

# Biogen and AbbVie Announce the Voluntary Worldwide Withdrawal of Marketing Authorizations for ZINBRYTA® (daclizumab) for Relapsing Multiple Sclerosis

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- *Patient safety is the top priority for Biogen and AbbVie.*
- *The European Medicines Agency has initiated an Article 20 referral procedure following reports of inflammatory encephalitis and meningoencephalitis.*
- *Given the nature and complexity of adverse events being reported, characterizing the evolving benefit/risk profile of ZINBRYTA will not be possible going forward given the limited number of patients being treated. Therefore, Biogen and AbbVie believe it is in the best interest of patients to voluntarily withdraw worldwide marketing authorizations for ZINBRYTA.*
- *Biogen will continue to work collaboratively with regulatory authorities and with healthcare providers in their management of ZINBRYTA patients.*

CAMBRIDGE, Mass. & NORTH CHICAGO, Ill.--(BUSINESS WIRE)--Biogen (Nasdaq:BIIB) and AbbVie (NYSE:ABBV) today announced the voluntary worldwide withdrawal of ZINBRYTA for relapsing multiple sclerosis. The companies believe that characterizing the complex and evolving benefit/risk profile of ZINBRYTA will not be possible going forward given the limited number of patients being treated.

“Biogen believes the voluntary worldwide withdrawal of ZINBRYTA, a treatment for relapsing multiple sclerosis, is in the best interest of patients,” said Alfred Sandrock, M.D., Ph.D., executive vice president and chief medical officer at Biogen. “Biogen and AbbVie continue to prioritize patient safety and the care of multiple sclerosis patients worldwide.”

Biogen will continue to work collaboratively with regulatory authorities in the withdrawal of product and with healthcare providers worldwide in their support of ZINBRYTA patients.

Patients currently treated with ZINBRYTA should contact their healthcare provider if they have any questions or concerns.

## **About ZINBRYTA**

ZINBRYTA (daclizumab) is currently available in the EU, U.S., Switzerland, Canada and Australia. ZINBRYTA is a prescription medicine used to treat adults with relapsing forms of multiple sclerosis (MS). Because of its risks, ZINBRYTA is generally used in people who have tried two or more MS medicines that have not worked well enough. It is not known if ZINBRYTA is safe and effective for use in children under 18 years of age.

## **About Biogen**

At Biogen, our mission is clear: we are pioneers in neuroscience. Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological and neurodegenerative diseases. Founded in 1978 as one of the world's first global biotechnology companies by Charles Weissman, Heinz Schaller, Kenneth Murray and Nobel Prize winners Walter Gilbert and Phillip Sharp, today Biogen has the leading portfolio of medicines to treat multiple sclerosis; has introduced the first and only approved treatment for spinal muscular atrophy; and is focused on advancing neuroscience research programs in Alzheimer's disease and dementia, multiple sclerosis and neuroimmunology, movement disorders, neuromuscular disorders, pain, ophthalmology, neuropsychiatry, and acute neurology. Biogen also manufactures and commercializes biosimilars of advanced biologics. We routinely post information that may be important to investors on our website at [www.biogen.com](http://www.biogen.com). To learn more, please visit [www.biogen.com](http://www.biogen.com) and follow us on social media – , , , YouTube .

### **Biogen Safe Harbor**

This press release contains forward-looking statements, including statements relating to the potential benefits, safety, and efficacy of ZINBRYTA, our strategy and plans, and our future expenses and other financial and operating results. These statements may be identified by words such as "aim," "anticipate," "believe," "could," "estimate," "except," "forecast," "may," "plan," "potential," "possible," "will," and similar expressions, and are based on our current beliefs and expectations. You should not place undue reliance on these statements or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including: the occurrence of adverse safety events; restrictions on use of our products or product liability claims; risks of unexpected costs or delays; the estimates and assumptions we make in preparing our financial statements; 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. Any forward-looking statements speak only as of the date of this press release, and we assume no obligation to update any forward-looking statement, whether as a result of new information, future developments, or otherwise.

### **About AbbVie**

AbbVie is a global, research-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at [www.abbvie.com](http://www.abbvie.com). Follow @abbvie on Twitter, Facebook or LinkedIn.

Some statements in this news release are, or may be considered, 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 2017 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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**Contact:**

BIOGEN MEDIA CONTACT:

David Caouette, +1 781-464-3260  
public.affairs@biogen.com

or

BIOGEN INVESTOR CONTACT:

Matt Calistri, +1 781-464-2442  
IR@biogen.com

or

ABBVIE MEDIA CONTACTS:

Jack Hirschfield, 224-458-0943  
Jack.hirschfield@abbvie.com

or

Markeisha Marshall, 224-501-4425  
Markeisha.marshall@abbvie.com

or

ABBVIE INVESTOR CONTACT:

Liz Shea, 847-935-2211  
Liz.shea@abbvie.com