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Clinigen's Foscavir® gains approval for HHV-6 encephalitis in Japan

Clinigen Group plc (AIM: CLIN, 'Clinigen'), the global pharmaceutical and services company, announces that Foscavir (foscarnet sodium) has received approval for the treatment of HHV-6 encephalitis from the Ministry of Health, Labour and Welfare ('MHLW') in Japan. Approval of the new indication by the MHLW follows reimbursement received in November 2018.

Foscavir is the first medicine in the world to receive approval from a Regulatory Authority for the treatment of HHV-6 encephalitis. The MHLW was also the first authority to grant the haematological stem cell transplantation license for this medicine in 2011. The latest approval follows significant effort and support from key opinion leaders ('KOLs') of the Japan Society of Hematopoietic Cell Transplantation.

This new indication for Foscavir provides healthcare professionals ('HCPs') in Japan with a licensed alternative to treat their patients. For Clinigen, it offers a further barrier to entry against competitive threat for Foscavir and diversifies the revenue streams associated with this medicine. Clinigen will now look to determine which other geographies could benefit from the new indication.

Benjamin Miny, Senior Vice President of Commercial Medicines, Clinigen Group, said:

"Gaining approval is great news for Clinigen and HCPs. For Clinigen it enhances our market offering in the second largest pharmaceutical market in the world, however, most importantly, we have been able to respond to the needs of HCPs and their patients directly. The KOLs in Japan have given us tremendous support to date and, through leveraging our expertise, we can now provide help to the HCPs to treat their patients."

"We will continue to ensure that our products provide significant benefit to HCPs and patients globally."

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Notes to Editors

About Foscavir® (foscarnet sodium)

Foscarnet is an antiviral agent with broad spectrum activity inhibiting the human virus of the herpes group, including herpes simplex virus (HSV) type 1 and 2, human herpes virus (HHV) 6, varicella zoster virus (VZV),

Epstein-Barr virus, cytomegalovirus (CMV) and other retroviruses, including human immunodeficiency virus (HIV) at concentrations not affecting normal cell growth.

Foscavir® is licensed in Japan for the treatment of:

- i) Cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome (AIDS)
- ii) Cytomegalovirus viremia and cytomegalovirus disease in hematopoietic stem cell transplant patients
- iii) Human herpesvirus 6 encephalitis after hematopoietic stem cell transplantation

About Clinigen Group

Clinigen Group plc (AIM: CLIN) is a global pharmaceutical and services company with a unique combination of businesses focused on providing ethical access to medicines. Its mission is to deliver the right medicine to the right patient at the right time through three areas of global medicine supply; clinical trial, unlicensed and licensed medicines. The Group has sites in North America, Europe, Africa and Asia Pacific. In October 2018, the Group acquired CSM, a specialist provider of packaging, labelling, warehousing and distribution services, with sites in the US and Europe, and iQone, a specialist pharmaceutical company in Switzerland.

For more information, please visit www.clinigengroup.com