6 April 2021

Clinigen to begin supplying Erwinase® in the UK

Clinigen Group plc (AIM: CLIN, 'Clinigen'), the global pharmaceutical Products and Services company, today announces that it will be providing access to Erwinase® *(L-asparaginase Erwinia chrysanthemi)* in the UK from the 6 April 2021. This is part of the global exclusive licensing and distribution agreement with Porton Biopharma ('PBL'), as previously announced on 16 April 2020.

Erwinase is approved in the UK as a component of a chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukaemia (ALL) who have developed hypersensitivity to E. coli-derived asparaginase. Erwinase is manufactured by PBL (PL 44403/0002) and Clinigen is responsible for marketing, packaging, labelling, storage and distribution.

With the onboarding of Erwinase coming earlier than originally anticipated this will bring forward an expected investment in working capital in-line with our previous guidance of £10m - £20m. Given the proximity to the year end and staggered roll out across each territory this is not expected to have a material impact on current year profit expectations.

Sam Herbert, Chief Operating Officer, Clinigen, said:

"Erwinase® is an important treatment option for healthcare professionals in the UK and this represents a major milestone since partnering with PBL. PBL has invested in enhancing its manufacturing to increase Erwinase® capacity and our ongoing focus is to ensure effective future supply in the UK and in other international markets where patients need access. At Clinigen our mission is to ensure the right medicines get to the right patients at the right time and we see Erwinase® as a key part of that mission."

Healthcare professionals can obtain ordering details about Erwinase by calling the Clinigen customer service team at +44 (0) 1932 824100 or emailing MedicineAccess@clinigengroup.com.

Patients seeking medical information should contact their physician.

- Ends -

Contact details

Clinigen Group plc
Sam Herbert, Chief Operating Officer

Tel: +44 (0) 1283 495010
Investors@Clinigen.com

Numis Securities Limited - Nominated Adviser & Joint Broker
James Black / Garry Levin / Freddie Barnfield

Tel: +44 (0) 20 7260 1000
Clinigen@Numis.com

RBC Capital Markets - Joint Broker **Tel: +44 (0) 20 7653 4000**
Marcus Jackson / Elliot Thomas

Instinctif Partners **Tel: +44 (0) 20 7457 2020**
Melanie Toyne-Sewell / Tim Linacre / Rozi Morris / Phillip Marriage clinigen@instinctif.com

Notes to Editors

About Clinigen Group

Clinigen Group plc (AIM: CLIN) is a global, specialist pharmaceutical services and products platform focused on providing ethical access to medicines. Its mission is to deliver the right medicine to the right patient at the right time. The Group operates from sites in North America, Europe, Africa and the Asia Pacific.

Clinigen has more than 1,250 employees across five continents in 16 countries, with supply and distribution hubs and operational centres of excellence in key long-term growth regions. The Group works with 34 of the top 50 pharmaceutical companies; interacting with over 5,000 hospitals across more than 115 countries.

For more information on Clinigen, please visit http://www.clinigen.com

About Erwinase® / Erwinaze®

Erwinase is indicated as a component of a chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukaemia (ALL) who have developed hypersensitivity to E. coli-derived asparaginase. Erwinase is indicated in paediatric patients from the age of 4 months and in adults.

Asparagine is an amino acid that is essential for cell growth; it is produced by most but not all cells. Mutated cancer cells in ALL rely on asparagine circulating in the blood for growth. L-asparaginases are a group of enzymes that lower circulating asparagine levels in the blood, thereby depriving the mutated cells of asparagine and inhibiting their growth.

There are several different types of L-asparaginase available on the market, each derived from a different bacterium. Patients receiving treatment with L-asparaginase derived from *Escherichia coli* (*E. coli*), who develop hypersensitivity to that form of the enzyme, may be able to continue treatment with Erwinase as the enzymes are immunologically distinct. Antibodies targeting *E. coli* derived L-Asparaginase have been shown not to cross-react with Erwinase.

About Acute Lymphoblastic Leukaemia (ALL)

Acute lymphoblastic leukemia (ALL) is a heterogenous hematologic disease characterized by the proliferation of immature lymphoid cells in the bone marrow, peripheral blood and other organs. Both adults and children can get the illness, but it is most often diagnosed in younger people. The incidence in the EU is thought to be 1.28 per 1 000 000 individuals annually, with significant age-related variations. Estimated new ALL cases in the US was estimated to be 6150 in 2020 according to the SEER program.

About Porton Biopharma Limited (PBL)

PBL is a biopharmaceutical development and manufacturing company. It was formed in April 2015 as a spin-out company of Public Health England, part of the Department of Health and Social Care. PBL is based at Porton Down,

Wiltshire, which has a long history of pharmaceutical development and manufacturing. Erwinase, the UK's anthrax vaccine, Dysport and other medical treatments have been developed at the site by the forerunners to PBL. PBL has approximately 350 staff and has a sole shareholder in the Department of Health and Social Care.