

After Five Years of Successful Experience Internationally, Biocon Biologics' HULIO® Biosimilar to Humira®, Now Available in the United States

BRIDGEWATER, New Jersey and BENGALURU, Karnataka, India, July 3, 2023

Biocon Biologics Ltd (BBL), a subsidiary of Biocon Ltd, today announced that HULIO® (adalimumab-fkjp) injection, a biosimilar to Humira® (adalimumab), is now available to patients in the United States after five years of experience in Europe and two years in Canada.

Biocon Biologics, which [recently announced](#) its acquisition of Viatris' global biosimilars business, has secured multiple biosimilar approvals in the U.S., Europe, and over 100 countries across the globe. With the acquisition of Viatris' biosimilars business, Biocon Biologics can now help provide patients and healthcare professionals with more accessible and affordable treatment options in diabetes, cancer and immunology therapeutic areas.

"The launch of HULIO®, our biosimilar adalimumab, in the United States is an important milestone for Biocon Biologics as it expands our well-known biosimilar product offering to patients in the United States. This launch builds on our strong presence in oncology and diabetes and re-affirms our commitment to enabling affordable access to biologics," said **Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd.**

"Biocon Biologics is pleased to make HULIO®, a patient-friendly, 2-click, prefilled pen available in the United States for patients with certain inflammatory diseases. There are no buttons to push. Patients remove the cap and push the device against their skin to trigger their injection. Designed and built with patients in mind, healthcare professionals and patients don't have to miss a beat with HULIO®; they simply, 'Click, Click, Go,'" said **Mathew Erick, Chief Commercial Officer of Advanced Markets, Biocon Biologics Ltd.**

See [Full Prescribing Information](#) including BOXED WARNING regarding Serious Infections and Malignancy.

To provide broad access for patients, Biocon Biologics is offering two options to health plans and pharmacy benefit managers. HULIO® is available at a list price (Wholesale Acquisition Cost) of 5% below the current Humira list price. Adalimumab-fkjp is also available at a list price of approximately 85% below the current Humira list price.

HULIO® meets the rigorous biosimilar approval standards of the FDA. Like Humira, HULIO® is citrate-free and is made without natural rubber latex (to help reduce hypersensitivity reactions). Biocon Biologics also offers HULIO360, a robust patient support program, which includes benefits

verification and prior authorization support, copay assistance, a bridge program for eligible patients, and at-home nurse injection training. To learn more, visit www.huliohcp.com.

HULIO is a registered trademark of Fujifilm Kyowa Kirin Biologics Co., Ltd., licensed to the Viatrix Companies. Effective November 29, 2022, Viatrix completed the sale of substantially all of its biosimilars portfolio (including related product trademarks) to Biocon Biologics Limited and its subsidiaries (“Biocon”) and the relevant marketing authorizations are in the process of being transferred. Viatrix Inc. and its subsidiaries (“Viatrix”) are not affiliates of Biocon but are providing certain transition services to Biocon following the transaction completion date, such as operating websites (including this site) relating to the biosimilars portfolio on Biocon’s behalf.

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IMPORTANT SAFETY INFORMATION AND INDICATIONS

WARNING: SERIOUS INFECTIONS AND MALIGNANCY SERIOUS INFECTIONS

Patients treated with adalimumab products including HULIO 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 HULIO if a patient develops a serious infection or sepsis. Reported infections include:

- **Active tuberculosis (TB), including reactivation of latent TB. Patients with TB have frequently presented with disseminated or extrapulmonary disease. Test patients for latent TB before HULIO use and during therapy. Initiate treatment for latent TB prior to HULIO 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 HULIO prior to initiating therapy in patients:

1) With chronic or recurrent infection, 2) who have been exposed to TB, 3) with a history of opportunistic infection, 4) who resided in or traveled in regions where mycoses are endemic, 5) with underlying conditions that may predispose them to infection. Monitor patients closely for the development of signs and symptoms of infection during and after treatment with HULIO, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

