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Biogen and Samsung Bioepis Announce New Data for Three Anti-TNF Biosimilar Development Candidates at EULAR 2015 Congress

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SB4 and SB2 biosimilar candidates demonstrated Phase III clinical comparability to respective reference products, etanercept (Enbrel®) and infliximab (Remicade®)

Pharmacokinetic equivalence data for SB5 biosimilar candidate of adalimumab (Humira®) also to be presented

If authorized by EMA, Biogen will market all three anti-TNF biosimilar candidates in Europe

ZUG, Switzerland--(BUSINESS WIRE [3])--Biogen [4] (NASDAQ: BIIB) and Samsung Bioepis Co., Ltd [5] today announced that results from their anti-TNF biosimilar portfolio are being presented at the European League Against Rheumatism Annual Congress (EULAR 2015) in Rome, June 10–13, 2015. Highlights include results from separate head-to-head Phase III studies showing clinical comparability of SB4 (etanercept) and SB2 (infliximab), which are biosimilar development candidates to their respective reference products Enbrel®[1] and Remicade®[2]. Also being presented are equivalence data from a Phase I pharmacokinetic (PK) study comparing SB5 (adalimumab), a biosimilar development candidate, with the reference product Humira®[3]. These results profile a promising anti-TNF biosimilar portfolio for the two companies.

“Biogen is committed to bringing biosimilars of advanced biologics to the healthcare market,” said John Cox, Executive Vice President of Pharmaceutical Operations and Technology at Biogen. “With our leading manufacturing capabilities and deep scientific expertise, we believe we are well positioned to bring the three most commonly used anti-TNF therapies to physicians, payers, and ultimately the patients who need them most.”

SB4 data highlights
The 24-week data from a Phase III study comparing SB4 with the etanercept reference product Enbrel in patients with moderate to severe rheumatoid arthritis, despite methotrexate therapy, showed equivalence in terms of clinical efficacy and safety.[i]

- A total of 596 patients were randomized to either SB4 (N=299) or the etanercept reference product (N=297)[i]
- The ACR20* response rate at week 24 in the per protocol set (PPS) was 78.1% in the SB4 group and 80.3% in the etanercept reference group, (adjusted difference -2.2%, 95% CI: -9.41%, 4.98%)[i]
- The ACR20 at 24 weeks was also shown to be equivalent in the full analysis set (FAS), at 73.8% for the SB4 group and 71.7% for the etanercept reference group (adjusted difference 1.92%, 95% CI: -5.24%, 9.07%)[i]
- SB4 was well-tolerated and demonstrated a comparable safety profile to the etanercept reference product[i]
- Full data from the 52-week study will be available at a later date

SB2 data highlights
The 30-week data from a Phase III study comparing SB2 with the infliximab reference product Remicade, in patients with moderate to severe rheumatoid arthritis demonstrated SB2 to have an equivalent ACR20 response and a comparable safety profile.[ii]

- A total of 584 patients were randomized to either SB2 (N=291) or the infliximab reference product (N=293)[ii]
- The ACR20 response rate at week 30 in the PPS was 64.1% with SB2 and 66.0% with the infliximab reference group (adjusted difference -1.88%, 95% CI: -10.26%, 6.51%)[ii]

- The ACR20 from the FAS also showed equivalence of SB2 to the infliximab reference group, at 55.5% vs. 59.0%, respectively (adjusted difference -2.95%, 95% CI: -10.88%, 4.97%)[ii]
- SB2 was well tolerated with a comparable safety, PK, and immunogenicity to the infliximab reference product[ii]

SB5 Data
Phase I results demonstrating PK equivalence between SB5, an adalimumab biosimilar candidate, and its reference product, Humira (US and European) will also be presented. SB5 and its reference products were generally well tolerated, with similar safety profiles.[iii]

SB4, SB2, and SB5 are being produced at Biogen's advanced biologics manufacturing plant in Hillerød, Denmark, a world-class, state-of-the-art biologic manufacturing facility.

"We are excited by the positive results from these three equivalence studies, including the Phase III data for SB4 and SB2. The results presented at EULAR are part of the robust data packages intended to support the global regulatory filings for each," said Christopher Hansung Ko, CEO of Samsung Bioepis.

Biogen at EULAR
Biogen is sponsoring a satellite symposium, "What rheumatologists need to know about biosimilars of complex biologics" chaired by Professor Thomas Dörner, Professor of Rheumatology and Clinical Immunology at Charité University Hospital Berlin, Germany. The symposium is taking place on Wednesday, June 10 at 1:00 pm Central European Summer Time (CEST) in Room 10 I at Fiera Roma.

Biogen also has an exhibition booth where attendees will be able to learn more about biosimilars of advanced biologics and how they are manufactured by taking a 360-degree 3D virtual tour of its Hillerød, Denmark manufacturing facility.

