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Clinigen to acquire US rights to Proleukin®

Clinigen Group plc (AIM: CLIN, 'Clinigen' or the 'Group'), the global pharmaceutical and services company, has signed an agreement with Novartis to acquire the US rights to Proleukin® (aldesleukin, human recombinant interleukin-2) for up to \$210m in cash, consisting of an upfront and deferred payments along with future sales related milestones.

Clinigen already owns the rights to Proleukin outside the US, which it acquired in July 2018.

Highlights

- Proleukin is indicated for metastatic melanoma and metastatic renal cell carcinoma in the US
 - Clinigen will be the exclusive global owner of the licensed version of this drug
 - Currently being used in around 80 active studies within the US across multiple disease areas
 - Has the potential to become an integral part of cancer combination therapies
- Total consideration: up to \$210m for US rights to Proleukin
 - Initial \$120m payable
 - \$60m deferred consideration over the 12 months following completion
 - A further \$30m consideration based on sales milestones
- In the year to 30 June 2018, in the US, Proleukin made revenue of \$60.0m according to IQvia (IMS). Gross profit margin is expected to be similar to other specialty medicines within the Commercial Medicines division
- The acquisition will be modestly EPS accretive in the current financial year as the product transitions to Clinigen, and at least 25% accretive in the first full financial year
- Clinigen has increased its debt facility from £300m to £375m; terms of the extended debt remain unchanged with the facility in place until October 2023
- Proleukin further diversifies the Commercial Medicines portfolio of niche hospital-only and critical care products. The Group currently owns three product assets within the US – Foscavir®, Ethyol® and Totect® with commercial rights currently licensed to Pfizer (Foscavir) and Cumberland Pharmaceuticals (Ethyol and Totect)

Clinigen expects adjusted EBITDA* in the six months ended 31 December 2018 to be £41.8m (2017: £34.4m) representing 22% reported growth or 8% growth on an organic basis**, underlining how the Group continues to be highly cash generative.

On completion, the Group's bank covenant leverage*** is expected to be around 2.4x net debt / EBITDA before reducing towards 2.0x by 31 December 2019.

The completion of the acquisition is subject to US anti-trust clearance and is expected to occur in April 2019.

Shaun Chilton, Group Chief Executive Officer, Clinigen, said:

“This highly earnings enhancing acquisition of US rights to Proleukin is significant to the whole Group not just the Commercial Medicines division.

“As part of Commercial Medicines, Proleukin is an excellent fit within our oncology and infectious disease medicines as well as diversifying our wider portfolio - it will be the largest product in the portfolio in terms of current sales. The product has significant potential for revitalisation, which will provide further breadth and diversity to the portfolio and material increases in revenues.

“For Clinigen as a whole, Proleukin creates an ideal platform to expand our existing footprint in the higher value US market and therefore enables us to exploit other opportunities across the business. This follows our acquisition last year of CSM and iQone which strengthened our Continental European footprint.

“At the financial level, the combination of this deal structure and the Group’s cash generative nature will ensure our debt profile reduces quickly over the next year.”

* Adjusted EBITDA excludes amortisation of acquired intangibles and products, and other non-underlying items relating to acquisitions, and includes the Group’s share of EBITDA from its joint venture.

** Year on year comparisons referred to as ‘organic’, are a measure of growth on a constant currency basis, excluding the impact of business and product acquisitions. Business and product acquisitions in the current period are excluded from organic EBITDA and for the acquisitions completing in the prior year, they are included on a pro-forma basis as if they occurred on the first day of the prior year. Organic growth is presented to aid the reader’s understanding of the underlying performance of the business.

*** Bank covenant leverage is calculated by dividing adjusted EBITDA of the Group for the last 12 months by net debt at the period end. Adjusted EBITDA includes the EBITDA from the businesses and assets acquired during the last 12 months, including on a pro forma basis the period prior to it becoming a member of the Group.

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Notes to Editors

About Proleukin (aldesleukin)

Proleukin (aldesleukin) is indicated for the treatment of adults with metastatic renal cell carcinoma (metastatic RCC). In certain markets Proleukin is also indicated for the treatment of adults with metastatic melanoma. Careful patient selection is mandatory prior to the administration of Proleukin.

Proleukin is a synthetic protein, and acts in the body in a very similar way to a human protein called interleukin-2 (IL-2). This protein is part of the immune system. IL-2 activates certain white blood cells in the body called lymphocytes, which fight against diseases and infections. IL-2 stimulates the production of lymphocytes in the body, and enhances the body's defences.

About metastatic renal cell carcinoma (metastatic RCC)

Renal cell carcinoma occurs when cancer cells form in the tubules of the kidney. Tubules are tiny tubes in your kidney that help filter waste products from your blood in order to make urine.

Smoking, hypertension, obesity, and hepatitis C all increase the risk of renal cell carcinoma. Renal cell carcinoma becomes metastatic renal cell carcinoma when it spreads beyond your kidney to your lymph system, bones, or other organs.

About metastatic melanoma

Melanoma is the rarest and most dangerous type of skin cancer. It begins in the melanocytes, which are the cells in your skin that produce melanin. Melanoma develops into growths on your skin, which often resemble moles. These growths or tumours may also come from existing moles. Melanomas can form on skin anywhere on your body, including inside the mouth or vagina.

Metastatic melanoma occurs when the cancer spreads from the tumour to other parts of your body. This is also known as stage 4 melanoma. Melanoma is the most likely of all skin cancers to become metastatic if not caught early.

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, as specialist pharmaceutical company in Switzerland.

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