Clinigen and Onxeo initiate Managed Access programme for belinostat in Europe for patients with peripheral T-cell lymphoma (PTCL)

Paris, April 24, 2017 – 18 :30 CEST. Clinigen Group plc's (AIM: CLIN, 'Clinigen' or the 'Group') Idis Managed Access (MA) division and Onxeo S.A (Euronext Paris, Nasdaq Copenhagen: ONXEO, 'Onxeo'), have agreed to launch a Managed Access programme for belinostat (Beleodaq®) in Europe. Belinostat is for use in patients with relapsed or refractory peripheral T-cell lymphoma (PTCL).

PTCL is a form of blood cancer comprising of a group of rare and aggressive non-Hodgkin lymphomas (NHL), a malignant lymphoproliferative disorder. PTCL accounts for approximately 10%-15% of all NHL cases.

Belinostat is a histone deacetylase inhibitor ('HDAC inhibitor') used to treat refractory or relapsed PTCL. The product received accelerated approval* by the US Food and Drug Administration ('FDA') in July 2014 due to the unmet medical need in this rare disease. There are no approved treatments for PTCL in Europe.

The programme allows physicians to request belinostat for individual patients for whom alternative treatment options are not currently available. This enables patients on a named patient basis in Europe** to benefit from belinostat treatment ahead of a potential European approval.

Steve Glass, Chief Commercial Officer, North America and Europe, of Clinigen said:

"There is a huge unmet need for patients with aggressive blood cancers such as PTCL. As the trusted global leader in access to unlicensed medicines, Clinigen is working in partnership with Onxeo to help patients gain access to this important medicine. As Clinigen and Idis MA, we have delivered over 220 Managed Access programmes to thousands of patients. We help physicians access medicines when no other treatment options are available reducing unmet clinical need. This aligns with our mission of getting the right medicine to the right patient at the right time."

Judith Greciet, Chief Executive Officer of Onxeo said:

"Consistent with our efforts to address the unmet needs of people diagnosed with relapsed or refractory PTCL, we are pleased to partner with Clinigen to establish this Named Patient programme. In selected European countries in which local health authorities permit the programme, the belinostat Managed Access programme will allow healthcare professionals to prescribe belinostat to specific patients."

Healthcare professionals can obtain details about the belinostat Managed Access programme by calling a Clinigen representative at: +44 (0) 1283 44 347, or emailing customer.services@clinigengroup.com.

*Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

** Programme will be launched in: United Kingdom, Germany, France, Spain, Italy, Denmark, Sweden, Norway, Finland, Belgium, The Netherlands, Luxembourg, and Austria.

About Peripheral T-Cell Lymphoma (PTCL)
Lymphoma is the most common blood cancer (www.lymphoma.org). Peripheral T-cell lymphoma (PTCL) is a sub-type of non-Hodgkin lymphoma (NHL). It comprises a group of rare and aggressive NHLs that develop from mature T-cells. PTCL accounts for approximately 10 to 15% of all NHL cases.

About belinostat
Belinostat has been approved via an accelerated pathway by the US FDA and is currently commercialised under the name Beleodaq® in the US as 2nd-line treatment of PTCL.

About Clinigen Group

Clinigen Group plc (AIM: CLIN) is a global pharmaceutical and services company with a unique combination of businesses focused on providing access to medicines. Its mission is to deliver the right medicine to the right patient at the right time.

The Group consists of five synergistic businesses focused in three areas of global medicine supply; clinical trial, unlicensed and licensed medicines.

Clinigen Clinical Trial Services is the global market leader in the management and supply of commercial medicines for clinical trials.

The Group is also the trusted global leader in ethically sourcing and supplying unlicensed medicines to hospital pharmacists and physicians for patients with a high unmet need, through three of its divisions: **Idis Managed Access** runs early access programs for innovative new medicines. **Idis Global Access** and **Link Healthcare** work directly with healthcare professionals to enable compliant access to unlicensed medicines on a global basis and niche essential licensed and generic medicines across Australasia, Africa and Asia (AAA region).

Clinigen Specialty Pharmaceuticals acquires global rights, revitalises and markets its own portfolio of niche hospital commercial products.

For more information, please visit www.clinigengroup.com

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Shaun Chilton, Group Chief Executive Officer
Steve Glass, Group Chief Commercial Officer, North America and Europe

About Onxeo

Onxeo is a biopharmaceutical company developing innovative drugs for the treatment of orphan diseases in oncology, driven by high therapeutic demand in one of the fastest growing segments of the pharmaceutical industry. Onxeo's objective is to become a major international player in the field of rare cancers. Its growth strategy is founded on the development of innovative, effective, and safe drugs based on breakthrough technologies that can make a real difference in the treatment of orphan oncology diseases and considerably improve the quality of life of patients affected by rare and aggressive cancers.

Onxeo's comprehensive portfolio features a broad orphan oncology pipeline, with 3 major products in several on-going preclinical and clinical programs, alone or in combination for various cancer indications.

The Company is headquartered in Paris, France with offices in Copenhagen, Denmark (Ticker: ONXEO, ISIN Code: FR0010095596, Euronext Paris and Nasdaq Copenhagen).

Learn more by visiting www.onxeo.com

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