- Do not start HULIO during an active infection, including localized infections.
- Patients older than 65 years, patients with co-morbid conditions, and/or patients taking concomitant immunosuppressants may be at greater risk of infection.
- If an infection develops, monitor carefully, and initiate appropriate therapy.
- Drug interactions with biologic products: A higher rate of serious infections has been observed in RA

patients treated with rituximab who received subsequent treatment with a TNF blocker. An increased risk of serious infections has been seen with the combination of TNF blockers with anakinra or abatacept, with no demonstrated added benefit in patients with RA. Concomitant administration of HULIO with other biologic DMARDs (e.g., anakinra or abatacept) or other TNF blockers is not recommended based on the possible increased risk for infections and other potential pharmacological interactions.

MALIGNANCY

Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF blockers including adalimumab products. Post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL), a rare type of T-cell lymphoma, have been reported in patients treated with TNF blockers including adalimumab products. These cases have had a very aggressive disease course and have been fatal. The majority of reported TNF blocker cases have occurred in patients with Crohn's disease or ulcerative colitis and the majority were in adolescent and young adult males. Almost all these patients had received treatment with azathioprine or 6-mercaptopurine (6-MP) concomitantly with a TNF blocker at or prior to diagnosis. It is uncertain whether the occurrence of HSTCL is related to use of a TNF blocker or a TNF blocker in combination with these other immunosuppressants.

- Consider the risks and benefits of HULIO treatment prior to initiating or continuing therapy in a patient with known malignancy.
- In clinical trials, more cases of malignancies were observed among HUMIRA-treated patients compared to control patients.
- Non-melanoma skin cancer (NMSC) was reported during clinical trials for HUMIRA-treated patients. Examine all patients, particularly those with a history of prolonged immunosuppressant or PUVA therapy, for the presence of NMSC prior to and during treatment with HULIO.
- In HULIO clinical trials, there was an approximate 3-fold higher rate of lymphoma than expected in the general U.S. population. Patients with chronic inflammatory diseases, particularly those with highly active disease and/or chronic exposure to immunosuppressant therapies, may be at higher risk of lymphoma than the general population, even in the absence of TNF blockers.
- Post-marketing cases of acute and chronic leukemia were reported with TNF blocker use. Approximately half of the post-marketing cases of malignancies in children, adolescents, and young adults receiving TNF blockers were lymphomas; other cases included rare malignancies associated with immunosuppression and malignancies not usually observed in children and adolescents.

HYPERSENSITIVITY

- Anaphylaxis and angioneurotic edema have been reported following administration of adalimumab products. If a serious allergic reaction occurs, stop HULIO and institute appropriate therapy.

HEPATITIS B VIRUS REACTIVATION

- Use of TNF blockers, including HULIO, may increase the risk of reactivation of hepatitis B virus (HBV) in patients who are chronic carriers. Some cases have been fatal.
- Evaluate patients at risk for HBV infection for prior evidence of HBV infection before initiating TNF blocker therapy.
- Exercise caution in patients who are carriers of HBV and monitor them during and after HULIO treatment.
- Discontinue HULIO and begin antiviral therapy in patients who develop HBV reactivation. Exercise caution when resuming HULIO after HBV treatment.

NEUROLOGIC REACTIONS

- TNF blockers, including adalimumab products, have been associated with rare cases of new onset or exacerbation of central nervous system and peripheral demyelinating diseases, including multiple sclerosis, optic neuritis, and Guillain-Barré syndrome.
- Exercise caution when considering HULIO for patients with these disorders; discontinuation of HULIO should be considered if any of these disorders develop.
- There is a known association between intermediate uveitis and central demyelinating disorders.

HEMATOLOGIC REACTIONS

- Rare reports of pancytopenia, including aplastic anemia, have been reported with TNF blockers. Medically significant cytopenia has been infrequently reported with adalimumab products.
- Consider stopping HULIO if significant hematologic abnormalities occur.

