FDA Approves BYDUREON™ -- The First and Only Once-Weekly Treatment for Type 2 Diabetes

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Provides Glycemic Control in a Once-Weekly Dose

SAN DIEGO and DUBLIN, Jan. 27, 2012 /PRNewswire/ -- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) and Alkermes plc (Nasdaq: ALKS) today announced that the U.S. Food and Drug Administration (FDA) has approved BYDUREON™ (exenatide extended-release for injectable suspension) – the first once-weekly treatment for type 2 diabetes. BYDUREON is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes in multiple clinical settings. BYDUREON will be available in pharmacies nationwide in February.

To view the multimedia assets associated with this release, please visit: http://www.multivu.com/mnr/53897-amylin-alkermes-plc-bydureon-fda-approved-treatment-type-2-diabetes

"With BYDUREON, U.S. physicians and patients can now choose a therapy that offers continuous blood sugar control in just one dose per week," said John Buse, M.D., Ph.D., professor of medicine, director of the Diabetes Care Center and chief of the Division of Endocrinology at the University of North Carolina School of Medicine in Chapel Hill. "New treatment options are essential for the millions of adults with type 2 diabetes who continue to struggle to achieve optimal blood sugar control."

The approval of BYDUREON (pronounced by-DUR-ee-on) was based on safety and efficacy data from the DURATION clinical trial program, in which treatment with BYDUREON resulted in improvements in glycemic control with just one dose per week. The approval was also based on clinical experience with BYETTA® (exenatide) injection, a twice-daily form of exenatide that has been available in the U.S. since June 2005 and is used in nearly 80 countries worldwide. BYDUREON uses Alkermes' proprietary technology for long-acting medications to provide a controlled release of exenatide.

"As the first and only once-weekly diabetes treatment, BYDUREON represents an important milestone in Amylin's promise to bring to market innovative therapies to help improve the lives of people with type 2 diabetes," said Daniel M. Bradbury, president and chief executive officer, Amylin Pharmaceuticals. "BYDUREON builds upon the proven benefits of BYETTA, offering significant improvements in glycemic control in a single weekly dose."

In the DURATION-5 head-to-head clinical study, after 24 weeks of treatment, patients taking once-weekly BYDUREON experienced a statistically superior reduction in A1C of 1.6 percentage points from baseline, compared to a reduction of 0.9 percentage points for patients taking BYETTA. A1C is a measure of average blood sugar over three months. Both treatment groups achieved statistically significant weight loss by the end of the study, with an average loss of 5.1 pounds for patients taking BYDUREON and 3.0 pounds for patients taking BYETTA (weight loss was a secondary endpoint).The most frequently reported adverse event in both groups was nausea, reported less frequently by BYDUREON users (14 percent) than by BYETTA users (35 percent). Other common treatment-emergent adverse events in the BYDUREON group included diarrhea, upper respiratory tract infection and injection site nodules. There were no major hypoglycemic events.

BYDUREON has been approved with a Risk Evaluation and Mitigation Strategy (REMS) to ensure that the benefits of BYDUREON outweigh the risk of acute pancreatitis and the potential risk of medullary thyroid carcinoma. As part of the REMS, Amylin has established a communication plan for healthcare professionals to help minimize these risks. In addition, Amylin will fulfill a number of post-marketing requirements to further assess the impact of BYDUREON on medullary thyroid cancer and cardiovascular disease. More information will be available at www.BYDUREON.com.

BYDUREON is provided in a straightforward single-dose tray so that patients can self-administer the once-weekly subcutaneous injection. In the DURATION clinical studies, the delivery system was well accepted by patients and physicians.

Amylin to Host Investor Conference Call
Amylin will host a conference call led by Mr. Bradbury to discuss the approval of BYDUREON today at 4:30 p.m. EST. A slide presentation accompanying the conference call will be made available through the "Investors" section of Amylin's corporate website at http://www.amylin.com/

The call will be webcast live through the "Investors" section of Amylin's corporate website, and a recording will be made available following the close of the call. To access the webcast, please log on to www.amylin.com approximately 15 minutes prior to the call to register, download and install any necessary audio software. For those without access to the Internet, the live call may be accessed by phone by calling (800) 857-5738 (U.S./Canada) or (415) 228-4970 (international), conference access code #7253303. A replay of the call will also be available by phone beginning approximately two hours after the close of the call and can be accessed at (800) 964-3620 (U.S./Canada) or (203) 369-3425 (international).

