients identified as carriers of HBV and closely monitor for active HBV infection during and following termination of therapy. Discontinue IMMGOLIS/IMMGOLIS INTRI in patients who develop HBV reactivation and initiate antiviral therapy with appropriate supportive treatment. Exercise caution when considering resumption of IMMGOLIS/IMMGOLIS INTRI and monitor patients closely.

Malignancies: Malignancies, some fatal, have been reported among children, adolescents, and young adults who received treatment with TNF-blocking agents (initiation of therapy ≤ 18 years of age), of which IMMGOLIS/IMMGOLIS INTRI is a member. Most of the patients were receiving concomitant immunosuppressants. The risks and benefits of IMMGOLIS/IMMGOLIS INTRI should be considered prior to initiating therapy in patients with a known malignancy other than a successfully treated nonmelanoma skin cancer (NMSC) or when considering continuing a TNF-blocker in patients who develop a malignancy.

Melanoma and Merkel cell carcinoma have been reported in patients treated with TNF-blocking agents, including golimumab products. Periodic skin examination is recommended for all patients, particularly those with risk factors for skin cancer.

Congestive Heart Failure (CHF): Cases of worsening CHF and new onset CHF have been reported with TNF blockers, including golimumab products. Some cases had a fatal outcome. Patients with CHF should be closely monitored during therapy. Discontinue IMMGOLIS/IMMGOLIS INTRI if new or worsening symptoms of CHF appear.

Demyelinating Disorders: Use of TNF blockers, of which IMMGOLIS/IMMGOLIS INTRI is a member, has been associated with rare cases of new onset or exacerbation of central nervous system demyelinating disorders, including multiple sclerosis, and peripheral demyelinating disorders, including Guillain-Barré syndrome. Prescribers should exercise caution in considering the use of IMMGOLIS/IMMGOLIS INTRI in patients with central or peripheral nervous system demyelinating disorders. Consider discontinuation of IMMGOLIS/IMMGOLIS INTRI if these disorders develop.

Autoimmunity: Treatment with TNF blockers, including IMMGOLIS/IMMGOLIS INTRI, may result in the formation of antinuclear antibodies and rarely, in the development of a lupus-like syndrome. If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with

Autoimmunity: Treatment with TNF blockers, including IMMGOLIS/IMMGOLIS INTRI, may result in the formation of antinuclear antibodies and rarely, in the development of a lupus-like syndrome. If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with IMMGOLIS/IMMGOLIS INTRI, treatment should be discontinued.

Use with Other Drugs: The concomitant use of a TNF blocker and abatacept or anakinra was associated with a higher risk of serious infections; therefore, the use of IMMGOLIS/IMMGOLIS INTRI in combination with these products is not recommended. Care should be taken when switching between biological disease modifying antirheumatic drugs since overlapping biological activity may further increase the risk of infection.

Upon initiation or discontinuation of IMMGOLIS/IMMGOLIS INTRI in patients being treated with CYP450 substrates with a narrow therapeutic index, monitoring of the effect (e.g., warfarin) or drug concentration (e.g., cyclosporine or theophylline) is recommended and the individual dose of the drug product may be adjusted as needed.

Hematologic Cytopenias: There have been reports of pancytopenia, leukopenia, neutropenia, agranulocytosis, aplastic anemia, and thrombocytopenia in patients receiving golimumab products. Exercise caution when using TNF blockers, including IMMGOLIS/IMMGOLIS INTRI, in patients who have or have had significant cytopenias.

Vaccinations/Therapeutic Infectious Agents: Patients treated with IMMGOLIS/IMMGOLIS INTRI may receive vaccinations, except for live vaccines. If possible, it is recommended that prior to initiating therapy with IMMGOLIS/IMMGOLIS INTRI, patients be brought up to date with all immunizations in agreement with current immunization guidelines.

It is recommended that therapeutic infectious agents not be given concurrently with IMMGOLIS/IMMGOLIS INTRI due to the possibility of clinical infections, including disseminated infections.

Hypersensitivity Reactions: Serious systemic hypersensitivity reactions (including anaphylaxis) have been reported following golimumab product administration. Some reactions occurred after the first administration of golimumab products. If an anaphylactic or other serious allergic reaction occurs, discontinue IMMGOLIS/IMMGOLIS INTRI and institute appropriate therapy.

Most Common Adverse Reactions: Most common adverse reactions with IMMGOLIS in adults (incidence > 5%) are upper respiratory tract infection, nasopharyngitis, and injection site reactions.

Most common adverse reactions with IMMGOLIS INTRI (incidence ≥ 3%) are: upper respiratory tract infection, alanine aminotransferase increased, viral infection, aspartate aminotransferase increased, neutrophil count decreased, bronchitis, hypertension, and rash.

