hikma.

Press Release

Hikma launches Tofacitinib oral solution in the US

London, 3 June 2026 – Hikma Pharmaceuticals PLC (Hikma, Group), a multinational pharmaceutical company, today announced the launch of Tofacitinib oral solution, 1 mg/mL, in a 240 mL bottle in the US. Tofacitinib oral solution is a generic of the FDA-approved reference listed drug XELJANZ® (tofacitinib) oral solution, marketed by Pfizer Inc.

“We are pleased to be one of the first to introduce Tofacitinib oral solution to patients in the US,” said Kristy Ronco, Chief Commercial Officer, Hikma Rx. “This launch demonstrates our commitment to improving patient access to high-quality medicines, particularly for patients with active psoriatic arthritis and juvenile idiopathic arthritis who depend on reliable access to effective treatments.”

Tofacitinib oral solution is indicated for the treatment of adult and pediatric patients, 2 years of age and older, with active psoriatic arthritis (PsA) and for pediatric patients 2 years of age and older with active polyarticular course juvenile idiopathic arthritis (pcJIA), who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers. The use of Tofacitinib Oral Solution in combination with biologic disease-modifying antirheumatic drugs (DMARDs) or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended in patients with PsA or pcJIA. Please see the full package insert for boxed warning and other important safety information.

According to IQVIA, US sales of XELJANZ® (tofacitinib) oral solution were approximately $16 million for the 12 months ending April 2026.

XELJANZ® is a registered trademark of Pfizer Inc.

- ENDS –

This product has been approved for marketing in the United States by the US FDA. This product approval does not confer the right on Hikma, or any other party, to market this product outside the United States.

About Hikma

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 9,400 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

Hikma Pharmaceuticals PLC (LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (LEI:549300BNS685UXH4JI75) (rated BBB/stable S&P and BBB/stable Fitch)

Enquiries

Hikma Pharmaceuticals PLC
Susan Ringdal — +44 (0)20 7399 2760/ +44 7776 477050
EVP, Strategic Planning and Global Affairs

Steven Weiss — +1 732 788 8279
US Communications

IMPORTANT SAFETY INFORMATION FOR TOFACITINIB ORAL SOLUTION

WARNINGS: SERIOUS INFECTIONS, MORTALITY, MALIGNANCY, MAJOR ADVERSE CARDIOVASCULAR EVENTS, and THROMBOSIS

SERIOUS INFECTIONS

Patients treated with tofacitinib are at increased risk for developing serious bacterial, fungal, viral, and opportunistic infections, including tuberculosis (TB), that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. Reported infections included:

- **Active TB, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent TB before tofacitinib use and during therapy. Treatment for latent infection should be initiated prior to tofacitinib use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

The risks and benefits of tofacitinib treatment should be carefully considered prior to initiating therapy in patients with chronic or recurrent infection.

Patients should be closely monitored for the development of signs and symptoms of infection during and after tofacitinib treatment, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy. If a serious infection develops, interrupt tofacitinib until the infection is controlled.

MORTALITY

In a large, randomized, postmarketing safety study in rheumatoid arthritis (RA) patients 50 years of age and older with at least one cardiovascular (CV) risk factor comparing tofacitinib tablets 5 mg or 10 mg twice a day to tumor necrosis factor (TNF) blockers, a higher rate of all-cause mortality, including sudden CV death, was observed with tofacitinib tablets 5 mg or 10 mg twice a day. Tofacitinib tablets 10 mg twice daily and tofacitinib extended-release tablets 22 mg once daily dosages are not recommended for the treatment of RA, psoriatic arthritis (PsA), ankylosing spondylitis (AS), or polyarticular course juvenile idiopathic arthritis (pcJIA).

MALIGNANCIES

Malignancies, including lymphomas and solid tumors, have occurred in patients treated with tofacitinib and other Janus kinase inhibitors used to treat inflammatory conditions. In RA patients, a higher rate of malignancies (excluding non-melanoma skin cancer (NMSC)) was observed in patients treated with tofacitinib tablets 5 mg or 10 mg twice a day compared with TNF blockers.

Lymphomas and lung cancers were observed at a higher rate in patients treated with tofacitinib tablets 5 mg or 10 mg twice a day in RA patients compared to those treated with TNF blockers. Patients who are current or past smokers are at additional increased risk.

MAJOR ADVERSE CARDIOVASCULAR EVENTS

RA patients 50 years of age and older with at least one cardiovascular risk factor, treated with tofacitinib tablets 5 mg or 10 mg twice daily, had a higher rate of major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke), compared to those treated with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue tofacitinib oral solution in patients that have experienced a myocardial infarction or stroke.

