Once-Weekly BYDUREON™ Provided Greater Glucose Control, Weight Loss and Lower Risk of Hypoglycemia Compared to Once- or Twice-Daily Levemir® in Type 2 Diabetes

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Late-Breaking Poster Presented at American Diabetes Association 2012

PHILADELPHIA--(BUSINESS WIRE)--Jun. 9, 2012-- Amylin Pharmaceuticals, Inc. (Nasdaq: AMLN) and Alkermes plc (Nasdaq: ALKS) today announced clinical study results which showed that a significantly greater proportion of patients treated with BYDUREON™ (exenatide extended-release for injectable suspension), the first and only once-weekly treatment for type 2 diabetes, achieved target glucose levels and weight loss compared to those treated with Levemir® (insulin detemir). The study is being presented at the 72nd Scientific Sessions of the American Diabetes Association in Philadelphia.

In the study, 44.1 percent of patients receiving BYDUREON, compared with 11.4 percent of those treated with insulin detemir, met the primary composite endpoint of A1C less than or equal to 7 percent and weight loss greater than or equal to 2.2 pounds (P less than 0.0001) at 26 weeks. Treatment with BYDUREON also resulted in greater improvement in A1C (-1.3 percentage points) than insulin detemir (-0.88 percentage points). A1C is a measure of average blood sugar over three months. Patients receiving BYDUREON lost an average of 5.9 pounds, while those receiving insulin detemir gained an average of 1.8 pounds, resulting in a treatment difference of 7.7 pounds.

"In this study, treatment with BYDUREON resulted in a significantly greater proportion of patients achieving target glucose levels compared to insulin detemir and was associated with weight loss and a lower risk of hypoglycemia," said Melanie J. Davies, M.D., FRCP, professor of diabetes medicine at the University of Leicester, United Kingdom and honorary consultant at University Hospitals of Leicester. "In everyday clinical practice, glycemic control, weight management and hypoglycemia risk are all critical factors in managing type 2 diabetes, and these data suggest that BYDUREON may be a good alternative to insulin detemir in type 2 diabetes patients who are not achieving adequate glycemic control on metformin with or without a sulfonylurea."

There were no events of major hypoglycemia in either group. Gastrointestinal-related and injection-site-related adverse events occurred more frequently with BYDUREON than with insulin detemir.

Study Details
This multicenter, open-label, parallel-arm study conducted in the United Kingdom and Ireland compared the efficacy and safety of BYDUREON with titrated insulin detemir in patients with type 2 diabetes inadequately controlled with metformin with or without a sulfonylurea. Patients were randomized to add-on therapy with BYDUREON (n=111) or insulin detemir (n=105) for 26 weeks. Insulin detemir was titrated to target fasting plasma glucose according to manufacturer labeling and a treat-to-target titration schedule. The primary endpoint was analyzed by means of logistic regression including factors for treatment, use of sulfonylurea and baseline A1C and weight. Secondary outcomes included glycemic control measures, cardiovascular markers and safety and tolerability.

About BYDUREON™ (exenatide extended-release for injectable suspension)
BYDUREON is the first and only once-weekly medicine to be approved by the U.S. Food and Drug Administration (FDA) for the treatment of type 2 diabetes. It is a once-weekly formulation of exenatide, the active ingredient in BYETTA® (exenatide) injection, which has been available in the U.S. since June 2005 and is used in nearly 80 countries worldwide. BYDUREON works with the body to help make its own insulin when needed, providing continuous glycemic control with just one dose per week. Using Alkermes' proprietary technology for long-acting medications, the biodegradable microspheres in each dose of BYDUREON provide a controlled release of exenatide throughout the week. BYDUREON was approved in the U.S. in January 2012 and in Europe in June 2011.

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 and BYETTA both contain the same active ingredient, exenatide, and therefore 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 is available at http://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 patient Medication Guide (www.BYDUREON.com/mg).

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 2 million patients since its introduction. See important safety information below. Additional information about BYETTA is available at http://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 patient Medication Guide (www.BYETTA.com/mg).

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 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 http://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 http://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. not being 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.

BYETTA is a registered trademark and BYDUREON is a trademark of Amylin Pharmaceuticals, Inc. All other marks are the marks of their respective owners.

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