CONGESTIVE HEART FAILURE

- Worsening and new onset congestive heart failure (CHF) has been reported with TNF blockers. Cases of worsening CHF have been observed with adalimumab products; exercise caution and monitor carefully.

AUTOIMMUNITY

- Treatment with adalimumab products may result in the formation of autoantibodies and, rarely, in development of a lupus-like syndrome. Discontinue treatment if symptoms of a lupus-like syndrome develop.

IMMUNIZATIONS

- Patients on HULIO should not receive live vaccines.
- Pediatric patients, if possible, should be brought up to date with all immunizations before initiating HULIO therapy.
- Adalimumab is actively transferred across the placenta during the third trimester of pregnancy and may affect immune response in the in utero exposed infant. The safety of administering live or live-attenuated vaccines in infants exposed to HULIO in utero is unknown. Risks and benefits should be considered prior to vaccinating (live or live-attenuated) exposed infants.

ADVERSE REACTIONS

- The most common adverse reactions in adalimumab clinical trials (>10%) were: infections (e.g., upper respiratory, sinusitis), injection site reactions, headache, and rash.

INDICATIONS

- **Rheumatoid Arthritis:** HULIO is indicated, alone or in combination with methotrexate or other non-biologic DMARDs, for reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis.
- **Juvenile Idiopathic Arthritis:** HULIO is indicated, alone or in combination with methotrexate, for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older.
- **Psoriatic Arthritis:** HULIO is indicated, alone or in combination with non-biologic DMARDs, for reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical

- function in adult patients with active psoriatic arthritis.
- **Ankylosing Spondylitis:** HULIO is indicated for reducing signs and symptoms in adult patients with active ankylosing spondylitis.
 - **Crohn's Disease:** HULIO is indicated for the treatment of moderately to severely active Crohn's disease in adults and pediatric patients 6 years of age and older.
 - **Ulcerative Colitis:** HULIO is indicated for the treatment of moderately to severely active ulcerative colitis in adults and pediatric patients 5 years of age and older.

Limitations of Use:

The effectiveness of HULIO has not been established in patients who have lost response to or were intolerant to TNF blockers.

- **Plaque Psoriasis:** HULIO is indicated for the treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. HULIO should only be administered to patients who will be closely monitored and have regular follow-up visits with a physician.

Please see [Full Prescribing Information](#) including **BOXED WARNING**.

About Biocon Biologics Limited:

Biocon Biologics Ltd. (BBL), a subsidiary of Biocon Ltd., is a unique, fully integrated, global biosimilars company committed to transforming healthcare and transforming lives by enabling affordable access to high quality biosimilars for millions of patients worldwide. It is leveraging cutting-edge science, innovative tech platforms, global scale manufacturing capabilities and world-class quality systems to lower costs of biological therapeutics while improving healthcare outcomes.

BBL has acquired the global biosimilars business of its long-standing partner Viatrix, which is a historic milestone in its value creation journey. Biocon Biologics has commercialized eight biosimilars in key emerging markets and advanced markets like U.S., EU, Australia, Canada, Japan.

The Company has a pipeline of 20 biosimilar assets across diabetology, oncology, immunology, and other non-communicable diseases. It has many 'firsts' to its credit in the biosimilars industry. As part of its environmental, social and governance (ESG) commitment, BBL is advancing the health of patients, people, and the planet to achieve key UN Sustainable Development Goals (SDGs). Website: www.bioconbiologics.com; Follow us on Twitter: @BioconBiologics for company updates.

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as Generic Formulations in the US, Europe & key emerging markets. It also has a pipeline of promising novel assets in immunotherapy under development. Website: www.biocon.com; Follow-us on Twitter: @bioconlimited for company updates.

Forward-Looking Statements: Biocon

This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our

expectations include, amongst other: general economic and business conditions in India and overseas, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.

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