



European Medicines Agency Validates Marketing Authorisation Application for ZINBRYTA™ (Daclizumab High-Yield Process) for Treatment of MS

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CAMBRIDGE, Mass. & NORTH CHICAGO, Ill.--([BUSINESS WIRE](#))--Today [Biogen](#) (NASDAQ: BIIB) and [AbbVie](#) (NYSE: ABBV) announced that the European Medicines Agency (EMA) has validated the companies' Marketing Authorisation Application (MAA) for ZINBRYTA™ (daclizumab high-yield process) for the treatment of relapsing forms of multiple sclerosis (MS) in the European Union (EU). Validation confirms that the submission is complete and signifies the initiation of the review process by the EMA's Committee for Medicinal Products for Human Use (CHMP).

"The submission and validation of the MAA are important milestones for ZINBRYTA and mean this investigational treatment is one step closer to potentially becoming available to MS patients who may benefit from its novel profile," said Gilmore O'Neill, vice president, Multiple Sclerosis Research and Development at Biogen.

The MAA included results from two clinical trials, DECIDE and SELECT, in which ZINBRYTA 150 mg was administered subcutaneously every four weeks in people with relapsing-remitting MS.

"We are committed to bringing to market medicines that may provide remarkable impact for patients, and the EMA validation of the MAA for ZINBRYTA is an important step in accomplishing that mission for MS patients," said Michael Severino, M.D., executive vice president of research and development and chief scientific officer, AbbVie.

About ZINBRYTA™ (daclizumab high-yield process)

ZINBRYTA (daclizumab high-yield process) is an investigational drug and 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 abnormally activated in multiple sclerosis (MS). ZINBRYTA modulates IL-2 signaling without causing general immune cell depletion. ZINBRYTA is believed to work by decreasing abnormally-activated T-cells and pro-inflammatory lymphoid tissue inducer cells, and increasing CD56^{bright} natural killer (NK) cells, which are important cells that help regulate the immune system.

Biogen and AbbVie are jointly developing ZINBRYTA.

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers to patients worldwide innovative therapies for the treatment of neurodegenerative diseases, hematologic conditions and autoimmune disorders. Founded in 1978, Biogen is one of the world's oldest independent biotechnology company and patients worldwide benefit from its leading multiple sclerosis and innovative hemophilia therapies. For product labeling, press releases and additional information about the company, please visit www.biogen.com.

Biogen Safe Harbor

This press release contains forward-looking statements, including statements about the potential impact of our product candidate ZINBRYTA. These statements may be identified by words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions, and are based on our current beliefs and expectations. 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 unexpected concerns may arise from additional data or analysis, regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our drug candidates, or we may encounter other unexpected hurdles. 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. AbbVie employs more than 26,000 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.

AbbVie 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, the likelihood that the transaction is consummated, the expected benefits of the transaction, 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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