Real World Data Being Presented at EULAR 2017 Demonstrate Acceptance and Confirm Sustainability of Effectiveness, Safety and Adherence among Patients Switching To BENEPALI® (Etanercept Biosimilar of Biogen) from Reference Etanercept

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ZUG, Switzerland--(BUSINESS WIRE)--Real world evidence from investigator-initiated studies supported by Biogen (NASDAQ: BIIB), demonstrating sustained efficacy and safety, and high acceptance and adherence in patients initiating treatment with BENEPALI® (etanercept), are being presented at the Annual European Congress of Rheumatology *(*EULAR) 2017*,* held 14–17 June in Madrid, Spain.[1,2,3] Within the EU, approximately 50,000 patients are currently being treated with anti-TNF biosimilars from Biogen across 16 countries.[4]

Two real world studies evaluate the safety and efficacy of BENEPALI® in patients following a switch from reference etanercept. In 1,548 patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) or axial spondyloarthritis (SpA) from the DANBIO registry, disease activity was shown to be largely unaffected at 3 months post-switch and comparable to that observed in the 3 months prior to switch.[1] Furthermore, in a separate cohort of 92 patients with RA, PsA or ankylosing spondylitis (AS) in the UK, a low rate of treatment discontinuations due to inefficacy or adverse events was demonstrated at 6 months post-switch.[2]

Further real world data highlight the acceptance of BENEPALI® and adherence to treatment among patients who were switched from reference etanercept, according to a defined transition protocol. In one UK study of 96 adult patients treated for RA, PsA or AS, 99% agreed to switch.[2] 91% of the group remained on BENEPALI® at 6 months.[2] In another study of 643 patients with rheumatic disease in the Netherlands, 99% (636 patients) agreed to switch to BENEPALI® from reference etanercept. At 3 months, 36 of the 636 patients had discontinued treatment.[3] Both studies reflect that treatment with BENEPALI® provides persistency within the expectations of the reference product.[2,3]

“Biogen continues to make a difference in the lives of patients through our portfolio of anti-TNF biosimilar products, which play an important role in ensuring more people have access to the treatments they need,” said Alpna Seth, Ph.D., Senior Vice President and Global Head of the Biosimilars Business Unit at Biogen. “Our ongoing efforts to forge partnerships with healthcare organizations and systems have opened doors for biosimilar adoption in a number of European countries, although more can be done to set the right policy environment so that all countries can unlock the full value of these therapies.”

The abstracts being presented at EULAR 2017, showcasing data from Biogen-supported studies, include:

- *Thakur K, et al. Etanercept Biosimilar Usage and Associated Cost Savings in Germany* [THU0656] – Thursday, June 15, 2017, 1:10pm CEST, Poster Area
- *Glintborg B, et al. Clinical Outcomes from a Nationwide Non-Medical Switch from Originator to Biosimilar Etanercept in Patients with Inflammatory Arthritis after 5 Months Follow-Up. Results from the DANBIO Registry* [FRI0190] – Friday, June 16, 2017, 1:40pm CEST, Poster Area
- *Tweehuysen L, et al. Higher Acceptance and Persistence Rates after Biosimilar Transitioning in Patients with a Rheumatic Disease after Employing an Enhanced Communication Strategy* [FRI0200] – Friday, June 16, 2017, 11:45am CEST, Poster Area
- *Sigurdardottir V, et al. Switching from Reference Product Etanercept to the Biosimilar SB4 in a Real-Life Setting: Follow-Up of 147 Patients* [SAT0173] – Saturday, June 17, 2017, 10:15am CEST, Poster Area
- *Holroyd C, et al. Switching from Bio-Original Etanercept to Biosimilar Etanercept SB4: Patient Acceptability and Outcomes in the Real World* [AB0377] – Publication Only

About BENEPALI ®

BENEPALI is an etanercept biosimilar to the reference product Enbrel®.[5] BENEPALI is approved in Europe for the treatment of adults with moderate to severe RA, psoriatic arthritis, non-radiographic axial spondyloarthritis and plaque psoriasis. BENEPALI is currently available in 16 European countries.[4]

About Biogen

Through cutting-edge science and medicine, Biogen discovers, develops and delivers innovative therapies worldwide for people living with serious neurological and neurodegenerative diseases. Founded in 1978, Biogen is a pioneer in biotechnology and today the Company has the leading portfolio of medicines to treat multiple sclerosis, has introduced the first and only approved treatment for spinal muscular atrophy, and is at the forefront of neurology research for conditions including Alzheimer’s disease, Parkinson’s disease and amyotrophic lateral sclerosis. Biogen also manufactures and commercializes biosimilars of advanced biologics. For more information, please visit www.biogen.com. Follow us on social media – Twitter, LinkedIn, Facebook, YouTube.

Biogen Safe Harbor

This press release includes forward-looking statements, including statements about the potential benefits of our products and programs and expected timing of results from clinical trials. 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. Drug development and commercialization is a lengthy and complex process, which involves a high degree of risk. Factors that could

cause actual results to differ materially from our current expectations include: the risk that unexpected concerns may arise from additional data or analysis, or regulatory authorities may require additional data or information or further studies, or may fail to approve, or refuse to approve, or may delay approval of our biosimilar drug candidates risks related to our dependence on third parties for the development and commercialization of biosimilars; risks of legal actions, regulatory scrutiny or other challenges to biosimilars; and the risks of other unexpected hurdles. For more detailed information on the risks and uncertainties associated with our drug development and commercialization activities, please review the Risk Factors section of our most recent annual or quarterly report filed with the Securities and Exchange Commission. These statements are based on our current beliefs and expectations, and speak only as of the date of this press release. We do not undertake any obligation to publicly update any forward-looking statements.

This medicinal product is subject to additional monitoring.

References

[1] Glintborg B, et al. Clinical outcomes from a nationwide non-medical switch from originator to biosimilar etanercept in patients with inflammatory arthritis after 5 months follow-up. Results from the DANBIO registry. Abstract presented at EULAR 14–17 June 2017, Madrid, Spain. Abstract #FRI0190.

[2] Holroyd C, et al. Switching from bio-original etanercept to biosimilar etanercept SB4: patient acceptability and outcomes in the real world. Abstract presented at EULAR 14–17 June 2017, Madrid, Spain. Abstract #AB0377.

[3] Tweehuysen L, et al. Higher Acceptance and Persistence Rates after Biosimilar Transitioning in Patients with a Rheumatic Disease after Employing an Enhanced Communication Strategy. Abstract presented at EULAR 14–17 June 2017, Madrid, Spain. Abstract #FRI0200.

[4] Biogen data on file. June 2017.

[5] Enbrel® is a registered trademark of Wyeth LLC.

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