The posters being presented at EULAR are as follows:

SB4 poster presentations:

- *A Phase III randomised, double-blind clinical study comparing SB4, an etanercept biosimilar, with etanercept reference product (Enbrel®) in patients with moderate to severe rheumatoid arthritis despite methotrexate therapy (24-week results)* [FRI0128] – Friday, June 12, 2015, 12.00 pm CEST, Hall 6
- *A Phase I pharmacokinetic study comparing SB4, an etanercept biosimilar, and etanercept reference product (Enbrel®) in healthy male subjects* [SAT0176] – Saturday, June 13, 2015 10.15 am CEST, Hall 6

SB2 poster presentations:

- *A randomised, double-blind, Phase III study comparing SB2, an infliximab biosimilar, to the infliximab reference product (Remicade®) in patients with moderate to severe rheumatoid arthritis despite methotrexate therapy* [SAT0152] – Saturday, June 13, 2015, 10.15 am CEST, Hall 6
- *A Phase I pharmacokinetic study comparing SB2, an infliximab biosimilar, and infliximab reference product (Remicade®) in healthy subjects* [SAT0144] – Saturday, June 13, 2015, 10.15 am CEST, Hall 6

SB5 poster presentation:

- *A Phase I pharmacokinetic study comparing SB5, an adalimumab biosimilar, and adalimumab reference product (Humira®) in healthy subjects* [FRI0110] – Friday, June 12, 2015, 12.00 pm CEST, Hall 6

Both SB4 and SB2 are currently under review by the European Medicines Agency (EMA), and if authorized could be available for use in the same indications as their respective reference products.

About SB4
The Marketing Authorization Application (MAA) for SB4 includes pivotal data from a Phase III, controlled, randomized, multicenter study in Europe comparing SB4 head-to-head with its etanercept reference product Enbrel.

In Europe, Enbrel is indicated for the treatment of a number of rheumatic diseases, including moderate to severe rheumatoid arthritis, psoriatic arthritis, non-radiographic axial spondyloarthritis, and plaque psoriasis. If authorized by the EMA, SB4 could also be available for use in these indications.

About SB2
The MAA for SB2 includes pivotal data from a Phase III, controlled, randomized, multicenter study in Europe comparing SB2 head to- head with its infliximab reference product Remicade.

In Europe, Remicade is indicated for moderate to severe rheumatoid arthritis, adult Crohn's disease, pediatric Crohn's disease, ulcerative colitis, pediatric ulcerative colitis, psoriatic arthritis, ankylosing spondylitis, and psoriasis. If authorized by the EMA, SB2 could also be available for use in these indications.

About SB5
SB5 is a biosimilar candidate in clinical development; an ongoing Phase III study is investigating the comparability of SB5 in the treatment of patients with moderate to severe rheumatoid arthritis compared with the EU- and US-sourced adalimumab reference product Humira.

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 [6].

About Samsung Bioepis
The company was established in 2012 as part of the Samsung group, and as a joint venture between Samsung Biologics and Biogen. Its mission is to produce affordable, high-quality biopharmaceutical products to many patients in need. The company aims to be the world-leading biopharmaceutical company with its heritage of innovation and advanced technologies. Please visit www.samsungbioepis.com [7] for more information.

Biogen Safe Harbor
This press release includes forward-looking statements, including statements about the potential to bring anti-TNF biosimilar product candidates to market. 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; the risk that regulatory authorities may require additional information or further studies, or may fail to approve or may delay approval of our product candidates; risks associated with manufacturing processes; risks related to our dependence on third parties for the development and commercialization of biosimilars; and the risk that we encounter 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.

*American College of Rheumatology (ACR) criteria measure improvement in tender or swollen joint counts and improvement in three of the following five parameters: 1) acute phase reactant (such as sedimentation rate), 2) patient assessment, 3) physician assessment, 4) pain scale, 5) disability/functional questionnaire. ACR20 refers to a 20% improvement in tender or swollen joint counts as well as 20% improvement in three of the other five criteria.

[1] Remicade is a registered trademark of Janssen Biotech, Inc.

[2] Enbrel is a registered trademark of Wyeth LLC

[3] Humira is a registered trademark of AbbVie Biotechnology Ltd

References

[i] Vencovský J, et al. A Phase III, randomised, double-blind clinical study comparing SB4, and etanercept biosimilar with etanercept reference product (Enbrel®) in patients with moderate to severe rheumatoid arthritis despite methotrexate therapy (24-week results). Presented at The European League Against Rheumatism Annual Congress (EULAR 2015), 12 June 2015, Rome, Italy.

[ii] Choe J-Y, et al. A randomised, double-blind, Phase III study comparing SB2, an infliximab biosimilar, to the infliximab reference product (Remicade®) in patients with moderate to severe rheumatoid arthritis despite methotrexate therapy. Presented at The European League Against Rheumatism Annual Congress (EULAR 2015), 13 June 2015, Rome, Italy.

[iii] Shin D, et al. A Phase I pharmacokinetic study comparing SB5, an adalimumab biosimilar, and adalimumab reference product (Humira®) in healthy subjects. Presented at The European League Against Rheumatism Annual Congress (EULAR 2015), 12 June 2015, Rome, Italy.

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