About BYDUREON™ (exenatide extended-release for injectable suspension)
BYDUREON, previously known as exenatide once weekly, is the first and only once-weekly medicine to be approved by the FDA for the treatment of type 2 diabetes. BYDUREON works with the body to help make its own insulin when needed, providing continuous glycemic control with just one dose per week. Each dose of BYDUREON is made up of biodegradable microspheres that provide a controlled release of exenatide throughout the week.

BYDUREON is an injectable prescription medicine that may improve blood sugar (glucose) in adults with type 2 diabetes mellitus, and should be used along with diet and exercise. BYDUREON is not recommended as the first medication to treat diabetes.

BYDUREON is a long-acting form of the medication in BYETTA® (exenatide) injection so both drugs should not be used together. BYDUREON is not

insulin and should not be taken instead of insulin. BYDUREON is not for people with type 1 diabetes or people with diabetic ketoacidosis. BYDUREON is not recommended for use in children. It is not known if BYDUREON is safe and effective in people with a history of pancreatitis or severe kidney problems. See important safety information below. Additional information about BYDUREON will be available at www.BYDUREON.com.

Important Safety Information for BYDUREON™ (exenatide extended-release for injectable suspension)

In animal studies, BYDUREON caused rats to develop tumors of the thyroid gland. Some tumors were cancers. It is not known if BYDUREON causes thyroid tumors or a type of thyroid cancer called medullary thyroid cancer (MTC) in people. BYDUREON should not be used if there is a personal or family history of MTC or Multiple Endocrine Neoplasia syndrome type 2.

Based on post-marketing data, exenatide has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Patients should be observed for signs and symptoms of pancreatitis after initiation of BYDUREON.

The risk of getting low blood sugar is higher if BYDUREON is taken with another medicine that can cause low blood sugar, such as a sulfonylurea. The dose of sulfonylurea may need to be lowered while BYDUREON is used. BYDUREON should not be used in people who have or had severe kidney problems and may cause or worsen problems with kidney function, including kidney failure. Patients should talk with their healthcare provider if they have severe problems with their stomach, such as delayed emptying of the stomach (gastroparesis) or problems with digesting food. Antibodies may develop with use of BYDUREON, which may lead to worsening or failure to achieve adequate glycemic control. Severe allergic reactions can happen with BYDUREON. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with BYDUREON or any other antidiabetic drug.

The most common side effects with BYDUREON include nausea, diarrhea, headache, vomiting, constipation, itching at injection site, a small bump (nodule) at the injection site, and indigestion. Nausea most commonly happens when first starting BYDUREON, but may become less over time.

These are not all the side effects from use of BYDUREON. A healthcare provider should be consulted about any side effect that is bothersome or does not go away.

For additional important safety information about BYDUREON, please see the full Prescribing Information (www.BYDUREON.com/pi) and Medication Guide (www.BYDUREON.com/mg), to be posted shortly.

About BYETTA® (exenatide) injection
BYETTA was the first glucagon-like peptide-1 (GLP-1) receptor agonist to be approved by the FDA for the treatment of type 2 diabetes. BYETTA exhibits many of the same effects as the human incretin hormone 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 an injectable prescription medicine that may improve blood sugar (glucose) control in adults with type 2 diabetes mellitus, when used with a diet and exercise program. It can also be used with metformin, a sulfonylurea, a thiazolidinedione or Lantus® (insulin glargine), which is a long-acting insulin.

BYETTA is not insulin and should not be taken instead of insulin. BYETTA should not be taken with short- and/or rapid-acting insulin. BYETTA is not for people with type 1 diabetes or people with diabetic ketoacidosis. BYETTA has not been studied in patients with a history of pancreatitis. Other antidiabetic therapies should be considered for these patients.

BYETTA provides sustained A1C control with potential weight loss (BYETTA is not a weight-loss product). BYETTA was approved in the U.S. in April 2005 and in Europe in November 2006 and has been used by more than 1.8 million patients since its introduction. See important safety information below. Additional information about BYETTA is available at www.BYETTA.com.

Important Safety Information for BYETTA® (exenatide) injection

Based on post-marketing data, BYETTA has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Patients should be observed for signs and symptoms of pancreatitis after initiation or dose escalation of BYETTA.

The risk of getting low blood sugar is higher if BYETTA is taken with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. The dose of sulfonylurea or insulin may need to be lowered while BYETTA is used. BYETTA should not be used in people who have severe kidney problems and may cause or worsen problems with kidney function, including kidney failure. Patients should talk with their healthcare provider if they have severe problems with their stomach, such as delayed emptying of the stomach (gastroparesis) or problems with digesting food. Antibodies may develop with use of BYETTA. Patients who develop high titers to exenatide could have worsening or failure to achieve adequate glycemic control. Severe allergic reactions can happen with BYETTA. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with BYETTA or any other antidiabetic drug.

