NDA 022-200

Initial REMS approval 01/2012
BYDUREON™ (exenatide extended-release for injectable suspension)
A glucogon-like peptide-1 (GLP-1) receptor agonist

Amylin Pharmaceuticals, Inc.

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

- To inform healthcare professionals about the risk of acute pancreatitis (including necrotizing and hemorrhagic pancreatitis) and the potential risk of medullary thyroid carcinoma associated with BYDUREON.

II. REMS ELEMENTS

A. Communication Plan

Amylin Pharmaceuticals will implement the following elements of a communication plan:

1. A Dear Healthcare Professional (DHCP) letter will be sent within 60 days of product approval or at the time of product launch, whichever is sooner, and again after 6 months. The letter will be available via a link from the BYDUREON website and through the medical information department for 1 year following approval of the REMS. The intended audience for this letter is Healthcare Professionals (HCPs) who are likely to prescribe BYDUREON.

The audience to receive the letter includes HCPs who have written at least one BYETTA prescription within the last 12 months, which includes physicians, nurse practitioners, and physicians' assistants predominantly in the specialties of endocrinology, internal medicine, and family practice. In addition, all endocrinology specialists and retail pharmacists will receive the letter. These data are obtained from IMS Health Xponent Plan Track Weekly™ and the

Amylin Customer Master database. The list is comprised of prescribers who have written BYETTA prescriptions within the past 12 months as well as all endocrinologists (prescribers and non-prescribers of BYETTA). Amylin will obtain electronic mail addresses for the targeted HCPs and send the DHCP letter via electronic mail. If a targeted HCP's email address is not available, or if an email is undeliverable, the HCP will receive the letter through the mail or via facsimile.

Within 60 days of product approval or at the time of product launch, whichever is sooner, and again after 6 months, Amylin will send the DHCP letter to the following professional organizations, and will request that the letter be provided to the members of the professional organizations: the American College of Physicians, the American Medical Association, the American Academy of Family Physicians, the American College of Osteopathic Family Physicians, the American College of Clinical Pharmacy, the American Pharmacists Association, the American Society of Health-System Pharmacists, the American Academy of Nurse Practitioners, the American Association of Clinical Endocrinologists, the Endocrine Society, the American Diabetes Association, the American Association of Diabetes Educators, the American Association of Physicians Assistants, the Association of Managed Care Pharmacy, the National Association of Managed Care Physicians.

The letter will be provided to MedWatch at the same time it is provided to the professional organizations.

The Dear Healthcare Professional letter is part of the REMS and is appended.

2. The Highlighted Information for Prescribers will be provided by Amylin representatives during the first discussion of BYDUREON with all HCPs detailed during the first 6 months after launch.

The Highlighted Information for Prescribers is part of the REMS and is appended.

All components of the communication plan will be updated to reflect any changes in labeling for the risks outlined above.

Amylin will make the REMS, the DHCP letter, the Medication Guide, the Highlighted Information for Prescribers, and professional labeling available via a REMS-specific link from the BYDUREON website as well as through the medical information department for 1 year after the initial date of approval. The Medication Guide, the Highlighted Information for Prescribers and professional labeling will also be available via hard copy from Amylin representatives and through Amylin's call center for 1 year after the initial date of approval.

The BYDUREON REMS web page is part of the REMS; the landing page screen shot is appended.

C. Elements to Assure Safe Use

Elements to Assure Safe Use are not required.

D. Implementation System

An Implementation System is not required.

E. Timetable for Submission of Assessments

Amylin Pharmaceuticals, Inc. will submit REMS Assessments to FDA at 1 year, 2 years and in the 7th year from the date of the initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment. Amylin Pharmaceuticals, Inc. will submit each assessment so that it will be received by the FDA on or before the due date.