Clinigen Group Reports Pan European Lifting of Marketing Authorization Suspension for VIBATIV® (telavancin)

Plans for phased Europe-wide launch starting in Q2 2014

Burton-on-Trent, UK – 18 March 2014 – Clinigen Group plc ('Clinigen' or the 'Group') (AIM: CLIN) today announced that the European Commission (EC) has ratified the positive opinion in January 2014 from the European Medicines Agency (EMA)'s Committee for Medicinal Products for Human Use (CHMP) to lift the Europe-wide suspension of Marketing Authorization for VIBATIV® (telavancin).

Clinigen anticipates the commercial launch will begin in the second quarter of 2014 and continue over the next 18 to 24 months as local pricing and reimbursement positions are agreed. In March 2013, Clinigen in-licensed telavancin into its specialty pharmaceuticals business, Clinigen SP, from Theravance, Inc. for commercialization in Europe.

Telavancin is a bactericidal, once-daily injectable antibacterial agent for the treatment of hospital-acquired pneumonia (HAP), including ventilator-associated pneumonia (VAP) known or suspected to be caused by methicillin resistant *Staphylococcus aureus* (MRSA) when other alternatives are not suitable[1].

In 2011 telavancin had been approved in Europe by the EMA. However, its use was suspended in 2012 following a halt in operations at the previous contract manufacturer. Between approval and suspension the drug had not been launched into the market and therefore was never previously available in Europe. Following the technical transfer to a new contract manufacturer, Clinigen has worked closely with the relevant EMA authorities to lift the suspension.

HAP caused by MRSA is an area of considerable unmet need; there is a limited choice of antibiotic therapies available to treat such serious Gram-positive infections and rates of clinical cure are considered to be low[2], together with increasing rates of resistance being reported.

"The addition of this novel anti-bacterial to the arsenal of possible therapeutic options for HAP may provide a lifeline for those seriously ill patients who have not responded to previous treatments," said Professor Robert Masterton of the Institute of Healthcare Associated Infection at the University of the West of Scotland and advisor to Clinigen. "Telavancin's safety profile compares well with first line treatment vancomycin and it is highly potent against MRSA including the organisms with reduced susceptibility to vancomycin."

Shaun Chilton, Chief Operating Officer, Clinigen Group said, "The lifting of the suspension is an important step in the phased commercial launch of telavancin throughout Europe. The decision by

the EMA follows many hours of work and demonstrates the dedication and expertise of our Specialty Pharmaceuticals team. We are working closely with the contract manufacturer to produce stock to prepare for the launch and beyond."

He added, "In the period before the commercial launch our global access program business, Clinigen GAP, will continue to manage a named patient program in Europe to provide access to telavancin for individual eligible patients via their healthcare professional."

[1] Annex I: Summary of Product Characteristics – VIBATIV.
http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/001240/WC500115364.pdf
Accessed: 14 Mar 2014
[2] Muscedere J. Which antibiotic for hospital acquired pneumonia caused by MRSA? *BMJ* 2014;348:g1469

- Ends -

About VIBATIV® (telavancin)
Telavancin is a bactericidal, once-daily, injectable lipoglycopeptide antibiotic with a dual mechanism of action whereby telavancin both inhibits bacterial cell wall synthesis and disrupts bacterial cell membrane function. The drug is indicated for the treatment of adults with hospital-acquired pneumonia including ventilator-associated pneumonia known or suspected to be caused by MRSA for use in situations where no other alternatives are suitable.

Telavancin, discovered and developed by Theravance, is approved in the United States (US) for the treatment of adult patients with complicated skin and skin structure infections (cSSSI) caused by susceptible isolates of Gram-positive bacteria, including *Staphylococcus aureus*, both methicillin-susceptible (MSSA) and methicillin-resistant (MRSA) strains, since 2009. In September 2011, the EC granted Marketing Authorization for telavancin for the treatment of nosocomial pneumonia (hospital-acquired), including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. In May 2012, the European Commission suspended Marketing Authorization for telavancin because the previous single-source drug product supplier did not meet the current Good Manufacturing Practice (cGMP) requirements for the manufacture of telavancin.

In June 2013, US Food and Drug Administration (FDA) approved telavancin for the treatment of adult patients with hospital-acquired and ventilator-associated bacterial pneumonia caused by susceptible isolates of *Staphylococcus aureus* when alternative treatments are not suitable. In addition, the US FDA approved Hospira (McPherson, Kansas, US) as the manufacturer of telavancin, and in August 2013 Theravance announced that it had re-established reliable product supply in the US. Clinigen and Theravance worked together with the relevant European Commission authorities to remove the Marketing Authorization suspension in March 2014; introduction of a phased commercial supply of telavancin to Europe is expected over the second and third quarter of 2014.

About Clinigen Group
The Clinigen Group is a specialty global pharmaceutical company headquartered in the UK, with offices in the US and Japan. The Group, dedicated to delivering 'the right drug, to the right patient at

the right time', has three operating businesses; Specialty Pharmaceuticals (Clinigen SP), Clinical Trials Supply (Clinigen CTS), and Global Access Programs (Clinigen GAP). Clinigen SP is focused on acquiring its own intellectual property in licensed, niche, hospital-only critical care medicines, increasing the value of these medicines by developing new formulations and indications, then registering and marketing them in defined global markets.

For more information, please visit www.clinigengroup.com.

Contact Details

Clinigen Group plc Tel: +44 (0) 1283 495 010
Peter George, Group Chief Executive Officer
Shaun Chilton, Group Chief Operating Officer

Instinctif Partners (media relations) Tel: +44 (0) 20 7457 2020
Melanie Toyne-Sewell/Stefanie Bacher/Jen Lewis Email: clinigen@instinctif.com