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Press Release

Bio-Thera Solutions and Hikma Pharmaceuticals announce FDA approval of STARJEMZA® (ustekinumab-hmny) Injection, a biosimilar referencing STELARA® (ustekinumab) Injection

Guangzhou and London – May 27, 2025 – Bio-Thera Solutions, Ltd (688177:SH), a commercial-stage biopharmaceutical company developing a pipeline of biosimilars and innovative assets and Hikma Pharmaceuticals PLC, along with its wholly owned subsidiary Hikma Pharmaceuticals USA Inc. today announced that the U.S. Food and Drug Administration (FDA) has approved STARJEMZA® (ustekinumab-hmny) Injection, a biosimilar referencing Stelara® (ustekinumab) Injection. STARJEMZA® is Bio-Thera's third FDA approved product.

Bio-Thera and Hikma entered into a license and commercialization agreement for STARJEMZA® in August 2021. Under the terms of the agreement, Bio-Thera is responsible for the development and manufacturing of the product. Hikma is responsible for the commercialization of STARJEMZA® in the United States.

"The approval of STARJEMZA® is another significant accomplishment for Bio-Thera, establishing Bio-Thera as a premier global biosimilar developer and manufacturer," said Shengfeng Li, CEO at Bio-Thera. "As our third FDA approved biosimilar, STARJEMZA® demonstrates Bio-Thera's commitment to developing more biosimilars, expanding patient access to important therapies."

"This approval and our partnership with Bio-Thera enables us to strongly enter the U.S. biosimilar market, building on our well-established position as a top-three domestic provider of sterile injectable medicines to U.S. hospitals, healthcare providers, and patients," said Dr. Bill Larkins, President of Hikma Injectables. "Tapping into the robust ongoing growth of the U.S. biosimilar market is a priority for Hikma. We are eager to use our excellent U.S. commercial capabilities to launch this important product and provide it to the many patients who will benefit from using it."

The FDA approval of STARJEMZA®, originally known as BAT2206, was based on a comprehensive analytical, non-clinical, and clinical data package submitted by Bio-Thera to the FDA. Extensive analytical characterization between STARJEMZA® and US and EU Stelara® was conducted on structural, physicochemical, and biological properties to support bio-similarity of STARJEMZA®. A randomized double-blind, single-dose, three-arm, parallel phase I study compared the pharmacokinetics, safety, and immunogenicity of STARJEMZA® with both the US and EU Stelara® in healthy volunteers. A multicenter, randomized, double-blind, parallel-arm, phase III study compared STARJEMZA® with Stelara® for efficacy,

safety, and immunogenicity in patients with moderate to severe plaque psoriasis. The totality of the evidence demonstrated that STARJEMZA® has similar efficacy, safety, immunogenicity, and quality as the reference product ustekinumab.

About STARJEMZA® (ustekinumab-hmny) Injection

STARJEMZA® is a biosimilar to Janssen's Stelara® which is a human monoclonal antibody that inhibits the bioactivity of human IL-12 and IL-23 by preventing shared p40 subunit from binding to the IL-12Rβ1 receptor chain of IL-12 (IL-12Rβ1/β2) and IL-23 (IL-12Rβ1/23R) receptor complexes on the surface of immune cells. IL-12 and IL-23 are involved in inflammatory and immune responses, such as natural killer cell activation, $CD4^+$ T-cell differentiation and following relative cytokines stimulated release. Abnormal regulation of IL-12 and IL-23 have been implicated as important contributors to chronic inflammation, including psoriasis, psoriatic arthritis (PsA), Crohn's disease (CD), and Ulcerative colitis (UC). Neutralizing human IL-12 and IL-23 by STARJEMZA® to prevent the relevant cell signaling in the Th1 or Th17 lineages can effectively block the pathologic processes of these immune disorders.

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. As a leader in next generation antibody discovery and engineering, the company has advanced multiple candidates into late-stage development, including five approved products: QLETLI® (adalimumab) and BETAGRIN® (bevifibatide citrate) Injection in China, STARJEMZA® in the US, and BAT1806/TOFIDENCE™ (tocilizumab) and AVZIVI® (bevacizumab-tnjn) in the US, a/k/a POBEVCY® in EU and China. In addition, the company has more than 20 promising candidates in clinical trials, focusing on immuno-oncology in the post-PD-1 era and targeted therapies such as antibody-drug conjugates (ADCs). For more information, please visit www.bio-thera.com/en/ or follow us on X (@bio_thera_sol) and WeChat (Bio-Thera).

