



EPIRUS Announces Positive 58 Week Follow Up Data for BOW015 for treatment of Rheumatoid Arthritis

BOW015 demonstrates therapeutic equivalence to Remicade® and confirms the safety of switching from Remicade to BOW015

BOSTON, September 23, 2014 - EPIRUS Biopharmaceuticals, Inc. (EPIRUS, NASDAQ: [EPRS](#)), a Boston-based biopharmaceutical company focused on the global development and commercialization of biosimilar monoclonal antibodies, today announced positive 58 week follow up data from its BOW015 efficacy and safety trial comparing BOW015, a biosimilar infliximab, to Remicade.

“The open label phase of the study was designed to provide data on long term safety and durability of response as well as long term safety for Remicade responders switching to BOW015. This data suggests the patients can safely be started and maintained on BOW015 and that patients can be safely switched from Remicade to BOW015,” said Michael Wyand, PhD, DVM, senior vice president of clinical, regulatory and manufacturing.

The overall study was comprised of a 16 week, double blinded, head to head comparison with Remicade for safety and efficacy followed by an open label phase where Remicade responders were switched to BOW015 and all patients were followed for the duration of the study. The study met its primary endpoint of ACR20 response, the American College of Rheumatology criteria for clinical improvement in patients with rheumatoid arthritis, indicating a 20% improvement across a series of diagnostic parameters.

In the open-label phase, patients who continued on BOW015 were compared to patients who received four doses of Remicade, followed by a switch to four doses of BOW015. Immune responses as well as overall safety and tolerability for BOW015 were comparable to the arm switched from Remicade to BOW015 and were consistent with the expected profile of Remicade. Further, ACR20 responses were durably maintained to 58 weeks from the week 16 primary endpoint previously reported.

The full data will be presented at an upcoming medical meeting.

About BOW015

BOW015 is a biosimilar version of infliximab, a biologic therapy marketed under the name Remicade. EPIRUS has previously reported positive Phase 1 and Phase 3 clinical data for BOW015. The Phase 3 trial previously met its predefined



endpoint and demonstrated the comparability of BOW015 to Remicade, as measured by ACR20 response in severe rheumatoid arthritis (RA) patients. The study also showed no meaningful differences between BOW015 and Remicade with regard to safety or immunogenicity.

More data on the Phase 3 study is available at www.abstracts2view.com/eular/.

Epirus is actively progressing applications for marketing approval for BOW015 in targeted global markets. In September 2014, EPIRUS announced final approval of BOW015 in India, the first infliximab biosimilar approved in India. Epirus also plans to initiate an additional Phase 3 trial in Europe in early 2015.

About EPIRUS

EPIRUS is building a global biosimilar enterprise to improve patient access to important medicines. EPIRUS' pipeline of biosimilar product candidates includes BOW015 (infliximab), BOW050 (adalimumab), and BOW030 (bevacizumab). The reference products for these product candidates – Remicade®, Humira®, and Avastin®, respectively – together generated \$26.2 billion in global sales in 2013.

The company's strategy for commercial success relies on targeted approaches for diverse global markets.

For emerging markets with accessible regulatory frameworks for biosimilars, EPIRUS develops partnerships with local companies to accelerate regulatory approval and commercialize its products.

For high-growth global markets where local manufacturing confers strategic and operational advantages, EPIRUS intends to use its SCALE™ platform to deliver an In Market, For Market™ manufacturing solution with local partners.

For large markets with an established biosimilar regulatory framework, such as Europe, EPIRUS plans to commercialize its products using a combination of direct sales and local distributors.

More information about EPIRUS can be found at www.epirusbiopharma.com

Forward Looking Statements

Any statements made herein relating to future financial or business performance, conditions, plans, prospects, trends, or strategies and other financial and business matters are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. In addition, when or if used in this document, the words "may," "could," "should,"



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