The most common side effects with BYETTA include nausea, vomiting, diarrhea, feeling jittery, dizziness, headache, acid stomach, constipation and weakness. Nausea most commonly happens when first starting BYETTA, but may become less over time.

These are not all the side effects from use of BYETTA. A healthcare provider should be consulted about any side effect that is bothersome or does not go away.

For additional important safety information about BYETTA, please see the full Prescribing Information (www.BYETTA.com/pi) and Medication Guide (www.BYETTA.com/mg).

About Diabetes
Diabetes affects nearly 26 million people in the U.S. and an estimated 347 million adults worldwide.[i],[ii] Approximately 90-95 percent of those affected have type 2 diabetes. In the U.S., diabetes costs more than $174 billion per year in direct and indirect medical expenses.[iii]

According to the Centers for Disease Control and Prevention's National Health and Nutrition Examination Survey, approximately 60 percent of people with diabetes do not achieve their target blood sugar levels with their current treatment regimen.[iv] In addition, 85 percent of type 2 diabetes patients are overweight and 55 percent are considered obese.[v] Data indicate that weight loss (even a modest amount) supports patients in their efforts to

achieve and sustain glycemic control.[vi],[vii]

About Amylin Pharmaceuticals
Amylin Pharmaceuticals is a biopharmaceutical company dedicated to improving lives of patients through the discovery, development and commercialization of innovative medicines. Amylin is committed to delivering novel therapies that transform the way diabetes, obesity and related metabolic disorders are treated. Amylin is headquartered in San Diego, Calif. and has a commercial manufacturing facility in Ohio. More information about Amylin Pharmaceuticals is available at www.amylin.com.

About Alkermes plc
Alkermes plc is a fully integrated, global biopharmaceutical company that applies its scientific expertise and proprietary technologies to develop innovative medicines that improve patient outcomes. The company has a diversified portfolio of more than 20 commercial drug products and a substantial clinical pipeline of product candidates that address central nervous system (CNS) disorders such as addiction, schizophrenia and depression. Headquartered in Dublin, Ireland, Alkermes plc has an R&D center in Waltham, Mass. and manufacturing facilities in Athlone, Ireland; Gainesville, Ga.; and Wilmington, Ohio. For more information, please visit Alkermes' website at www.alkermes.com.

Forward-Looking Statement
This press release contains forward-looking statements about Amylin and Alkermes. 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/or BYDUREON and the revenues generated from these products may be affected by competition; unexpected new data; safety and technical issues; clinical trials not being completed in a timely manner, not confirming previous results, not being predictive of real-world use or not achieving the intended clinical endpoints; label expansion requests or New Drug Application filings not being submitted and/or accepted in a timely manner or receiving regulatory approval; the commercial launch of BYDUREON in the U.S. being delayed or not successful; or manufacturing and supply issues. The potential for BYETTA and/or BYDUREON 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 development and commercialization of pharmaceutical products. These and additional risks and uncertainties are described more fully in Amylin's and Alkermes' SEC filings including their Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K. Amylin and Alkermes undertake no duty to update these forward-looking statements.

[i] Diabetes Statistics. American Diabetes Association. Available at: http://www.diabetes.org/diabetes-basics/diabetes-statistics/. Accessed January 19, 2012.

[ii] Danaei G, Finucane MM, Lu Y, et al. National, regional, and global trends in fasting plasma glucose and diabetes prevalence since 1980: systematic analysis of health examination surveys and epidemiological studies with 370 country-years and 2.7 million participants. Lancet. 2011;DOI:10.1016/S0140-6736(11)60679-X.

[iii] Direct and Indirect Costs of Diabetes in the United States. American Diabetes Association. Available at: http://www.diabetes.org/how-to-help/action/resources/cost-of-diabetes.html. Accessed January 19, 2012.

[iv] Saydah SH, Fradkin J, Cowie CC. Poor control of risk factors for vascular disease among adults with previously diagnosed diabetes. JAMA. 2004;291:335-42.

[v] Bays HE, Chapman RH, Grandy S. The relationship of body mass index to diabetes mellitus, hypertension and dyslipidaemia: comparison of data from two national surveys. Int J Clin Pract. 2007;61:737-47.

[vi] Nutrition Recommendations and Interventions for Diabetes: a position statement of the American Diabetes Association. Diabetes Care. 2008;31 Suppl 1;S61-78.

[vii] Anderson JW, Kendall CW, Jenkins DJ. Importance of weight management in type 2 diabetes: review with meta-analysis of clinical studies. J Am Coll Nutr. 2003;22:331-9.

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