



## **Data from EPIRUS' Phase 3 Study of BOW015, a biosimilar infliximab, to be Presented as a Late Breaking Poster at the American College of Rheumatology Annual Meeting**

*Poster Presentation will Include 54-Week Results of a Randomized Double-Blind Active Comparator Study to Remicade®*

**BOSTON, November 17, 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 they will present data from their Phase 3 study, "BOW015, a Biosimilar Infliximab, in Patients with Active Rheumatoid Arthritis on Stable Methotrexate Doses: 54-Week Results of a Randomized, Double-Blind, Active Comparator Study," at the 2014 Annual Scientific Meeting of the American College of Rheumatology and the Association of Rheumatology Health Professionals (ACR/ARHP), November 18, in Boston, MA. Dr. Jonathan Kay, Professor of Medicine, University of Massachusetts Medical School, Director of Clinical Research, Division of Rheumatology, University of Massachusetts Memorial Medical Center, is the lead author.

The poster includes positive 54-week follow up data from the BOW015 efficacy and safety trial comparing BOW015, a biosimilar infliximab, to Remicade. The study met its primary endpoint of ACR20 response, the American College of Rheumatology criteria for clinical improvement in patients with rheumatoid arthritis, indicating 20% improvement in a group of clinical parameters. The first segment of the study was a 16-week, double-blinded, head-to-head comparison of BOW015 to Remicade for safety and efficacy and was followed by an open label phase in which Remicade responders were switched to BOW015. All patients were then followed for the duration of the 58 week study.

"The results of this study suggest that patients can be safely switched from Remicade to BOW015," said Dr. Kay. "I am pleased that the ACR selected this study for presentation as a late breaking abstract, since this study demonstrates the efficacy and safety of BOW015 to treat the many patients who suffer with rheumatoid arthritis and other inflammatory diseases."

The poster, #L20, will be displayed from Sunday, November 16 to Tuesday November 18 and will be presented on Tuesday, November 18, from 9 am — 11



am EDT in Exhibit Hall B. The abstract is available online through the ACR website at [www.rheumatology.org](http://www.rheumatology.org).

"We are pleased to share the latest data on our lead compound with the rheumatology community," said Amit Munshi, president and CEO of EPIRUS. "This data demonstrates the long term durability of the response and safety of BOW015 therapy and represent another important step in making this drug available to patients globally."

### **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 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/](http://www.abstracts2view.com/eular/).

EPIRUS is actively progressing applications for marketing approval for BOW015 in targeted global markets. 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. EPIRUS also has two additional undisclosed preclinical product candidates.

EPIRUS' strategy for commercial success relies on targeted approaches for diverse global markets.

For Developed 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.



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

For high-growth Local Production 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.

More information about EPIRUS can be found at [www.epirusbiopharma.com](http://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, including the long-term safety and prospects of BOW015, 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,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “plan,” “predict” and similar expressions and their variants, as they relate to EPIRUS or its management, before or after the recent Zalicus merger, may identify forward-looking statements. EPIRUS cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, which change over time. Important factors that may cause actual results to differ materially from the results discussed in the forward-looking statements or historical experience include risks and uncertainties, including the failure by EPIRUS to secure and maintain relationships with collaborators; risks relating to clinical trials; risks relating to the commercialization, if any, of EPIRUS’ proposed product candidates (such as marketing, regulatory, product liability, supply, competition, and other risks); dependence on the efforts of third parties; dependence on intellectual property; and risks that EPIRUS may lack the financial resources and access to capital to fund proposed operations. Further information on the factors and risks that could affect EPIRUS’ business, financial conditions and results of operations are contained in EPIRUS’ filings with the U.S. Securities and Exchange Commission, which are available at [www.sec.gov](http://www.sec.gov). The forward-looking statements represent the estimates of EPIRUS as of the date hereof only, and EPIRUS specifically disclaims any duty or obligation to update forward-looking statements.

Other risks and uncertainties are more fully described in EPIRUS’ filings with the U.S. Securities and Exchange Commission, which are available at [www.sec.gov](http://www.sec.gov). Existing and prospective investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The statements made herein speak only as of the date stated herein, and subsequent events and developments may cause EPIRUS’ expectations and beliefs to change.



While EPIRUS may elect to update these forward-looking statements publicly at some point in the future, EPIRUS specifically disclaims any obligation to do so, whether as a result of new information, future events or otherwise, except as required by law. These forward-looking statements should not be relied upon as representing EPIRUS' views as of any date after the date stated herein.

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