



Biogen and Xbrane Announce Commercialization and License Agreement for Proposed Biosimilar Referencing CIMZIA® (Certolizumab pegol) with the Potential to Treat Rheumatoid Arthritis

February 7, 2022

Biosimilars have the potential to broaden patient access to effective and more affordable treatments and generate healthcare savings

CAMBRIDGE, Mass and SOLNA, Sweden, Feb. 07, 2022 (GLOBE NEWSWIRE) -- [Biogen](#) Inc. (Nasdaq: BIIB) and Xbrane Biopharma AB (STO: XBRANE) today announced that they have entered into a commercialization and license agreement to develop, manufacture, and commercialize Xcimzane™, a preclinical monoclonal antibody that is a proposed biosimilar referencing CIMZIA® (certolizumab pegol)¹.

CIMZIA®'s primary indication is for rheumatoid arthritis in adults as well as axial spondylarthritis, psoriasis and Crohn's disease. In 2020 global sales of CIMZIA® were 1.8 billion Euro². Under the terms of the agreement, Biogen will gain exclusive global regulatory, manufacturing, and commercial rights to Xcimzane™ and will be the Marketing Authorization Holder.

"We aim to bring more biosimilars products to more patients and more geographies and we are excited to bring this additional asset to our Biosimilars pipeline," said Ian Henshaw, Head of Global Biosimilars at Biogen. "This preclinical biosimilar candidate has the potential to add another option for patients living with Rheumatoid Arthritis and other indications."

"Given their vast development and commercialization experience, we are convinced that Biogen is the best possible partner we could have for Xcimzane™," said Martin Åmark, CEO of Xbrane Biopharma AB. "Today's announcement confirms Xbrane's ambition to become a global biosimilar developer."

Under the terms of the agreement, Biogen will make an upfront payment of \$8 million to Xbrane. Should certain development and commercial milestones be achieved, Xbrane will be eligible to receive up to \$80 million in potential milestone payments. Xbrane is also eligible to receive tiered royalties. Xbrane will be responsible for the completion of pre-clinical development of Xcimzane™ and Biogen will be responsible for all remaining development activities and costs required to achieve Marketing Authorization in all territories, including those for clinical development.

About Biosimilars

Biosimilars are biologic products that have been demonstrated to be similar in efficacy, safety and immunogenicity to the originator's approved reference product, with the advantage that they can offer significant cost savings. Biosimilars may lower healthcare system costs broadly, creating headroom for innovation and could enable governments to potentially redirect savings to priorities such as increasing access to transformative therapies.

About Biogen

As pioneers in neuroscience, Biogen discovers, develops, and delivers worldwide innovative therapies for people living with serious neurological diseases as well as related therapeutic adjacencies. One of the world's first global biotechnology companies, Biogen was founded in 1978 by Charles Weissmann, Heinz Schaller, Sir Kenneth Murray, and Nobel Prize winners Walter Gilbert and Phillip Sharp. Today, Biogen has a leading portfolio of medicines to treat multiple sclerosis, has introduced the first approved treatment for spinal muscular atrophy, and is providing the first and only approved treatment to address a defining pathology of Alzheimer's disease. Biogen is also commercializing biosimilars and focusing on advancing the industry's most diversified pipeline in neuroscience that will transform the standard of care for patients in several areas of high unmet need.

In 2020, Biogen launched a bold 20-year, \$250 million initiative to address the deeply interrelated issues of climate, health, and equity. Healthy Climate, Healthy Lives™ aims to eliminate fossil fuels across the company's operations, build collaborations with renowned institutions to advance the science to improve human health outcomes, and support underserved communities.

The company routinely posts information that may be important to investors on its website at www.biogen.com. To learn more, please visit www.biogen.com and follow Biogen on social media – [Twitter](#), [LinkedIn](#), [Facebook](#), [YouTube](#).

About Xbrane Biopharma AB

Xbrane Biopharma AB develops biological drugs based on a patented platform technology that provides significantly lower production costs compared to competing systems. Xbrane has a portfolio of biosimilar candidates targeting €11 billion in annual sales of the respective reference products, with the leading one under registration in Europe. Xbrane's head office is in Solna, just outside Stockholm. Xbrane is listed on Nasdaq Stockholm under the ticker XBRANE.

