22nd September 2021

Clinigen signs European agreement with Secura Bio for the exclusive supply and distribution of COPIKTRA®

Clinigen Group plc (AIM: CLIN, 'Clinigen'), the global pharmaceutical Services and Products company, announces it has signed an exclusive agreement with Secura Bio, Inc ('Secura Bio') for the supply and distribution of COPIKTRA® in most of Europe.

COPIKTRA® was granted marketing authorization by the European Medicines Agency in May 2021 as monotherapy for the treatment of adults with relapsed or refractory Chronic Lymphocytic Leukemia (CLL) in patients who have received at least two prior therapies and for the treatment of Follicular Lymphoma (FL) that is refractory to at least two prior systemic therapies. The goal of therapy for patients with these cancers is to improve overall survival and quality of life. COPIKTRA® is a dual inhibitor of PI3K-delta and gamma pathways, which are involved in the proliferation of malignant cells and are thought to play a role in the formation and maintenance of the supportive tumor microenvironment.

PRIMO, a Phase 2 study, also seeks to evaluate COPIKTRA® for patients with relapsed or refractory peripheral T-cell lymphoma.

Under the terms of the agreement Clinigen will market, supply and distribute COPIKTRA® into 39 countries across Europe including Austria, Belgium, Croatia, Czech Republic, Denmark, Finland, France, Greece, Hungary, Ireland, Italy, The Netherlands, Poland, Portugal, Spain, Sweden and Switzerland. Secura Bio will promote and distribute COPIKTRA directly in Germany and the United Kingdom.

Sam Herbert, Chief Operating Officer and Head of Products Division, Clinigen, said:

"Clinigen is very pleased to be partnering with Secura Bio. This new and exclusive agreement will help address a significant unmet need for patients with B-cell blood cancers across Europe. This agreement underlines Clinigen's strength in partnering with pharmaceutical companies and leveraging our significant commercial knowledge and infrastructure to ensure the right medicine gets to the right patients at the right time."

Joseph M. Limber, President and Chief Executive Officer, Secura Bio, said:

"Partnering with Clinigen will enable COPIKTRA, an oncology treatment with a novel mode of action, to be widely and rapidly available to patients across Europe. Leveraging Clinigen's commercial resources, supply and distribution infrastructure and regulatory expertise will allow physicians and patients throughout Europe to gain access to a valuable option to combat the debilitating illnesses of CLL and FL. We are excited to have Clinigen to ensure successful market access, commercialization and supply of COPIKTRA in Europe."

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Contact details

Clinigen Group plc Sam Herbert, Group Chief Operating Officer Rob Fox, VP Investor Relations and Corporate Development	**+44 (0) 1283 495010** investors@clinigengroup.com
Consilium Strategic Communications Mary-Jane Elliott / Matthew Cole / Jessica Hodgson	**Tel: +44 (0) 20 3709 5700** Clinigen@consilium-comms.com
Secura Bio, Inc Mark Spring, Chief Financial Officer	**Tel: +1 (702) 465-4196** mspring@securabio.com

Notes to Editors

About Clinigen Group

Clinigen Group plc (AIM: CLIN) is a global, specialist pharmaceutical services and products company 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 centres of excellence in key long-term growth regions. The Group works with 34 of the top 50 pharmaceutical companies; interacting with over 20,000 healthcare professionals across more than 120 countries.

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

About Chronic Lymphocytic Leukemia (CLL) and Follicular Lymphoma (FL)

CLL and FL are slow-growing incurable blood cancers that can lead to life-threatening complications such as anemia, serious infections, and bone marrow failure requiring treatment

About Secura Bio

Secura Bio is an integrated, commercial-stage pharmaceutical company dedicated to the worldwide development and commercialization of impactful oncology therapies for physicians and their patients. For more information on Secura Bio, please visit www.securabio.com.

About COPIKTRA®(duvelisib)

COPIKTRA is an oral inhibitor of phosphoinositide 3-kinase (PI3K), and the first United States FDA approved dual inhibitor of PI3K-delta and PI3K-gamma, two enzymes known to help support the growth and survival of malignant cells. PI3K signaling may lead to the proliferation of malignant cells and is thought to play a role in the formation and maintenance of a supportive tumor microenvironment. COPIKTRA is also being developed for the treatment of peripheral T-cell lymphoma (PTCL), for which it has received Fast Track status in the United States and is being investigated in combination with other agents through investigator-sponsored studies.
For more information on COPIKTRA, please visit www.COPIKTRA.com. For more information on COPIKTRA EU Product Information, please visit https://www.ema.europa.eu/en/medicines/human/EPAR/copiktra. For information about duvelisib clinical trials can be found on www.clinicaltrials.gov.