Biogen and AbbVie Receive FDA Approval of Once-Monthly ZINBRYTA™ (Daclizumab) for Multiple Sclerosis

May 27, 2016

Approval Supported by Largest and Longest Head-to-Head Phase 3 Study Conducted in Multiple Sclerosis (MS)

ZINBRYTA Significantly Reduced Multiple Measures of Disease Activity in Patients with Relapsing MS

CAMBRIDGE, Mass. & NORTH CHICAGO, Ill.--(BUSINESS WIRE)--The U.S. Food and Drug Administration (FDA) approved ZINBRYTA™ (daclizumab), a new once-monthly, self-administered, subcutaneous treatment for relapsing forms of multiple sclerosis (RMS), Biogen (NASDAQ: BIIB) and AbbVie (NYSE: ABBV) announced today. Because of its safety profile, the use of ZINBRYTA should generally be reserved for patients who have had an inadequate response to two or more therapies indicated for the treatment of multiple sclerosis (MS).

“The FDA approval of ZINBRYTA reflects our long-term commitment to bringing therapies to the community that meet the diverse needs of people living with MS,” said Alfred Sandrock, M.D., Ph.D., executive vice president and chief medical officer at Biogen. “ZINBRYTA is the first once-monthly, self-administered treatment in MS, and it demonstrated superior efficacy over a widely used interferon. Clinical data showed ZINBRYTA significantly reduced relapses and brain lesions for up to three years compared to AVONEX® (interferon beta-1a) intramuscular injection, and has a positive benefit-risk profile with monthly patient monitoring.”

The FDA approval of ZINBRYTA is primarily based on results from two clinical trials, including DECIDE, the largest and longest head-to-head Phase 3 clinical trial ever conducted in MS. The Phase 2b SELECT and Phase 3 DECIDE studies were global, randomized, double-blind, controlled studies that involved approximately 2,400 people living with RMS. Some patients in DECIDE were treated for up to three years.

In DECIDE and SELECT, ZINBRYTA significantly reduced the annualized relapse rate (ARR), the primary endpoint of the studies, by 45 percent compared to AVONEX up to 144 weeks and by 54 percent compared to placebo at 52 weeks (both $p<0.0001$), respectively.

“MS patients are in need of therapeutic choices to help manage their disease and ZINBRYTA is an important new option for patients,” said Michael Severino, M.D., executive vice president, research and development and chief scientific officer, AbbVie. “AbbVie is committed to making a remarkable impact on the lives of patients, including in MS where there are particular unmet needs.”

Results from DECIDE showed that ZINBRYTA demonstrated superior efficacy across multiple measures of MS disease activity (relapses and MRI) compared to AVONEX, including a significant reduction in the mean number of new or newly enlarging T2-hyperintense lesions by 54 percent compared to AVONEX at 96 weeks ($p<0.0001$).

Additionally, the study showed at up to 144 weeks on ZINBRYTA, 67 percent of patients were relapse free compared to 51 percent of the patients taking AVONEX.

The ZINBRYTA label includes a boxed warning for the risk of hepatic injury, including autoimmune hepatitis, and other immune-mediated disorders. Because of these risks, access to ZINBRYTA in the United States is restricted to prescribers, pharmacies and patients enrolled in the ZINBRYTA Risk Evaluation and Mitigation Strategy (REMS) Program, which includes required monthly liver function tests.

“MS affects each person differently, so it is critical that people have additional therapeutic options to address their needs throughout the course of the disease,” said Jeffrey English, M.D., director of clinical research, Multiple Sclerosis Center of Atlanta. “ZINBRYTA provides a meaningful new treatment option that demonstrates efficacy and offers once-monthly dosing.”

While the precise mechanism of action of ZINBRYTA is unknown, it is thought to work differently from other disease-modifying therapies by binding to CD25, a subunit of the interleukin-2 (IL-2) receptor found on activated lymphocytes, cells believed to underlie the biology of MS. Total lymphocyte, T and B cell counts decreased less than 10 percent from baseline during the first year of treatment. The effects on total lymphocyte counts returned to baseline within approximately eight to 12 weeks after the last dose of ZINBRYTA.

The most common adverse reactions (incidence at least 5 percent and at least 2 percent higher incidence than comparator) that occurred in ZINBRYTA-treated patients were nasopharyngitis (inflammation of the nose and a part of the throat), upper respiratory tract infection, rash, influenza, dermatitis, oropharyngeal (part of the throat) pain, bronchitis, eczema, and lymphadenopathy (enlargement of the lymph nodes) compared with AVONEX; and upper respiratory tract infection, depression, rash, pharyngitis (inflammation of part of the throat), and increased alanine aminotransferase (ALT; a type of liver enzyme) compared with placebo. The U.S. ZINBRYTA prescribing information also includes warnings and precautions for hepatic injury, immune-mediated disorders, acute hypersensitivity (inflammatory reaction), infections, depression and suicide.

For more information on ZINBRYTA, and prescribing information including the boxed warning, visit www.ZINBRYTA.com.

