



Biogen and AbbVie Receive Positive Opinion from the CHMP on ZINBRYTA™ (Daclizumab) for Treatment of Multiple Sclerosis

April 29, 2016

- Positive Benefit-Risk Profile of ZINBRYTA Supported by Large Head-to-Head Phase 3 DECIDE Study -

CAMBRIDGE, Mass. & NORTH CHICAGO, Ill.--([BUSINESS WIRE](#))--The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) has adopted a positive opinion recommending the granting of a marketing authorization for ZINBRYTA™ (daclizumab) intended for the treatment of relapsing forms of multiple sclerosis (RMS), [Biogen](#) (NASDAQ: BIIB) and [AbbVie](#) (NYSE: ABBV) announced today. ZINBRYTA is a once-monthly, self-administered, subcutaneous investigational treatment for RMS. ZINBRYTA is also currently under regulatory review in the United States, Switzerland, Canada and Australia.

"For people with relapsing forms of MS (RMS) and active disease, ZINBRYTA has the potential to offer robust efficacy, a manageable safety profile through patient monitoring, and once-monthly subcutaneous dosing," said Alfred Sandrock, M.D., Ph.D., executive vice president and chief medical officer at Biogen. "ZINBRYTA may offer another option for people with multiple sclerosis (MS) with its targeted mechanism of action (MOA) which did not cause broad and prolonged immune cell depletion."

The CHMP positive opinion is now referred to the European Commission (EC), which grants marketing authorizations for centrally authorized medicines in the European Union. A decision from the EC is expected within the coming months.

"Together with Biogen, AbbVie is committed to meeting the needs of patients with MS, and the positive opinion issued by the CHMP is a critical step that moves us closer to bringing ZINBRYTA to patients in Europe," said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie.

According to the CHMP opinion, the benefits of ZINBRYTA are its ability to reduce the annualized relapse rate (ARR), as well as the risk of 24-week confirmed disability progression. The opinion is based on results from two clinical trials, DECIDE and SELECT, in which ZINBRYTA 150 mg, administered subcutaneously every four weeks improved results on key measures of MS disease activity in patients with RMS compared to AVONEX 30 mcg intramuscular injection administered weekly and placebo, respectively.

In the DECIDE study, the overall incidence of adverse events was similar in the ZINBRYTA and AVONEX groups. In patients treated with ZINBRYTA compared to AVONEX, there was an increased incidence of serious infections (4% versus 2%), serious cutaneous reactions (2% versus <1%), elevations of liver transaminases greater than five times the upper limit of normal (6% versus 3%), gastrointestinal disorders (31% versus 24%), and depression (8% versus 6%).

About ZINBRYTA™ (daclizumab)

ZINBRYTA (daclizumab) is an investigational compound being developed for the treatment of relapsing forms of MS. ZINBRYTA is a new form of a humanized monoclonal antibody that selectively binds to the high-affinity interleukin-2 (IL-2) receptor subunit (CD25) that is expressed at high levels on T-cells that become activated in people with MS. ZINBRYTA modulates IL-2 signaling without general immune cell depletion.

Biogen and AbbVie are jointly developing ZINBRYTA.

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers worldwide innovative therapies for people living with serious neurological, autoimmune and rare diseases. Founded in 1978, Biogen is one of the world's oldest independent biotechnology companies and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For more information, please visit www.biogen.com. Follow us on [Twitter](#).

Biogen Safe Harbor

This press release contains forward-looking statements, including statements about the anticipated timing of the EC's decision on the marketing authorization for ZINBRYTA, and potential impact of ZINBRYTA, if approved. These statements may be identified by words such as "believe," "expect," "may," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. You should not place undue reliance on these statements. Drug development and commercialization involve a high degree of risk. Factors which could cause actual results to differ materially from our current expectations include the risk that the EC may fail to approve or may delay approval of ZINBRYTA or may not follow the recommendation of the CHMP, uncertainty of success in commercialization of ZINBRYTA. For more detailed information on the risks and uncertainties associated with our drug development and commercialization activities and risks relating to our collaborations with third parties, please review the Risk Factors section of our most recent annual or quarterly report filed with the Securities and Exchange Commission. Any forward-looking statements speak only as of the date of this press release and we assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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, Pharmacylics, 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](#) 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," in AbbVie's 2014 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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