

# EPIRUS Biopharmaceuticals Remicade® Biosimilar, Infimab™, Launches in India

Infimab (BOW015) Launches one quarter ahead of schedule with commercialization partner Ranbaxy Laboratories Limited

**BOSTON, MA – December 2, 2014** - EPIRUS Biopharmaceuticals, Inc. (EPIRUS, NASDAQ: <u>EPRS</u>), a Boston-based biopharmaceutical company focused on the global development and commercialization of biosimilar monoclonal antibodies, today announced the launch of its first product, Infimab (BOW015), the first infliximab biosimilar in India.

Infimab, a Remicade (infliximab) biosimilar, is being launched in cooperation with EPIRUS' commercialization partner Ranbaxy Laboratories Limited (Ranbaxy). Infimab will be manufactured by Reliance Life Sciences at a facility in Mumbai. Remicade is currently marketed globally for the treatment of inflammatory diseases including rheumatoid arthritis, Crohn's Disease, ankylosing spondylitis, ulcerative colitis, psoriatic arthritis and psoriasis.

"The launch of Infimab in the fourth quarter of this year is earlier than anticipated and demonstrates our ability to execute with our partner," said Amit Munshi, president and CEO of EPIRUS. "Infimab represents an affordable solution for patients and may expand patient access to this important medicine. With this first launch, and a diverse pipeline in development, we look forward to continuing to provide solutions for patients globally."

Under the terms of its licensing agreement with EPIRUS, Ranbaxy has the rights to commercialize Infimab in other markets in Southeast Asia and North Africa.

#### **About INFIMAB (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:

http://acrabstracts.org/abstracts/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/



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 <a href="https://www.epirusbiopharma.com">www.epirusbiopharma.com</a>

### **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 <a href="https://www.sec.gov">www.sec.gov</a>. 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 <a href="https://www.sec.gov">www.sec.gov</a>. 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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Remicade® is a registered trademark of Johnson and Johnson (www.jnj.com) Humira® is a registered trademark of AbbVie (www.abbvie.com) Avastin® is a registered trademark of Genentech (www.gene.com)



 $In fimab^{\tiny{\mathsf{TM}}} \ is \ a \ trademark \ filed \ for \ registration \ by \ Ranbaxy \ Laboratories \ (\underline{www.ranbaxy.com})$