Lilly, Bristol-Myers Squibb Stop Enrollment in One of Two Phase III Lung Cancer Trials of Necitumumab

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INDIANAPOLIS and PRINCETON, N.J., Feb. 2, 2011 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY [1]) and Bristol-Myers Squibb Company (NYSE: BMY [2]) announced today that they have stopped enrollment in one of their two global Phase III studies evaluating necitumumab, an investigational anti-cancer agent, as a first-line treatment for advanced non-small cell lung cancer (NSCLC).

(Logo: http://photos.prnewswire.com/prnh/20031219/LLYLOGO)

The randomized, multi-center, open-label Phase III trial, named INSPIRE, is evaluating the addition of necitumumab, a fully-human IgG1 monoclonal antibody, to a combination of ALIMTA® (pemetrexed for injection) and cisplatin compared to a regimen of ALIMTA and cisplatin, as a first-line treatment for patients with advanced nonsquamous NSCLC. No new safety issues were seen in the control arm with Alimta and cisplatin.

The decision to stop enrollment followed an independent Data Monitoring Committee (DMC) recommendation that no new or recently enrolled patients continue treatment in the trial because of safety concerns related to thromboembolism (blood clots) in the experimental arm of the study. The DMC also noted that patients who have already received two or more cycles of necitumumab appear to have a lower ongoing risk for these safety concerns. These patients may choose to remain on the trial, after being informed of the additional potential risks. Investigators will continue to assess patients after two cycles to determine if there is a potential benefit from treatment.

As noted earlier, necitumumab continues to be studied in a Phase III trial named SQUIRE. This study is evaluating necitumumab as a potential treatment for a different type of lung cancer called squamous non-small cell lung cancer in combination with GEM
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