

MEDIA ALERT

AbbVie's Venetoclax Receives EAMS Positive Scientific Opinion in Chronic Lymphocytic Leukaemia (CLL) from the MHRA in the UK, first in any blood cancer for the scheme

- *Venetoclax is an investigational therapy with trials in relapsed or refractory CLL,¹ an area of high unmet need*
- *It is AbbVie's first oncology therapy in the UK and the first treatment for CLL to be made available through the Early Access to Medicines Scheme (EAMS)^{2,3}*

Maidenhead, UK, 23 August, 2016 – AbbVie announced today that the UK's Medicines and Healthcare products Regulatory Agency (MHRA) has granted venetoclax, its investigational treatment for Chronic Lymphocytic Leukaemia (CLL), a positive scientific opinion through the Early Access to Medicines Scheme (EAMS). The decision means that patients with certain types of difficult-to-treat CLL can now potentially gain access to venetoclax while the relevant regulatory bodies continue to review the Marketing Authorisation Application.

There are over 3,000 new cases of CLL in the UK each year, with the average age of diagnosis being 71.^{4,5} Through EAMS, venetoclax is indicated for the treatment of adult patients with CLL in the presence of 17p deletion or TP53 mutation, and who are unsuitable for or have failed a B-cell receptor pathway inhibitor (BCRi). In addition, venetoclax can be used in the treatment of adult patients with CLL in the absence of 17p deletion or TP53 mutation, and who are unsuitable for or have failed both chemo-immunotherapy and a BCRi.

The aim of EAMS is to provide earlier availability of promising innovative medicines to UK patients who have high unmet clinical need, and has only been granted to four medicines since its inception in 2014.^{2,3}

“As part of AbbVie's fight against CLL we are delighted to receive the EAMS positive scientific opinion which will help ensure that eligible patients with limited current treatment options gain access to this therapy as soon as possible,” says Alice Butler, Medical Director, AbbVie UK. “AbbVie is proud to have entered into the voluntary EAMS and today's positive announcement marks another important step for patients with CLL.”

Venetoclax's mode of action works by targeting the B-cell lymphoma-2 (BCL-2) protein, which regulates cell survival, restoring the body's ability to trigger cancer cell self-destruction (apoptosis).^{1,6} The treatment represents an important potential option for difficult-to-treat CLL patients who have certain

genetic mutations, or those who have failed BCRI treatments, and who have previously had limited treatment options.

Venetoclax is currently under review by the European Medicines Agency (EMA).

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About AbbVie

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharmacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.com. Follow [@abbvie](https://twitter.com/abbvie) on Twitter or view careers on our [Facebook](#) or [LinkedIn](#) page.

Forward-Looking Statements

Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry.

Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," of AbbVie's 2015 Annual Report on Form 10-K, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.

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¹ Stilgenbauer, S., et al (2016) "Venetoclax in Relapsed/Refractory Chronic Lymphocytic Leukemia with 17p Deletion: a multicenter, open-label, phase 2 study." *Lancet Oncol*. DOI: [http://dx.doi.org/10.1016/S1470-2045\(16\)30019-5](http://dx.doi.org/10.1016/S1470-2045(16)30019-5)

² UK Government. Early access to medicines scheme (EAMS): scientific opinions. Available at: <https://www.gov.uk/government/collections/early-access-to-medicines-scheme-eams-scientific-opinions>. Accessed August 2016.

³ UK Government. Expired early access to medicines scheme scientific opinions. Available at: <https://www.gov.uk/government/publications/early-access-to-medicines-scheme-expired-scientific-opinions/expired-early-access-to-medicines-scheme-scientific-opinions>. Accessed August 2016.

⁴ American Cancer Society. (2013) Leukemia – Chronic Lymphocytic. Available at: <http://www.cancer.org/acs/groups/cid/documents/webcontent/003111-pdf.pdf> Accessed August 2016.

⁵ Cancer Research UK. CLL incidence. Available at: <http://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/leukaemia-ctl/incidence> Accessed August 2016.

⁶ Souers, A.J., et al. Nat Med, 2013. 19(2): p. 202-8.