THROMBOSIS

Thrombosis, including pulmonary embolism, deep venous thrombosis, and arterial thrombosis have occurred in patients treated with tofacitinib and other Janus kinase inhibitors used to treat inflammatory conditions. Many of these events were serious and some resulted in death. RA patients 50 years of age and older with at least one cardiovascular risk factor treated with tofacitinib tablets 5 mg or 10 mg twice daily compared to TNF blockers had an observed increase in incidence of these events. Avoid tofacitinib

oral solution in patients at risk. Discontinue tofacitinib oral solution and promptly evaluate patients with symptoms of thrombosis.

INDICATIONS AND USAGE

Tofacitinib oral solution is indicated for the treatment of adult and pediatric patients 2 years of age and older with active psoriatic arthritis (PsA) and for pediatric patients 2 years of age and older with active polyarticular course juvenile idiopathic arthritis (pcJIA), who have had an inadequate response or intolerance to one or more TNF blockers.

- **Limitations of Use**—Use of tofacitinib in combination with biologic disease-modifying antirheumatic drugs (DMARDs) or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended in patients with PsA or pcJIA.

WARNINGS AND PRECAUTIONS

- **Serious Infections**—Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral or other opportunistic pathogens have been reported in patients receiving tofacitinib. The most common serious infections reported with tofacitinib included pneumonia, urinary tract infection, cellulitis, herpes zoster, bronchitis, septic shock, diverticulitis, gastroenteritis, appendicitis and sepsis. Other serious infections that were not reported in clinical studies may also occur. Avoid use of tofacitinib in patients with an active, serious infection, including localized infections.

  Among opportunistic infections, tuberculosis and other mycobacterial infections, cryptococcosis, histoplasmosis, esophageal candidiasis, pneumocystosis, multi-dermatomal herpes zoster, cytomegalovirus infections, BK virus infection and listeriosis were reported with tofacitinib. The risks and benefits of treatment should be considered prior to initiating tofacitinib in patients:

  - with chronic or recurrent infection
  - who have been exposed to tuberculosis
  - with a history of a serious or an opportunistic infection
  - who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or
  - with underlying conditions that may predispose them to infection

  Closely monitor patients for the development of signs and symptoms of infection during and after treatment with tofacitinib. Interrupt tofacitinib if a patient develops a serious infection, an opportunistic infection or sepsis. In patients who develop a new infection during treatment with tofacitinib, promptly complete diagnostic testing appropriate for an immunocompromised patient; initiate appropriate antimicrobial therapy and monitor the patients closely.

  Caution is also recommended in patients with a history of chronic lung disease, or in those who develop interstitial lung disease, as they may be more prone to infections.

  Evaluate and test patients for latent or active TB infection prior to and per applicable guidelines during administration of tofacitinib. Consider anti-TB therapy prior to administration of tofacitinib in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed and for patients with a negative test for latent TB but who have risk factors for TB infection. Consultation with a physician with expertise in the treatment of TB is recommended to aid in the decision about whether initiating anti-TB therapy is appropriate for an individual patient. Monitor patients closely for the development of signs and symptoms of TB, including patients who tested negative for latent TB infection prior to initiating therapy. Treat patients with latent TB with standard antimycobacterial therapy before administering tofacitinib.

  Viral reactivation, including cases of herpes virus reactivation, was observed in clinical studies with tofacitinib. Postmarketing cases of hepatitis B reactivation have been reported in patients treated with tofacitinib.

- **Increased Risk of Mortality** —Adult patients with rheumatoid arthritis (RA), 50 years of age and older, with at least one cardiovascular risk factor treated with tofacitinib tablets 5 mg or 10 mg twice a day had a higher observed rate of all-cause mortality, including sudden cardiovascular death, compared to those treated with TNF blockers in a large, randomized, postmarketing safety study.

Tofacitinib tablets/tofacitinib oral solution given at a dosage of 10 mg twice daily is not recommended for the treatment of PsA or pcJIA.

- **Malignancy and Lymphoproliferative Disorders**—Malignancies, including lymphomas and solid cancers, were observed in clinical studies of tofacitinib tablets.

  In RA Safety Study 1, a higher rate of malignancies (excluding non-melanoma skin cancer; NMSC) was observed in patients treated with tofacitinib tablets 5 mg or 10 mg twice a day compared with TNF blockers. Patients who are current or past smokers are at additional increased risk.

  Lymphomas and lung cancers were observed at a higher rate in patients treated with tofacitinib tablets 5 mg or 10 mg twice a day compared to those treated with TNF blockers.

  Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with tofacitinib, particularly in patients with a known malignancy (other than a successfully treated NMSC), patients who develop a malignancy while on treatment and patients who are current or past smokers.

  Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

- **Major Adverse Cardiovascular Events (MACE)**—In RA Safety Study 1, patients with RA who were 50 years of age and older with at least one cardiovascular risk factor and treated with tofacitinib tablets 5 mg or 10 mg twice daily had a higher rate of MACE defined as cardiovascular death, non-fatal myocardial infarction (MI) and non-fatal stroke, compared to those treated with TNF blockers. Patients who are current or past smokers are at additional increased risk. Discontinue tofacitinib in patients that have experienced a MI or stroke.

  Consider the benefits and risks for the individual patient prior to initiating or continuing therapy with tofacitinib, particularly in patients who are current or past smokers and patients with other cardiovascular risk factors. Inform patients about the symptoms of serious cardiovascular events and the steps to take if they occur. Tofacitinib tablets/tofacitinib oral solution given at a dosage of 10 mg twice daily is not recommended for the treatment of PsA or pcJIA.

- **Thrombosis**—Thrombosis, including pulmonary embolism, deep venous thrombosis and arterial thrombosis, have occurred in patients treated with tofacitinib tablets and other Janus kinase (JAK) inhibitors used to treat inflammatory conditions. Many of these events were serious and some resulted in death. Avoid tofacitinib in patients that may be at increased risk of thrombosis. Promptly evaluate patients with symptoms of thrombosis and discontinue treatment with tofacitinib.

- **Gastrointestinal (GI) Perforations**—GI perforations may occur with tofacitinib. Events of GI perforation have been reported in clinical studies with tofacitinib tablets, although the role of JAK inhibition in these events is not known. In these studies, many patients with RA received background therapy with nonsteroidal anti-inflammatory drugs (NSAIDs). Promptly evaluate patients treated with tofacitinib who may be at increased risk for GI perforation (e.g., patients with a history of diverticulitis or taking NSAIDs) and who present with new onset abdominal symptoms for early identification of GI perforation.

- **Hypersensitivity Reactions**—Angioedema and urticaria that may reflect drug hypersensitivity have been observed in patients receiving tofacitinib. Some events were serious. If a serious hypersensitivity reaction occurs, promptly discontinue tofacitinib while evaluating the potential cause or causes of the reaction.

- **Laboratory Abnormalities**
  Lymphocyte Abnormalities—Treatment with tofacitinib tablets was associated with initial lymphocytosis at one month of treatment followed by a gradual decrease in mean absolute lymphocyte counts. Monitor lymphocyte counts at baseline and every 3 months thereafter. Avoid initiation of tofacitinib in patients with a lymphocyte count <500 cells/mm^3. Treatment with tofacitinib is not recommended in patients who develop a confirmed absolute lymphocyte count <500 cells/mm^3. Lymphocyte counts <500 cells/mm^3 in these patients were associated with an increased incidence of treated and serious infections.

  Neutropenia—Treatment with tofacitinib tablets was associated with an increased incidence of neutropenia (<2,000 cells/mm^3) compared to treatment with placebo. Monitor neutrophil counts at baseline and after 4-8 weeks of treatment and every 3 months thereafter. Avoid initiation of tofacitinib in patients with ANC <1,000 cells/mm^3). For patients who develop a persistent ANC of 500-1,000 cells/mm^3, interrupt dosing until ANC is

≥1,000 cells/mm^3. In patients who develop an ANC <500 cells/mm^3, treatment with tofacitinib is not recommended.

Anemia—Monitor hemoglobin at baseline and after 4-8 weeks of treatment and every 3 months thereafter. Avoid initiation of tofacitinib in patients with a hemoglobin level <9 g/dL. Interrupt treatment with tofacitinib in patients who develop hemoglobin levels <8 g/dL or whose hemoglobin level drops >2 g/dL on treatment until hemoglobin values have normalized.

Liver Enzyme Elevations—Treatment with tofacitinib tablets was associated with an increased incidence of liver enzyme elevation compared to treatment with placebo. Most of these abnormalities occurred in studies with background DMARD therapy (primarily methotrexate). Routine monitoring of liver tests and prompt investigation of the causes of liver enzyme elevations is recommended to identify potential cases of drug-induced liver injury. If drug-induced liver injury is suspected, interrupt tofacitinib until this diagnosis has been excluded.

Lipid Elevations—Treatment with tofacitinib tablets was associated with dose-dependent increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol and high-density lipoprotein (HDL) cholesterol. Maximum changes in these lipid parameters were generally observed within 6 weeks. There were no clinically relevant changes in LDL/HDL cholesterol ratios. Perform assessment of lipid parameters approximately 4-8 weeks following initiation of tofacitinib therapy.

- **Vaccinations**—Avoid use of live vaccines concurrently with tofacitinib. Prior to initiating tofacitinib, update immunizations in agreement with current immunization guidelines. The interval between live vaccinations and initiation of tofacitinib therapy should align with current vaccination guidelines regarding immunosuppressive agents.

