FDA Accepts Biologics License Application For ZINBRYTA (Daclizumab High-Yield Process) For Treatment of MS

April 29, 2015

BLA Acceptance Follows EMA's Validation of Biogen and AbbVie's MAA for ZINBRYTA

CAMBRIDGE, Mass. & NORTH CHICAGO, Ill.--(BUSINESS WIRE)--Today Biogen (NASDAQ: BIIB) and AbbVie (NYSE: ABBV) announced that the U.S. Food and Drug Administration (FDA) has accepted for review the companies' Biologics License Application (BLA) requesting marketing approval of ZINBRYTA™ (daclizumab high-yield process) for relapsing forms of multiple sclerosis (MS).

"We are pleased by the FDA's acceptance of our BLA for ZINBRYTA, which we believe has the potential to help people living with MS," said Gilmore O'Neill, vice president, Multiple Sclerosis Research and Development at Biogen. "We look forward to working with both U.S. and European regulatory authorities to bring this investigational treatment to MS patients as soon as possible."

Biogen and AbbVie announced in March 2015 that their Marketing Authorisation Application for ZINBRYTA was validated by the European Medicines Agency for review in the European Union.

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

"This is an important milestone in the development program for ZINBRYTA and moves us a step closer to potentially bringing a new treatment option to patients with MS," said Michael Severino, M.D., executive vice president, Research and Development and Chief Scientific Officer at AbbVie.

About ZINBRYTA™ (daclizumab high-yield process)
ZINBRYTA (daclizumab high-yield process) is an investigational treatment and 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 abnormally activated in 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, 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 companies 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 ZINBRYTA, if approved. 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.

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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