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## **UK Court Rules Against Lilly in Alimta Vitamin Regimen Patent Lawsuit**

INDIANAPOLIS, Feb. 12, 2016 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the UK High Court decided the Alimta® (pemetrexed disodium) vitamin regimen patent would not presently be infringed by Actavis marketing pemetrexed trometamol in the UK, France, Italy and Spain with instructions to dilute the product only with dextrose solution.

In June of 2015, the UK Court of Appeal held that Lilly's patent would be indirectly infringed by Actavis marketing certain alternative salt forms of pemetrexed with instructions to dilute the product with saline solution. However, the Court of Appeal left open the question of whether an alternative salt form with instructions to dilute only in dextrose solution would infringe.

The court based its decision of non-infringement on Actavis complying with its stated intentions as to how it will market its product and certain circumstances not changing over the remaining life of the patent. In its decision, the UK court accepts that it is not able to predict what will happen in the future and expressly allows either party to ask for the decision to be revisited if there is a material change of circumstances at any point in the remaining life of the patent, which expires in June 2021.

Lilly plans to seek permission to appeal today's decision to the UK Court of Appeal.

In major European countries, the compound patents for Alimta expired in December 2015. The Alimta vitamin regimen patents expire in June 2021.

"We strongly disagree with the ruling by the UK High Court granting a declaration of non-infringement on the Alimta vitamin regimen patents under these circumstances. We plan to seek permission to appeal this ruling," said Michael J. Harrington, senior vice president and general counsel for Lilly.

In addition, Lilly has applied for permission to appeal the direct infringement aspect of the June 2015 Court of Appeal decision to the UK Supreme Court. That request is pending.

In a separate proceeding in the first quarter of 2015, the Dusseldorf Court of Appeal ruled the Alimta vitamin regimen patent would not be infringed by a generic competitor that has stated intent to market pemetrexed dipotassium in Germany after the compound patent expiration in December 2015. Lilly has recently been granted permission to appeal this ruling to the Federal Supreme Court of Germany, which is scheduled to be heard mid-2016. Lilly has also recently received a preliminary injunction against a different generic competitor to restrict marketing of a copycat pemetrexed product.

In the fourth quarter of 2015, a generic competitor unilaterally withdrew its appeal in the case regarding the validity of the Alimta vitamin regimen patent before the Technical Board of Appeal of the European Patent Office (EPO). In view of the withdrawal of the appeal, the decision of the Opposition Division of the EPO finding the patents valid is final, and there cannot be further validity challenges to the vitamin regimen patents for Alimta centrally before the EPO.

### **About Eli Lilly and Company**

Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at [www.lilly.com](http://www.lilly.com) and <http://newsroom.lilly.com/social-channels>. C-LLY

This release contains forward-looking statements regarding European Alimta patent litigation. These statements are based on management's current expectations but actual results may differ materially. There can be no assurance that the company will prevail in any appeal. Also, the company cannot predict whether generic pemetrexed will be marketed prior to the resolution of this litigation. Other risk factors that may affect the company's results can be found in the company's latest Forms 10-K and 10-Q filed with the U.S. Securities and Exchange Commission.

Alimta® (pemetrexed, Lilly)

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The Lilly logo is rendered in a vibrant red, cursive script. The letters are thick and fluid, with a classic, elegant feel. The 'L' is particularly large and loops back, while the 'y' has a long, sweeping tail that extends downwards and to the right.

Logo - <http://photos.prnewswire.com/prnh/20031219/LLYLOGO>

To view the original version on PR Newswire, visit:<http://www.prnewswire.com/news-releases/uk-court-rules-against-lilly-in-alimta-vitamin-regimen-patent-lawsuit-300219409.html>

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