London Stock Exchange

RNS Miscellaneous

CORRECTION: Clinigen Updates Re FDA on Erwinaze

CLINIGEN GROUP PLC
Released 08:21:38 01 December 2021

RNS Number : 1815U
Clinigen Group plc
01 December 2021

1st December 2021

CORRECTION: Clinigen updates re FDA on Erwinaze®

HEADLINE ALTERATION

The headline for the (Clinigen) announcement released on Dec 1 at 0700am under RNS No 721U should read ("Clinigen Notes FDA Response to Porton Biopharma Limiited's Biologics License Application for Erwinaze").

The announcement text is unchanged and is reproduced in full below.

Clinigen Group plc (AIM: CLIN, 'Clinigen'), the global pharmaceutical Services and Products company, announces today that it has been informed by Porton Biopharma Limited ('PBL') that the US Food and Drug Administration ('FDA') has issued a Complete Response Letter ('CRL') regarding PBL's Biologics License Application ('BLA') for Erwinaze® (asparaginase *Erwinia chrysanthemi)*, an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia ('ALL') who have developed hypersensitivity to *E. coli*-derived asparaginase, which means the BLA cannot be approved in its current form.

As previously announced on 16 April 2020, Clinigen signed a global licensing and distribution agreement with PBL to commercialise and distribute Erwinaze®/Erwinase®. Clinigen currently supplies Erwinase® into more than 30 licensed and unlicensed markets outside the US. The CRL does not impact these markets.

PBL is in the process of reviewing the CRL and will provide Clinigen with an update as soon as the discussions regarding the response with the FDA have been completed.

Due to the recent negotiation of more favourable commercial terms with PBL, cost savings linked to the delayed roll out of Erwinaze® in the US and the continued strength of the pipeline Clinigen maintains its FY22 guidance for EBITDA growth of 5% to 10%, and continues to expect strong, sustained growth in the years thereafter in line with current market forecasts.

Sam Herbert, Group Chief Operating Officer, Clinigen, said:

"Although this is disappointing news for patients in the US, we look forward to supporting our partner PBL to ensure that patients in need outside the US are able to access Erwinase®. To that end, we continue to supply Erwinase® in ex-US markets."

- Ends -

Information within this announcement is deemed by Clinigen to constitute inside information for the purposes of the UK version of the Market Abuse Regulation (EU no. 596/2014)

Contact details

Clinigen Group plc — **Tel: +44 (0) 1283 495010**
Sam Herbert, Group Chief Operating Officer & Head of Products Division — Investors@Clinigengroup.com
Rob Fox, VP Investor Relations and Corporate Development

Numis — **Tel: +44 (0) 20 7260 1000**
James Black / Garry Levin / Freddie Barnfield — Clinigen@Numis.com

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

Consilium Strategic Communications — **Tel: +44 (0) 20 3709 5700**
Mary-Jane Elliott / Matthew Cole / Jessica Hodgson — Clinigen@consilium-comms.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 1,000 employees across five continents in 14 countries, with supply and distribution hubs and operational centers 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 120 countries.

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

About Erwinase

Erwinase (asparaginase *Erwinia chrysanthemi*) is an asparagine specific enzyme indicated as a component of a multi-agent chemotherapeutic regimen for the treatment of patients with acute lymphoblastic leukemia ('ALL') who have developed hypersensitivity to *E. coli*-derived asparaginase. Erwinase is indicated in pediatric 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 *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.

Erwinia L-asparaginase is marketed under the name Erwinase outside the United States by Porton Biopharma Limited, with Clinigen as the exclusive licensed distributor.

About Acute Lymphoblastic Leukemia (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. In 2021, there are approximately 5,690 new cases of ALL (3,000 in males and 2,690 in females) in the U.S, accounting for less than half of 1% of all cancers, according to the American Cancer Society.

About Porton Biopharma Limited (PBL)

PBL is a biopharmaceutical development and manufacturing company with approximately 400 staff. It was formed in April 2015 as a spin-out company of Public Health England and has a sole shareholder in 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, Dysport, the UK's anthrax vaccine, and other medical treatments have been developed at the site.

information, please contact rns@lseg.com or visit www.rns.com.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our Privacy Policy.

END

MSCVFLBBFLLFFBV