About the DECIDE Study

DECIDE was a two- to three-year, Phase 3, global, randomized, double-blind, multicenter study in patients with relapsing forms of multiple sclerosis (RMS) designed to determine if ZINBRYTA would provide superior outcomes for certain clinical endpoints compared to treatment with AVONEX® (interferon beta-1a) 30 mcg intramuscular (IM) injection. DECIDE was an active comparator study with two groups: 150 mg of subcutaneous (SC) ZINBRYTA every four weeks (n=919) was compared to AVONEX IM once weekly (n=922).

About the SELECT Study

SELECT was a multicenter, randomized, double-blind, Phase 2b study that evaluated the efficacy and safety of ZINBRYTA 150 mg (n=208) and 300 mg (n=209) subcutaneous every four weeks for one year versus placebo (n=204) in patients with RMS.

About ZINBRYTA™ (daclizumab)

ZINBRYTA is being developed globally for relapsing forms of multiple sclerosis (RMS). In the U.S. only, due to its safety profile, ZINBRYTA is indicated for the treatment of adults with RMS, and should generally be reserved for patients who have had an inadequate response to two or more therapies.

The recommended dosage of ZINBRYTA is 150 mg, self-administered subcutaneously on a monthly basis. The European Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) recently granted a positive opinion for ZINBRYTA. The opinion of the CHMP has been referred to the European Commission for final decision on approval. ZINBRYTA is also currently under regulatory review in Switzerland, Canada and Australia.

In clinical trials, ZINBRYTA demonstrated superior efficacy in relapse reduction and MRI, key measures of MS disease activity, compared to AVONEX® (interferon beta-1a) IM injection and placebo.

ZINBRYTA is a humanized IgG1 monoclonal antibody that selectively binds to the high-affinity interleukin-2 (IL-2) receptor subunit (CD25). CD25 is expressed at high levels on T-cells that become activated in people with MS.

The U.S. ZINBRYTA prescribing information includes a boxed warning for a risk of hepatic injury and immune-mediated disorders. It also includes warnings and precautions for hepatic injury, immune-mediated disorders, acute hypersensitivity, infections, depression and suicide. The most common adverse reactions (incidence at least 5 percent and at least 2 percent higher incidence than comparator) that occurred in ZINBRYTA-treated patients were nasopharyngitis, upper respiratory tract infection, rash, influenza, dermatitis, oropharyngeal pain, bronchitis, eczema, and lymphadenopathy compared with AVONEX; and upper respiratory tract infection, depression, rash, pharyngitis, and increased alanine aminotransferase (ALT) compared with placebo.

Biogen and AbbVie are co-promoting ZINBRYTA in the United States.

About Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, often disabling disease that attacks the central nervous system, which is made up of the brain, spinal cord and optic nerves. Symptoms may be mild or severe, ranging from numbness in the limbs to paralysis or loss of vision. The progression, severity and specific symptoms of MS are unpredictable and vary from one person to another.[1] MS affects more than 2.3 million people worldwide.[2] Relapsing MS is the most common form of the disease, accounting for 85 percent of cases, and is characterized by clearly defined acute attacks with full recovery or with residual deficit upon recovery.[3]

Patient Support

As part of the companies' ongoing commitment to people living with MS, extra support will be provided through Biogen's Above MS™ program. These world-class services are thoughtfully crafted around the informational, emotional, financial and logistical needs that come with living with MS. Join the Above MS program by calling: 1-800-456-2255, Monday-Friday, 8:30 a.m. - 8 p.m. ET.

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 includes forward-looking statements, including statements about the potential therapeutic effects and benefits of ZINBRYTA. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "will," and other words and terms of similar meaning. You should not place undue reliance on these statements. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including uncertainty of success in commercialization of ZINBRYTA, which may be impacted by, among other things, slower than anticipated acceptance of ZINBRYTA by patients and the medical community, competition in the MS market, the effectiveness of sales and marketing efforts, problems with the manufacturing process for ZINBRYTA, the occurrence of adverse safety events, difficulties in obtaining or changes in the availability of reimbursement for ZINBRYTA and Biogen's other MS products, failure to obtain regulatory approvals in other jurisdictions, failure to protect intellectual property and other proprietary rights, product liability claims, third party collaboration risks, and the other risks and uncertainties that are described in the Risk Factors section of Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission (SEC). Any forward-looking statements speak only as of the date of this press release and Biogen assumes 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, 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 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, 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.

[1] National Multiple Sclerosis Society (NMSS). *What is MS?* Date accessed: May 27, 2016. http://www.nationalmssociety.org/What-is-MS.

[2] NMSS. *Who Gets MS? (Epidemiology).* Date accessed: May 27, 2016. http://www.nationalmssociety.org/What-is-MS/Who-Gets-MS.

[3] NMSS. *Types of MS.* Date accessed: May 27, 2016. http://www.nationalmssociety.org/What-is-MS/Types-of-MS.

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ZINBRYTA™ (daclizumab) was approved by the U.S. FDA on May 27, 2016. (Photo: Business Wire)
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