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Clinigen launches Managed Access Program with BeiGene for zanubrutinib

Clinigen Group plc (AIM: CLIN, 'Clinigen'), the global pharmaceutical Products and Services company, has launched a Managed Access Program (MAP) for BeiGene, Ltd. , a commercial-stage biotechnology company focused on developing and commercializing innovative medicines worldwide.

A MAP, also being referred to as a Pre-Reimbursement Access Program by BeiGene, is a program which gives patients early access to a medicine that has either not yet been approved for use in the patient's country, or is approved but not yet reimbursed by health insurers and therefore not yet commercially available. These programs are key to bridging the gap for patients between approval and reimbursement. The MAP will provide zanubrutinib initially to prescribed patients with Waldenström macroglobulinemia (WM) in specific European countries.

Under the terms of the agreement Clinigen will manage all elements of the program including HCP enquiry management, regulatory oversight, logistics and access management.

Pete Belden, Executive Vice President Services Division, Clinigen said:

"We are pleased to be partnering with BeiGene to make zanubrutinib available for patients with this rare and serious condition. This aligns with our mission to ensure the right patient gets the right medicine at the right time."

Healthcare professionals can obtain details about the zanubrutinib Pre-Reimbursement Access Program by calling the customer service team at +44 1932 824001 or emailing medicineaccess@clinigengroup.com.

Patients seeking medical information should contact their physician.

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Contact details

Clinigen plc Pete Belden, EVP Services Division	+44 (0) 1283 495010
Instinctif Partners Melanie Toyne-Sewell / Phillip Marriage / Nathan Billis	+44 (0) 20 7457 2020 clinigen@instinctif.com

Notes to Editors

About zanubrutinib

Zanubrutinib is a small molecule inhibitor of Bruton's tyrosine kinase, or BTK. BTK is a key component of the B-cell receptor signalling pathway and is an important regulator of cell proliferation and cell survival and various B cell malignancies. BTK inhibitors such as zanubrutinib block BTK activation, leading to growth inhibition and cell death in certain malignant B cells. Zanubrutinib is being evaluated globally as a monotherapy and in combinations in pivotal Phase 3 trials in WM and other B cell malignancies including chronic lymphocytic leukemia (CLL) and mantle cell lymphoma (MCL). In March 2021, zanubrutinib was approved in Canada for the treatment of WM.

Zanubrutinib (marketed in the United States and China under the brand name BRUKINSA®) is a small molecule inhibitor of Bruton's tyrosine kinase (BTK), discovered by BeiGene scientists, that is currently being evaluated globally in a broad pivotal clinical program as a monotherapy and in combination with other therapies to treat various B-cell malignancies.

BRUKINSA is approved in the following indications and regions:

- For the treatment of mantle cell lymphoma (MCL) in adult patients who have received at least one prior therapy (United States, November 2019)*;
- For the treatment of MCL in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) in adult patients who have received at least one prior therapy (China, June 2020)**;
- For the treatment of relapsed or refractory MCL (United Arab Emirates, February 2021); and
- For the treatment of Waldenström's macroglobulinemia (WM) in adult patients (Canada, March 2021).

The U.S. Food and Drug Administration (FDA) has accepted a supplemental new drug application (sNDA) for BRUKINSA for the treatment of adult patients with WM. The Prescription Drug User Fee Act (PDUFA) target action date is October 18, 2021. Currently, more than 20 marketing applications for BRUKINSA have been submitted, covering more than 40 countries and regions globally, including the United States, China, and European Union.

* This indication was approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.

** This indication was approved under conditional approval. Complete approval for this indication may be contingent upon results from one or more ongoing randomized, controlled confirmatory clinical trials.

About Waldenström macroglobulinemia

WM is a rare indolent B-cell lymphoma that occurs in less than two percent of patients with non-Hodgkin's lymphoma (NHL). The disease usually affects older adults and is primarily found in the bone marrow, although lymph nodes and the spleen may be involved.[1] In Europe, the estimated incidence of WM is approximately 7 for every 1 million men and 4 for every 1 million women.[2]

About Clinigen

Clinigen Group plc (AIM: CLIN) is a global, specialist pharmaceutical services and products platform 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 1,250 employees across five continents in 16 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 5,000 hospitals across more than 115 countries.

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

About BeiGene

BeiGene is a global, commercial-stage biotechnology company focused on discovering, developing, manufacturing, and commercializing innovative medicines to improve treatment outcomes and access for patients worldwide. Our 5,400+ employees around the world are committed to expediting the development of a diverse pipeline of novel therapeutics. We currently market two internally discovered oncology medicines: BTK inhibitor BRUKINSA® (zanubrutinib) in the United States and China, and anti-PD-1 antibody tislelizumab in China. We also market or plan to market in China additional oncology products in China licensed from Amgen Inc., Celgene Logistics Sàrl, a Bristol Myers Squibb (BMS) company, and EUSA Pharma; and have entered a collaboration with Novartis Pharma AG for Novartis to develop and commercialize tislelizumab in North America, Europe, and Japan. To learn more about BeiGene, please visit www.beigene.com and follow us on Twitter at @BeiGeneUSA.

Notes:

1. Lymphoma Research Foundation. Available at https://lymphoma.org/aboutlymphoma/nhl/wm/. Accessed December 2020.
2. Buske, S, et al. Treatment and outcome patterns in European patients with Waldenström macroglobulinemia: a large, observational, retrospective chart review. The Lancet Haematology 2018; 5: e0299-309.