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EPIRUS Announces Reprioritization of Pipeline to Solely Focus on Biosimilars to Treat Rare Diseases and Key Leadership Changes

- 1 *New strategy to focus exclusively on BOW080 (eculizumab biosimilar) and BOW070 (tocilizumab biosimilar) in rare diseases with a combined target market opportunity of close to \$6 billion of innovator sales estimated in 2020*
- 1 *Amit Munshi steps down as president and chief executive officer; Dr. Scott Rocklage, founding chief executive officer of Cubist and currently a company director appointed as chief executive officer and Dr. Michael Wyand named president and chief operating officer*

BOSTON, May 09, 2016 (GLOBE NEWSWIRE) -- [EPIRUS Biopharmaceuticals, Inc.](#) (Nasdaq:EPRS), a biosimilar company focused on the global development and commercialization of biosimilar monoclonal antibodies (mAbs), today announced reprioritization of the company's pipeline to focus exclusively on developing biosimilars for the treatment of rare diseases. This includes reallocating the Company's resources to focus on the development of BOW080 (eculizumab; reference biologic Soliris®) for the potential treatment of ultra-rare blood disorders and BOW070 (tocilizumab; reference biologic Actemra®) for the potential treatment of an uncommon [lymphoproliferative](#) disorder known as Castleman's disease.

With the prioritization of the Company's rare disease biosimilar assets, EPIRUS will suspend lead program BOW015 (infliximab, reference biologic Remicade®) and work to further evaluate strategic options for the program, which may include partnerships, divestitures and/or other value-generating alternatives. The Company's decision to suspend its BOW015 program is based on cost-savings, not technical reasons, and the program remains ready to commence its planned global Phase 3 clinical study. The focus on high-value biosimilars that treat rare diseases also necessitates a restructuring of operations and elimination up to approximately 40 percent of positions in the Company's workforce. The Company is taking this action in response to the evolving biosimilar competitive and business landscape, in order to focus on markets that are more targeted and may yield marketed products through a more capital-efficient development pathway.

Additionally, effective immediately, Amit Munshi has stepped down as president, chief executive officer and as a member of the Company's board. Scott Rocklage, Ph.D., a current Company board member, managing partner at 5AM Ventures and founding chief executive officer of Cubist Pharmaceuticals, has been appointed chief executive officer. Michael Wyand, DVM, Ph.D., the Company's current chief technology officer and a key force in building the rare disease pipeline, has been promoted to president and chief operating officer.

"Amit has been instrumental in establishing EPIRUS as a leading biosimilar company," said Scott Rocklage, Ph.D., chief executive officer, EPIRUS Biopharmaceuticals. "We appreciate his very significant contributions to our business over his four years at EPIRUS."

"We are extremely excited to focus on rare diseases and this represents a significant milestone for both the Company and the community, as there exists an unmet need for cost-effective therapies in the rare disease space," said Michael Wyand, DVM Ph.D., president, EPIRUS Biopharmaceuticals. "Our initial market research with hematologists indicates that physicians are receptive to, and likely to prescribe biosimilars for, rare diseases. We look forward to paving the way for biosimilars focused in rare diseases."

About EPIRUS

EPIRUS Biopharmaceuticals (NASDAQ:EPRS) is a biosimilar company focused on the global development and commercialization of rare disease biosimilar monoclonal antibodies (mAbs). EPIRUS' goal is to improve global patient access to important, cost-effective medicines. The Company's current pipeline of biosimilar product candidates includes:

[BOW070](#) (tocilizumab, reference biologic Actemra®); [BOW080](#) (eculizumab, reference biologic Soliris®); and additional undisclosed assets. The projected innovator or class sales for these products are estimated at almost \$6 billion in global sales in 2020, according to EvaluatePharma®.

About BOW080 and BOW070

BOW080 (eculizumab; reference biologic Soliris®) is a complement inhibitor being evaluated for the potential treatment of ultra-rare blood disorders such as, paroxysmal nocturnal hemoglobinuria (PNH) and atypical hemolytic uremic syndrome (aHUS). BOW070 (tocilizumab; reference biologic Actemra®), an immunosuppressive drug, will be solely focused on the potential treatment for an uncommon [lymphoproliferative](#) disorder known as Castleman's disease.

Forward-Looking Statements

Various statements in this release 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, may identify forward-looking statements. EPIRUS cautions that these forward-looking statements are subject to numerous assumptions, risks, and uncertainties, such as EPIRUS' ability to access sufficient capital resources in the near term to fund its operations, including the rare disease biosimilar activities described in this press release, as to which EPIRUS can provide no assurance. 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 risk that EPIRUS may lack the financial resources and access to capital to fund proposed operations; risks associated with the change in EPIRUS' strategy to focus solely on rare diseases; the failure by EPIRUS to secure and maintain relationships with collaborators and single-source contract manufacturers; risks relating to in-house cell line and process development activities; risks relating to clinical development; 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; risks related to the loss of any of EPIRUS' key management personnel; and other factors that are described in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of EPIRUS' annual report on Form 10-K for the fiscal year ended December 31, 2015 and other SEC filings, which are on file with the SEC and available on the SEC's website at www.sec.gov. In addition to the risks described above and in EPIRUS' annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other filings with the SEC, other unknown or unpredictable factors also could affect EPIRUS' results. There can be no assurance that the actual results or developments anticipated by EPIRUS will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, EPIRUS. Therefore, no assurance can be given that the outcomes stated in such forward-looking statements and estimates will be achieved.

All written and verbal forward-looking statements attributable to EPIRUS or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to herein. EPIRUS cautions investors not to rely too heavily on the forward-looking statements EPIRUS makes or that are made on its behalf. The information in this release is provided only as of the date of this release, and EPIRUS undertakes no obligation, and specifically declines any obligation, to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

ⁱ Remicade is a registered trademark of Johnson and Johnson; Actemra is a registered trademark of Chugai Seiyaku Kabushiki Kaisha Corp., a member of the Roche Group; and Soliris is a registered trademark of Alexion Pharmaceuticals, Inc.

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