About Hikma Pharmaceuticals

(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB/stable S&P and BBB-/positive Fitch) Hikma helps put better health within reach every day for millions of people around the world. For more than 45 years, we've been creating high-quality medicines and making them accessible to the people who need them. Headquartered in the UK, we are a global company with a local presence across North America, the Middle East and North Africa (MENA) and Europe, and we use our unique insight and expertise to transform cutting-edge science into innovative solutions that transform people's lives. We're committed to our customers, and the people they care for, and by thinking creatively and acting practically, we provide

them with a broad range of branded and non-branded generic medicines. Together, our 9,500 colleagues are helping to shape a healthier world that enriches all our communities. We are a leading licensing partner, and through our venture capital arm, are helping bring innovative health technologies to people around the world. For more information, please visit: www.hikma.com

Cautionary Note Regarding Forward-Looking Statements

This news release contains certain forward-looking statements relating to STARJEMZA®/BAT2206 or the product pipelines in general of Bio-Thera Solutions and Hikma. Readers are strongly cautioned that reliance on any forward-looking statements involves known and unknown risks and uncertainties. The forward-looking statements include, among others, those containing "could," "may," "should," "will," "would," "anticipate," "believe," "plan," "promising," "potentially," or similar expressions. They reflect the company's current views with respect to future events that are based on what the company believes are reasonable assumptions in view of information currently available to Bio-Thera Solutions and Hikma and are not a guarantee of future performance or developments. Actual results and events may differ materially from information contained in the forward-looking statements as a result of a number of factors, including, but not limited to, risks and uncertainties inherent in pharmaceutical research and development, such as the uncertainties of pre-clinical and clinical studies, for example, the development processes could be lengthy and high in vitro affinity may not translate to desired results in vivo or successful clinical studies. Other risks and uncertainties include challenges in obtaining regulatory approvals, manufacturing, marketing, competition, intellectual property, product efficacy or safety, changes in global healthcare situation, changes in the company's financial conditions, and changes to applicable laws and regulations, etc. Forward-looking statements contained herein are made only as of the date of their initial publication. Unless required by laws or regulations, Bio-Thera Solutions and Hikma undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, changes in the company's views or otherwise.

1) STARJEMZA® is a registered trademark of Hikma Pharmaceuticals USA Inc.
2) STELARA® is a registered trademark of Johnson and Johnson
3) QLETLI® is a registered trademark of Bio-Thera Solutions, Ltd.
4) BETAGRIN® is a registered trademark of Bio-Thera Solutions, Ltd.
5) TOFIDENCE™ is a trademark of Organon LLC
6) AVZIVI® is a registered trademark of Sandoz
7) POBEVCY® is a registered trademark of Bio-Thera Solutions, Ltd.

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Important Safety Information for STARJEMZA® (ustekinumab-hmny) Injection

CONTRAINDICATIONS

STARJEMZA is contraindicated in patients with clinically significant hypersensitivity to ustekinumab products or to any of the excipients in STARJEMZA.

WARNINGS & PRECAUTIONS

- **Infections** - Ustekinumab products may increase the risk of infections and reactivation of latent infections. Serious bacterial, mycobacterial, fungal, and viral infections were observed in patients receiving ustekinumab products. Avoid initiating treatment with STARJEMZA in patients with any clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to initiating use of STARJEMZA in patients with a chronic infection or a history of recurrent infection. Serious infections requiring hospitalization, or otherwise clinically significant infections, reported in clinical trials included the following:
    - Plaque Psoriasis: diverticulitis, cellulitis, pneumonia, appendicitis, cholecystitis, sepsis, osteomyelitis, viral infections, gastroenteritis, and urinary tract infections.
    - Psoriatic arthritis: cholecystitis.
    - Crohn's disease: anal abscess, gastroenteritis, ophthalmic herpes zoster, pneumonia, and listeria meningitis.
    - Ulcerative colitis: gastroenteritis, ophthalmic herpes zoster, pneumonia, and listeriosis.

- **Theoretical Risk for Vulnerability to Particular Infections** - Individuals genetically deficient in IL-12/IL-23 are particularly vulnerable to disseminated infections from mycobacteria (including nontuberculous, environmental mycobacteria), salmonella (including nontyphi strains), and Bacillus Calmette-Guerin (BCG) vaccinations. Serious infections and fatal outcomes have been reported in such patients.
- **Pre-treatment Evaluation for Tuberculosis** - Evaluate patients for tuberculosis infection prior to initiating treatment with STARJEMZA. Avoid administering STARJEMZA to patients with active tuberculosis infection.
- **Malignancies** - Ustekinumab products are immunosuppressants and may increase the risk of malignancy. The safety of ustekinumab products has not been evaluated in patients who have a history of malignancy or who have a known malignancy. There have been post-marketing reports of the rapid appearance of multiple cutaneous squamous cell carcinomas in patients receiving ustekinumab products who had pre-existing risk factors for developing non-melanoma skin cancer.
- **Hypersensitivity Reactions** - Hypersensitivity reactions, including anaphylaxis and angioedema, have been reported with ustekinumab products. If an anaphylactic or other clinically significant hypersensitivity reaction occurs, institute appropriate therapy and discontinue STARJEMZA.
- **Posterior Reversible Encephalopathy Syndrome (PRES)** - Two cases of posterior reversible encephalopathy syndrome (PRES), also known as Reversible Posterior Leukoencephalopathy Syndrome (RPLS), were reported in clinical trials. Cases have also been reported in postmarketing experience in patients with psoriasis, psoriatic arthritis, and Crohn's disease. Clinical presentation included headaches, seizures, confusion, visual disturbances, and imaging changes consistent with PRES a few days to several months after ustekinumab product initiation. A few cases reported latency of a year or longer. Patients recovered with supportive care following withdrawal of ustekinumab products. Monitor all patients treated with STARJEMZA for signs and symptoms of PRES. If PRES is suspected, promptly administer appropriate treatment and discontinue STARJEMZA.
- **Immunizations** - Prior to initiating therapy with STARJEMZA, patients should receive all age-appropriate immunizations as recommended by current immunization guidelines. Patients being treated with STARJEMZA should avoid receiving live vaccines. Avoid administering BCG vaccines during treatment with STARJEMZA or for one year prior to initiating treatment or one year following discontinuation of treatment. Caution is advised when administering live vaccines to household contacts of patients receiving STARJEMZA because of the potential risk for shedding from the household contact and transmission to patient. Non-live vaccinations received during a course of STARJEMZA may not elicit an immune response sufficient to prevent disease.
- **Noninfectious Pneumonia** - Cases of interstitial pneumonia, eosinophilic pneumonia, and cryptogenic organizing pneumonia have been reported during post-approval use of ustekinumab