INDICATIONS

IMMGOLIS is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate
- adult patients with moderately to severely active ulcerative colitis (UC)

IMMGOLIS INTRI is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

IMMGOLIS INTRI is a tumor necrosis factor (TNF) blocker indicated for the treatment of:

- adult patients with moderately to severely active rheumatoid arthritis (RA) in combination with methotrexate

To report SUSPECTED ADVERSE REACTIONS, contact Accord BioPharma Inc at 1-866-941-7875 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

IMMGOLIS (golimumab-sldi) injection is supplied in a 50 mg/0.5 mL and 100 mg/mL single-dose prefilled syringe.

IMMGOLIS INTRI (golimumab-sldi) injection is supplied in a 50 mg/4 mL (12.5 mg/mL) solution in a single-dose vial.

Click here for full Prescribing Information for IMMGOLIS.

Click here for full Prescribing Information for IMMGOLIS INTRI.

SIMPONI and SIMPONI ARIA® (golimumab)are registered trademarks of Johnson & Johnson and its affiliates.

About Accord BioPharma

Accord BioPharma, Inc., the U.S. specialty division of Intas Pharmaceuticals, seeks to provide affordable, accessible, patient-centric therapies in oncology, immunology, and central nervous system (CNS) therapies. With a focus on improving the patient experience, Accord BioPharma goes beyond the biology of medicine to see disease from the patients' perspective and develop high-quality therapies that impact patients' lives. The company is advancing an ambitious pipeline with the goal of bringing 20 biosimilars to the U.S. market by 2030.

The company's current commercial portfolio includes the full UDENYCA® (pegfilgrastim-cbqv) franchise, including the UDENYCA prefilled syringe, autoinjector, and on-body injector, IMULDOSA® (ustekinumab-srlf), a biosimilar to Stelara® (ustekinumab), HERCESSI™ (trastuzumab-strf), a biosimilar to Herceptin® (trastuzumab), and CAMCEVI® (leuprolide) 42 mg injectable emulsion. Please refer to the Important Safety Information and full Prescribing Information for these products, and to the Boxed Warning for HERCESSI.

Accord BioPharma has received FDA approval on five additional products: CAMCEVI® (leuprolide) ETM (every three months), OSVYRTI® (denosumab-desu) – a biosimilar to PROLIA® (denosumab), JUBEREQ® (denosumab-desu) – a biosimilar to XGEVA® (denosumab), FILKRI™ (filgrastim-laha) – a biosimilar to NEUPOGEN® (filgrastim), and ENNUMO™ (pegfilgrastim-pccg) – a biosimilar to NEULASTA® (pegfilgrastim). The company plans to announce the commercial launch of these products later this year. Please refer to the Important Safety Information and full Prescribing Information for these products, and to the Boxed Warning for OSVYRTI. For more information, visit AccordBioPharma.com.

About Bio-Thera Solutions

Bio-Thera Solutions, Ltd., a leading innovative, global biopharmaceutical company in Guangzhou, China, is dedicated to researching and developing novel therapeutics for the treatment of cancer, autoimmune, cardiovascular, eye diseases, and other severe unmet medical needs, as well as biosimilars for existing, branded biologics to treat a range of cancer and autoimmune diseases. For more information, please

cardiovascular, eye diseases, and other severe unmet medical needs, as well as biosimilars for existing, branded biologics to treat a range of cancer and autoimmune diseases. For more information, please visit https://www.bio-thera.com/

References:

1. IMMGOLIS (golimumab-sldi) Full Prescribing Information. Accord BioPharma.
2. IMMGOLIS INTRI (golimumab-sldi) Full Prescribing Information. Accord BioPharma.

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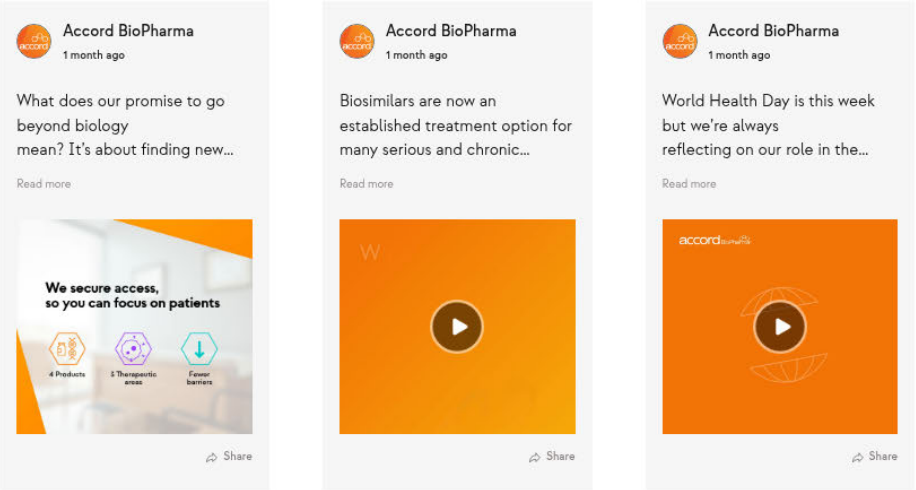

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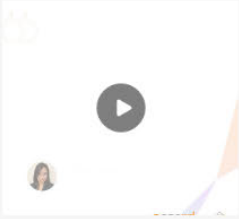

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