For more information, visit www.xbrane.com

Biogen Safe Harbor

This news release contains forward-looking statements, including statements made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, relating to the potential benefits and results that may be achieved through Biogen's proposed agreement with Xbrane Biopharma AB; the anticipated completion and timing of the proposed transaction; the potential benefits, safety and efficacy of Xcimzane™; risks and uncertainties associated with drug development and commercialization; the potential of Biogen's commercial business and pipeline programs; Biogen's strategy and plans; and potential cost healthcare savings related to biosimilars. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. 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 without limitation, risks that the proposed transaction will not be completed in a timely manner or at all; the possibility that certain closing conditions to

the proposed transaction will not be satisfied; uncertainty as to whether the anticipated benefits of the proposed transaction can be achieved; risks of unexpected costs or delays or other unexpected hurdles; uncertainty of success in the development and potential commercialization of Xcimzane™, which may be impacted by, among other things, unexpected concerns that may arise from additional data or analysis, the occurrence of adverse safety events, failure to obtain regulatory approvals in certain jurisdictions, failure to protect and enforce data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; risks of legal actions, regulatory scrutiny or other challenges to biosimilars; the direct and indirect impacts of the ongoing COVID-19 pandemic on Biogen's business, results of operations and financial condition; the risks of doing business internationally, including currency exchange rate fluctuations; product liability claims; and third party collaboration risks. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Biogen's expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in Biogen's most recent annual or quarterly report and in other reports Biogen has filed with the U.S. Securities and Exchange Commission. These statements are based on Biogen's current beliefs and expectations and speak only as of the date of this news release. Biogen does not undertake any obligation to publicly update any forward-looking statements, whether as a result of new information, future developments or otherwise.

Xbrane Cautionary Statement

This news release contains forward-looking statements, relating to the potential benefits and results that may be achieved through Xbrane's proposed agreement with Biogen; the anticipated completion and timing of the proposed transaction; the potential benefits, safety and efficacy of Xcimzane; risks and uncertainties associated with drug development and commercialization; the potential of Xbrane's commercial business and pipeline programs; Xbrane's strategy and plans; and potential cost healthcare savings related to biosimilars. These forward-looking statements may be accompanied by words such as "aim," "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "potential," "possible," "will," "would" and other words and terms of similar meaning. Drug development and commercialization involve a high degree of risk, and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. 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 without limitation, risks that the proposed transaction will not be completed in a timely manner or at all; the possibility that certain closing conditions to the proposed transaction will not be satisfied; uncertainty as to whether the anticipated benefits of the proposed transaction can be achieved; risks of unexpected costs or delays or other unexpected hurdles; uncertainty of success in the development and potential commercialization of Xcimzane™, which may be impacted by, among other things, unexpected concerns that may arise from additional data or analysis, the occurrence of adverse safety events, failure to obtain regulatory approvals in certain jurisdictions, failure to protect and enforce data, intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; risks of legal actions, regulatory scrutiny or other challenges to biosimilars; the direct and indirect impacts of the ongoing COVID-19 pandemic on Xbrane's business, results of operations and financial condition; the risks of doing business internationally, including currency exchange rate fluctuations; product liability claims; and third party collaboration risks. The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from Xbrane's expectations in any forward-looking statement. Investors should consider this cautionary statement, as well as the risk factors identified in Xbrane's most recent annual or quarterly report and in other reports Xbrane has filed. These statements are based on Xbrane's current beliefs and expectations and speak only as of the date of this news release. Xbrane does not undertake any obligation to publicly update any forward-looking statements, whether because of new information, future developments or otherwise.

References

¹ CIMZIA® is a registered trademark of UCB

² Company reported sales

https://reports.ucb.com/FbContent.ashx/pub_1000/downloads/v210225063440/UCB%20ANNUAL%20REPORT%202020_v6.4.5.pdf

MEDIA CONTACT:

Biogen

Ashleigh Koss

+ 1 908 205 2572

public.affairs@biogen.com

Xbrane Biopharma AB

Martin Åmark, CEO

+46 76 309 37 77

martin.amark@xbrane.com

INVESTOR CONTACT:

Biogen

Mike Hencke

+1 781 464 2442

IR@biogen.com

Xbrane Biopharma AB

Anette Lindqvist, CFO/IR

+46 76 325 60 90

anette.lindqvist@xbrane.com