BYETTA® - First in a New Class of Medicines for Treatment of Type 2 Diabetes - Is Accepted by Scottish Medicines Consortium for Use Before Patients Start Insulin Therapy

INDIANAPOLIS and SAN DIEGO, Jul 10, 2007 (PR Newswire Europe via COMTEX News Network) -- This appraisal decision, as well as the recent reimbursement approval in Sweden, opens access for more European patients who have not achieved adequate glycaemic control on metformin and/or sulphonylureas -

Eli Lilly and Company (NYSE: LLY) and Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) welcomed today the recent decision by the Scottish Medicines Consortium (SMC) on the use of BYETTA(R) (exenatide) in Scotland. The decision states that exenatide is restricted for use in National Health Service (NHS) Scotland for the treatment of type 2 diabetes mellitus in combination with metformin and/or sulphonylureas in patients who have not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.(1)

Exenatide has shown non-inferiority to two insulin regimens with which it has been compared and has a beneficial effect on weight. It is restricted to use as an alternative to insulin in patients who have failed treatment on metformin and/or sulphonylureas and in whom insulin would be the next treatment option.(1)

"Exenatide is the first incretin mimetic to be appraised by the SMC," said Andrew Hotchkiss, General Manager at Lilly UK. "Diabetes affects 170,000 people in Scotland(2) and we are delighted that the innovative nature of this new medicine and its potential benefit to patients has been recognised by the SMC."

BYETTA is the first in a new class of medicines for the treatment of type 2 diabetes known as incretin mimetics.

As well as the positive guidance from the SMC on the use of BYETTA, there has recently been a reimbursement approval for BYETTA in Sweden where the Pharmaceutical Benefits Board (LFN) concluded that BYETTA should be reimbursed in the pharmaceutical benefits system for use in people with type 2 diabetes.(3)

About BYETTA(R) (exenatide) injection

BYETTA is the first in a class of medicines for the treatment of type 2 diabetes called incretin mimetics. BYETTA exhibits many of the same effects as the human incretin hormone glucagon like peptide-1 (GLP-1). GLP-1 improves blood sugar after food intake through multiple effects that work in concert on the stomach, liver, pancreas and brain. BYETTA is approved in the European Union as adjunctive therapy to improve blood sugar control in patients with type 2 diabetes who have not achieved adequate glycaemic control on maximally tolerated doses of metformin and/or a sulphonylurea, two common oral diabetes medications.(4) BYETTA provides sustained HbA1c control, low incidence of hypoglycaemia when used with metformin and progressive weight loss. In three separate insulin comparator studies, patients initiating exenatide generally lost weight while patients initiating insulin therapy generally gained weight.(5,6,7) In addition, when compared to insulin glargine, exenatide was associated with a lower incidence of hypoglycaemia when used with metformin.(8)

Important Safety Information for BYETTA(R) (exenatide) injection

In clinical studies, the most common side effects were hypoglycaemia (low blood sugar) when taken with a sulphonylurea, nausea (feeling sick), vomiting and diarrhoea. For the full list of all side effects reported with BYETTA, see the Package Leaflet. BYETTA should not be used in people who may be hypersensitive (allergic) to exenatide or any of the other ingredients.

About Diabetes

Diabetes affects an estimated 246 million adults worldwide and more than 48 million in Europe.(9,10) Approximately 90 to 95 percent of those are affected by type 2 diabetes, a condition characterized by failure of the pancreatic beta cells to adequately respond to the increased demands for insulin that occur as a result of obesity-related insulin resistance.(11) Type 2 diabetes usually occurs in adults over the age of 40, but is increasingly common in younger people.(10) In virtually every developed society, diabetes is ranked among the leading causes of blindness, renal failure and lower limb amputation, as well as death through its effects on cardiovascular disease (70-80 percent of people with diabetes die of cardiovascular disease).(12) The calculated estimates of the costs of diabetes care in Europe amount to 42.8 billion International Dollars per year.(13)

About Lilly and Amylin

Through a long-standing commitment to diabetes care, Lilly provides patients with breakthrough treatments that enable them to live longer, healthier and fuller lives. Since 1923, Lilly has been the industry leader in pioneering therapies to help health care professionals improve the lives of people with diabetes, and research continues on innovative medicines to address the unmet needs of patients.