ADVERSE REACTIONS
The following clinically significant adverse reactions are described in greater detail in the Warnings and Precautions section, above, and in the Full Prescribing Information for tofacitinib oral solution:

- Serious Infections
- Increased Risk of Mortality
- Malignancy and Lymphoproliferative Disorders
- MACE
- Thrombosis
- GI Perforations
- Hypersensitivity Reactions
- Laboratory Abnormalities

Clinical Trials Experience
Adverse Reactions in Adults with PsA
The safety profile observed in adults with active PsA treated with tofacitinib tablets was consistent with the safety profile observed in adults with RA. The most common serious adverse reactions in adults with RA were serious infections. Adverse reactions reported in ≥2% of patients on tofacitinib tablets 5 mg or 10 mg twice daily and at least 1% greater than in tofacitinib-treated patients than that observed in placebo with or without DMARD in the RA trials were upper respiratory infection, nasopharyngitis, diarrhea, headache and hypertension.

Adverse Reactions in Pediatric Patients 2 Years of Age and Older With pcJIA
In general, the types of adverse reactions in pediatric patients 2 years of age and older with pcJIA were consistent with those seen in adults with RA and PsA.

Postmarketing Experience
The following adverse reactions have been identified during post-approval use of tofacitinib. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Immune system disorders: Drug hypersensitivity (events such as angioedema and urticaria have been observed)

Skin and subcutaneous tissue disorders: Acne

DRUG INTERACTIONS

- **Strong CYP3A4 Inhibitors (e.g., ketoconazole) or Moderate CYP3A4 Inhibitors Concomitantly Used With CYP2C19 Inhibitors (e.g., fluconazole)**—Increased exposure to tofacitinib. Dosage modification of tofacitinib is recommended.

- **Strong CYP3A4 Inducers (e.g., rifampin)**—Decreased exposure to tofacitinib and may result in loss of or reduced clinical response. Concomitant use with tofacitinib is not recommended.

- **Immunosuppressive Drugs (e.g., azathioprine, tacrolimus, cyclosporine)**—Risk of added immunosuppression; concomitant use of tofacitinib with biologic DMARDs or potent immunosuppressants has not been studied in patients with PsA or pcJIA. Concomitant use with tofacitinib is not recommended.

USE IN SPECIFIC POPULATIONS

- **Pregnancy**—The available data with tofacitinib use in pregnant women are insufficient to draw conclusions about a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. In animal reproduction studies, fetocidal and teratogenic effects were noted when pregnant rats and rabbits received tofacitinib during the period of organogenesis at exposures multiples of 73-times and 6.3-times the maximum recommended dose of 10 mg twice daily, respectively. The background risks of major birth defects and miscarriage for the indicated populations are unknown.

- **Lactation**—Breastfeeding is not recommended during treatment and for at least 18 hours after the last dose of tofacitinib oral solution.

- **Females and Males of Reproductive Potential**—Consider pregnancy planning and prevention for females of reproductive potential. Treatment with tofacitinib may result in reduced fertility in females of reproductive potential. It is not known if this effect is reversible.

- **Pediatric Use**—The safety and effectiveness of tofacitinib have not been established in pediatric patients less than 2 years of age.

- **Geriatric Use**—The frequency of serious infection among tofacitinib tablets-treated patients 65 years of age and older was higher than among those adults under the age of 65.

- **Renal Impairment**—The recommended dosage of tofacitinib in patients with moderate or severe renal impairment is lower than the recommended dosage in patients with normal renal function.

- **Hepatic Impairment (HI)**—Tofacitinib is not recommended in patients with severe HI. The recommended tofacitinib dosage in patients with moderate HI is lower than for patients with normal hepatic function.

PATIENT COUNSELING INFORMATION

Advise the patient or caregiver to read the FDA-approved patient labeling (Medication Guide) for more information about the potential for serious infections, increased risk of certain cancers, increased risk of MACE, thrombosis, hypersensitivity and the signs and symptoms associated with these conditions.

Advise pregnant females and females of reproductive potential of the potential risk to a fetus. Advise females to inform their prescriber of a known or suspected pregnancy. Advise women not to breastfeed during treatment with tofacitinib and for at least 18 hours after the last dose of tofacitinib. Advise females of reproductive potential that tofacitinib may impair fertility.

For more information, please see the Full Prescribing Information for tofacitinib oral solution.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit https://www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information about tofacitinib oral solution, please contact Hikma Pharmaceuticals USA Inc. 1-800-962-8364.

Distributed by: Hikma Pharmaceuticals USA Inc.; Berkeley Heights, NJ 07922

HK-3548 v1