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Press Release

Hikma expands licensing agreement with Celltrion for Remsima® subcutaneous formulation in MENA

London, 7 February 2022 – Hikma Pharmaceuticals PLC (Hikma), the multinational pharmaceutical company, announces an exclusive licensing agreement with South Korea-based Celltrion, Inc. and Celltrion Healthcare, Inc. (Celltrion) for Remsima® subcutaneous (SC), the first subcutaneous formulation of infliximab.

The agreement provides Hikma with exclusive rights to commercialise Remsima® SC, the world's first subcutaneous formulation of infliximab, in all of its MENA markets. It builds on Hikma's existing partnership with Celltrion for three of its biosimilar products, Truxima® (rituximab), Remsima® (infliximab) and Herzuma® (trastuzumab). Remsima® SC is used in the treatment of rheumatoid arthritis and a number of other conditions.

"We are very excited to build on the success of our long-term agreement with Celltrion and add Remsima® subcutaneous to our portfolio of biosimilar products in the MENA region," said Mazen Darwazah, Hikma's Executive Vice Chairman and President of MENA. "Subcutaneous administration has been shown to be effective, safe, well-tolerated and generally preferred by patients. This new formulation enables administration outside of the hospital setting, allowing more patients access to the treatment. This is another example of Hikma using its capabilities to increase access to important medicines and introduce delivery systems that can improve the quality of life of patients as part of our mission to put better health within reach, every day."

About Remsima® (CT-P13) intravenous (IV) formulation
Remsima® IV is usually given as 3 mg per kg/body weight in rheumatoid arthritis (RA) and as 5 mg per kg/body weight for the other indications. Infliximab IV is given as an infusion over two hours. All patients are monitored for any reactions during the infusion and for at least one to two hours afterwards.

About Remsima® CT-P13 subcutaneous (SC) formulation
A 120 mg fixed dose of Remsima® SC has been granted marketing authorisation in the EU, in adults regardless of body weight, in all previously approved indications for the IV formulation. Remsima® SC has three administration options; via a pre-filled pen (auto injector), pre-filled syringe or pre-filled syringe with needle safeguard. The SC formulation has the potential to enhance treatment options for the use of infliximab biosimilar by providing high consistency in drug exposure and a convenient method of administration. CT-P13 SC is currently approved in 41 countries and commercialized in 13 countries. It is approved for the treatment of patients with ankylosing spondylitis, Crohn's disease, ulcerative colitis, psoriatic arthritis and psoriasis, and rheumatoid arthritis.

About CT-P13 (biosimilar infliximab)
CT-P13 is developed and manufactured by Celltrion, Inc. and was the world's first monoclonal antibody biosimilar approved by the European Commission (EC). It is indicated for the treatment of eight autoimmune diseases including RA and IBD. It was approved by the EC under the trade name Remsima® in September 2013 and launched in major EU countries in early 2015. The US FDA approved CT-P13 in April 2016 under the trade name Inflectra®. CT-P13 is approved in more than 98 countries (as of October 2021) including the US, Canada, Japan and throughout Europe.

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Enquiries

Hikma Pharmaceuticals PLC

Susan Ringdal
EVP, Strategic Planning and Global Affairs
+44 (0)20 7399 2760/ +44 7776 477050
uk-investors@hikma.uk.com

Dana Alhusseini
Communication Manager
+962 6 580 2900
Dalhusseini@hikma.com

About Hikma
(LSE: HIK) (NASDAQ Dubai: HIK) (OTC: HKMPY) (rated BBB-/stable S&P and BBB-/stable Fitch)

Hikma helps put better health within reach every day for millions of people around the world. For more than 40 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 the United States (US), 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 8,600 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

About Celltrion Healthcare
Celltrion Healthcare is committed to delivering innovative and affordable medications to promote patients' access to advanced therapies. Its products are manufactured at state-of-the-art mammalian cell culture facilities, designed and built to comply with the US FDA cGMP and the EU GMP guidelines. Celltrion Healthcare endeavours to offer high-quality cost-effective solutions through an extensive global network that spans more than 110 different countries. For more information please visit: https://www.celltrionhealthcare.com/en-us