Lilly, a leading innovation-driven corporation, is developing a growing portfolio of first-in-class and best-in-class pharmaceutical products by applying the latest research from its own worldwide laboratories and from collaborations with eminent scientific organizations. Headquartered in Indianapolis, Indiana, Lilly provides answers - through medicines and information - for some of the world's most urgent medical needs.

Amylin Pharmaceuticals is a biopharmaceutical company committed to improving lives through the discovery, development and commercialization of innovative medicines. Amylin has developed and gained approval for two first-in-class medicines for diabetes. Amylin's research and development activities leverage the company's expertise in metabolism to develop potential therapies to treat diabetes and obesity. Amylin is located in San Diego, California with over 1,700 employees nationwide.

This press release contains forward-looking statements about Lilly and Amylin. Actual results could differ materially from those discussed or implied in this press release due to a number of risks and uncertainties, including the risk that BYETTA and the revenues generated from BYETTA may be affected by competition, unexpected new data, technical issues, clinical trials not confirming previous results or predicting future results, label expansion requests not being submitted in a timely manner or receiving regulatory approval, or manufacturing and supply issues. The potential for BYETTA may also be affected by government and commercial reimbursement and pricing decisions, the pace of market acceptance, or scientific, regulatory and other issues and risks inherent in the commercialization of pharmaceutical products. These and additional risks and uncertainties are described more fully in Lilly and Amylin's most recently filed United States Securities Exchange Commission documents such as their Quarterly Reports on Form 10-Q. Lilly and Amylin undertake no duty to update these forward-looking statements.

REFERENCES

(1) www.scottishmedicines.org.uk

(2) Diabetes UK: State of the Nations 2006. January 2007

(3) Swedish Pharmaceutical Benefits Board (LFN) www.lfn.se

(4) The European Public Assessment Report for Byetta. Available at http://www.emea.europa.eu/humandocs/Humans/EPAR/byetta/byetta.htm. Accessed July 5, 2007.

(5) Barnett AH, Trautmann M, Burger J, Johns D, Kim D, Brodows R, Festa A, Roberts A. A comparison of exenatide and insulin glargine in patients using a single oral antidiabetic agent. Data disclosure at the 42nd annual meeting of the European Association of the Study of Diabetes. September 16, 2006.

(6) Heine RJ, Van Gaal LF, Johns D, Mihm MJ, Widel MH, Brodows RG. Exenatide versus insulin glargine in patients with suboptimally controlled type 2 diabetes: A randomized trial. Annals of Internal Medicine 2005; 143(8):559-69.

(7) Nauck MA, Duran S, Kim D, Johns D, Northrup J, Festa A, Brodows B, Trautmann M. A comparison of twice-daily exenatide and biphasic insulin aspart in patients with type 2 diabetes who were suboptimally controlled with sulfonylurea and metformin: A noninferiority study. Diabetologia 2007; 50:259-267

(8) Trautmann ME., Burger J., Johns D., Brodows R., Okerson T., Roberts A., and Barnett A. Less hypoglycemia with exenatide versus insulin glargine, despite similar HbA1c improvement, in patients with T2DM adjunctively treated with metformin. Data disclosure at the 67th Scientific Sessions of the American Diabetes Association, June 24, 2007, Abstract # 0172-OR.

(9) The International Diabetes Federation Diabetes Atlas. Available at: http://www.idf.org/home/index.cfm?unode=3B96906B-C026-2FD3-87B73F80BC22682A. Accessed June 14, 2007.

(10) The International Diabetes Federation, Prevalence / All diabetes. Available at http://www.eatlas.idf.org/Prevalence/All_diabetes/.

(11) Turner RC, Cull CA, Frighi V, Holman RR. Glycemic control with diet, sulfonylurea, metformin, or insulin in patients with type 2 diabetes mellitus: progressive requirement for multiple therapies (UKPDS 49). JAMA 1999; 281(21):2005-2012.

(12) The International Diabetes Federation, Complications. Available at http://www.eatlas.idf.org/Complications/

(13) The International Diabetes Federation, Diabetes Atlas, Second edition. The Economic Impact of Diabetes. 2003:186.

Derin Denham of Eli Lilly and Company, +1-317-277-6749 office, or
+1-317-370-1435 cell; NewsCom:
http://www.newscom.com/cgi-bin/prnh/20031219/LLYLOGO, PRN Photo Desk,
photodesk@prnewswire.com

Copyright (C) 2007 PR Newswire Europe

News Provided by COMTEX