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English Court Rules Against Lilly in Alimta Vitamin Dosage Regimen Patent Lawsuit

INDIANAPOLIS, May 15, 2014 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) today announced that the English High Court has determined that the vitamin dosage regimen patents for Alimta[®] (pemetrexed) would not be infringed by a generic competitor that has stated an intent to market certain alternative salt forms of pemetrexed in several European countries upon expiry of the Alimta compound patents in 2015. The decision came in the case of *Actavis UK Limited and others v. Eli Lilly and Company*.

The English court ruled that Alimta's vitamin dosage regimen patent would not be infringed by a generic competitor that had stated its intent to market certain alternative salt forms of pemetrexed in the United Kingdom prior to the U.K. patent's expiration in mid-2021. In addition, the English court granted corresponding declarations of non-infringement regarding Alimta's vitamin dosage regimen patents in France, Italy and Spain. Lilly plans to seek permission to appeal today's ruling to the Court of Appeal.

The compound patents for Alimta in major European countries remain in force and are expected to provide exclusivity through 2015. In a parallel infringement case on one of the alternative salt forms of pemetrexed earlier this year, the Regional Court of Dusseldorf in Germany ruled in Lilly's favor regarding infringement of Alimta's vitamin dosage regimen patent under German law. Lilly agrees with the decision in Germany, which is currently under appeal.

"We strongly disagree with the ruling by the English High Court regarding infringement of Alimta's vitamin dosage regimen patents," said Michael J. Harrington, senior vice president and general counsel for Lilly. "Lilly takes the view that the court did not correctly apply the legal standards in the U.K. and failed to make the assessments for France, Italy and Spain using the correct approach as required by national laws in those countries."

Harrington continued, "Although Alimta's compound patents remain in force and are expected to provide exclusivity in major European countries through 2015, we continue to believe that Alimta's vitamin dosage regimen patents would be infringed by the entry of generic pemetrexed in Europe prior to June, 2021. The significant scientific research that Lilly performed in support of those vitamin dosage regimen patents deserves intellectual property protection. We plan to seek permission to appeal this ruling."

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 and <http://newsroom.lilly.com/social-channels>. C-LLY

This release contains forward-looking statements regarding the 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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