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PRESS RELEASE

AbbVie receives CHMP positive opinion for Venclyxto™ (venetoclax) tablets for appropriate patients with difficult-to-treat chronic lymphocytic leukaemia

- *CHMP recommends Venclyxto™ (venetoclax) monotherapy for the treatment of chronic lymphocytic leukaemia (CLL) in the presence of 17p deletion or TP53 mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor; and for the treatment of CLL in the absence of 17p deletion or TP53 mutation in adult patients who have failed both chemo-immunotherapy and a B-cell receptor pathway inhibitor*
- *CLL patients who harbour the 17p deletion or TP53 mutations often have a poor prognosis and limited treatment options*[1]
- *If granted conditional marketing authorisation by the European Commission, venetoclax would become the first approved BCL-2 inhibitor in Europe*

October 14, 2016 – AbbVie (NYSE: ABBV), a global biopharmaceutical company, today announced that the European Committee for Medicinal Products for Human Use (CHMP) has granted a positive opinion for Venclyxto™ (venetoclax) tablets for the treatment of patients with difficult-to-treat chronic lymphocytic leukaemia (CLL). The CHMP recommends approval of venetoclax monotherapy in the presence of 17p deletion or TP53 mutation in adult patients who are unsuitable for or have failed a B-cell receptor pathway inhibitor; and for the treatment of CLL in the absence of 17p deletion or TP53 mutation in adult patients who have failed both chemo-immunotherapy and a B-cell receptor pathway inhibitor. The European Commission will review the opinion and make a final decision on conditional marketing authorisation in late 2016.

“People living with CLL who harbour the 17p deletion or TP53 mutation and/or have failed other treatments have limited options and typically a poor prognosis. Today’s CHMP positive opinion marks a major step forward for these patients,” said Michael Severino, M.D., executive vice president of research and development and chief scientific officer, AbbVie. “This innovation delivers on AbbVie’s promise to develop cancer medicines where an unmet need exists. We will continue to work with European regulators to make this treatment option available to appropriate CLL patients.”

CLL, a cancer of the bone marrow and blood, is typically a slow-progressing cancer. Those with the 17p deletion or TP53 mutations often have a particularly poor prognosis[1] and a median life expectancy of less than two to three years with standard regimens.[2] While some targeted therapies have demonstrated efficacy in this patient population, some patients may relapse or experience intolerability and have to discontinue treatment.[3] The 17p deletion – a genomic alteration in which a part of chromosome 17 is absent – is found in 3 to 10% of previously untreated CLL cases and up to 30 to 50% of relapsed or refractory CLL cases.[1] A TP53 mutation occurs in 8 to 15% of patients at first-line treatment and up to 35 to 50% of cases in refractory CLL.[1]

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Professor Peter Hillmen, Consultant Haematologist, Leeds Teaching Hospitals NHS Trust and Coordinating Investigator of venetoclax studies in the UK said; “Chronic lymphocytic leukaemia can be extremely challenging to treat, especially in patients whose CLL has certain genetic mutations, has failed prior therapy and/or for patients who are unsuitable for existing treatments. The treatment options for these patients are currently very limited but we have seen extremely impressive responses in such patients in the trials of venetoclax. It is therefore important to see that venetoclax is one step closer to licence in the UK as it provides patients with an important treatment option.”

The BCL-2 protein blocks apoptosis (programmed cell death) of cells, including some cancer cells, and can be overexpressed in CLL cells.[4] Venetoclax, which is given once daily, selectively inhibits the BCL-2 protein.[4]

The positive CHMP opinion is a recommendation for approval to the European Commission. Review of the Marketing Authorisation Application (MAA) is being conducted under the centralised licensing procedure. If approved, the conditional marketing authorisation will be valid in all 28 member states of the European Union, as well as Iceland, Liechtenstein and Norway.

-**ends**-

Notes to editors

About Venclyxto™ (venetoclax)
Venclyxto™(venetoclax) is an investigational oral B-cell lymphoma-2 (BCL-2) inhibitor being evaluated for the treatment of patients with various blood cancer types.[5,6,7,8] The BCL-2 protein prevents apoptosis (programmed cell death) of some cells, including lymphocytes, and can be overexpressed in some cancer types. Venetoclax is designed to selectively inhibit the function of the BCL-2 protein.[4]

Venetoclax is being developed by AbbVie and Genentech, a member of the Roche Group. It is commercialised solely by AbbVie outside of the U.S. Together, the companies are committed to BCL-2 research with venetoclax, which is currently being evaluated in Phase 3 clinical trials for the treatment of relapsed/refractory chronic lymphocytic leukaemia (CLL), along with studies in several other cancers.

In April 2016, the U.S. Food and Drug Administration (FDA) granted accelerated approval of venetoclax tablets for the treatment of patients with CLL with 17p deletion, as detected by an FDA-approved test, who have received at least one prior therapy.[5] The FDA approved this indication under accelerated approval based on overall response rate, and continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial.[5]

Venetoclax is under evaluation by Health Authorities in multiple countries, and is currently approved in the U.S. and Argentina. AbbVie is currently working with regulatory agencies around the world to bring this medicine to eligible patients in need.

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In the UK, venetoclax has been issued with a positive Early Access to Medicines Scheme (EAMS) Scientific Opinion by the MHRA allowing eligible patients to potentially receive access through this scheme prior to receipt of the EU marketing authorisation.

About AbbVie in Oncology

AbbVie is striving to outsmart cancer by working with scientists, physicians, industry peers, patient advocacy groups and most importantly patients, to discover, develop and provide new therapies that will have a remarkable impact on the lives of people around the world affected by cancer. Our goal is to provide medicines that make a transformational improvement in cancer treatment and outcomes for cancer patients. By exploring and investing in new pathways, technologies and approaches, AbbVie is breaking ground in some of the most widespread and difficult-to-treat cancers. We are also exploring solutions to help patients obtain access to our cancer medicines. With the acquisition of Pharmacyclics in 2015 and Stemcentrx in 2016, and through several collaborations, AbbVie's oncology portfolio consists of marketed medicines and a pipeline containing multiple new molecules being evaluated worldwide in nearly two hundred clinical trials in 20 different tumor types.

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.co.uk.

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[3] Stilgenbauer, S. et al. Venetoclax in relapsed or refractory chronic lymphocytic leukaemia with 17p deletion: a multicentre, open-label, phase 2 study. *Lancet Oncol*. 2016; 17:768-778.
[4] Davids, M.S. and Letai, A. ABT-199: A New Hope for Selective BCL-2 Inhibition *Cancer Cell*. 2013. February 11; 23(2): 139-141.

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[5] Clinicaltrials.gov. NCT01889186: A study of the efficacy of ABT-199 in subjects with relapsed or refractory chronic lymphocytic leukemia with the 17p deletion. Accessed October 2016.
[6] Clinicaltrials.gov. NCT01994837: A Phase 2 Study of ABT-199 in subjects with Acute Myelogenous Leukemia (AML). Accessed October 2016.
[7] Clinicaltrials.gov. NCT01794520: Study evaluating ABT-199 in subjects with relapsed or refractory Multiple Myeloma. Accessed October 2016.
[8] Clinicaltrials.gov. NCT01328626: A Phase 1 study evaluating the safety and pharmacokinetics of ABT-199 in subjects with relapsed or refractory Chronic Lymphocytic Leukemia and Non-Hodgkin Lymphoma. Accessed Ocotber 2016.

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