products. Clinical presentations included cough, dyspnea, and interstitial infiltrates following one to three doses. Serious outcomes have included respiratory failure and prolonged hospitalization. If diagnosis is confirmed, discontinue STARJEMZA and institute appropriate treatment.

ADVERSE REACTIONS

Serious adverse reactions associated with STARJEMZA include Infections, Malignancies, Hypersensitivity Reactions, Posterior Reversible Encephalopathy Syndrome (PRES), and Noninfectious Pneumonia.

Immunogenicity - Approximately 6 to 12.4% of subjects treated with ustekinumab in plaque psoriasis and psoriatic arthritis clinical trials developed antibodies to ustekinumab, which were generally low-titer. In plaque psoriasis clinical trials, antibodies to ustekinumab were associated with reduced or undetectable serum ustekinumab concentrations and reduced efficacy. In plaque psoriasis trials, the majority of subjects who were positive for antibodies to ustekinumab had neutralizing antibodies. In Crohn's disease and ulcerative colitis clinical trials, 2.9% and 4.6% of subjects, respectively, developed antibodies to ustekinumab when treated with ustekinumab for approximately one year. No apparent association between the development of antibodies to ustekinumab and the development of injection site reactions was seen.

Postmarketing Experience - The following adverse reactions have been reported during post-approval use of ustekinumab products:

- Immune system disorders: Serious hypersensitivity reactions (including anaphylaxis and angioedema), other hypersensitivity reactions (including rash and urticaria).
- Infections and infestations: Lower respiratory tract infection (including opportunistic fungal infections and tuberculosis).
- Neurological disorders: Posterior Reversible Encephalopathy Syndrome (PRES).
- Respiratory, thoracic, and mediastinal disorders: Interstitial pneumonia, eosinophilic pneumonia, and cryptogenic organizing pneumonia.
- Skin reactions: Pustular psoriasis, erythrodermic psoriasis, hypersensitivity vasculitis.

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DRUG INTERACTIONS

- **Concomitant Therapies** - In plaque psoriasis trials the safety of ustekinumab products in combination with immunosuppressive agents or phototherapy has not been evaluated. In psoriatic arthritis trials, concomitant MTX use did not appear to influence the safety or efficacy of ustekinumab. In Crohn's disease and ulcerative colitis induction trials, immunomodulators (6-MP, AZA, MTX) were used concomitantly in approximately 30% of subjects and corticosteroids were used concomitantly in approximately 40% and 50% of Crohn's disease and ulcerative colitis subjects, respectively. Use of these concomitant therapies did not appear to influence the overall safety or efficacy of ustekinumab.
- **CYP450 Substrates** - The formation of CYP450 enzymes can be suppressed by increased levels of certain cytokines (e.g., IL-1, IL-6, TNFα, IFN) during chronic inflammation. Thus, use of ustekinumab products, antagonists of IL-12 and IL-23, could normalize the formation of CYP450 enzymes. A CYP-mediated drug interaction effect was not observed in subjects with Crohn's disease.
- **Allergen Immunotherapy** - Ustekinumab products have not been evaluated in patients who have undergone allergy immunotherapy. Ustekinumab products may decrease the protective effect of allergen immunotherapy (decrease tolerance) which may increase the risk of an allergic reaction to a dose of allergen immunotherapy. Therefore, caution should be exercised in patients receiving or who have received allergen immunotherapy, particularly for anaphylaxis.

INDICATIONS AND USAGE

STARJEMZA is indicated for the treatment of:

- adults and pediatric patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
- adults and pediatric patients 6 years of age and older with active psoriatic arthritis.
- adult patients with moderately to severely active Crohn's disease.
- adult patients with moderately to severely active ulcerative colitis.

For additional Important Safety Information, please refer to the Package Insert for full prescribing information, available on www.hikma.com.

To report SUSPECTED ADVERSE REACTIONS, contact Hikma Pharmaceuticals USA Inc. at 1-877-845-0689 or FDA at 1-800 FDA-1088 or www.fda.gov/medwatch.

For Product Inquiry call 1-877-845-0689.

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