

EXHIBIT E

TJ Preuss

From: TJ Preuss
Sent: Tuesday, October 08, 2013 5:32 PM
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Cc: 'raymond.williams@dlapiper.com'; RLopez@lopezmchugh.com; Matthew Lopez (mlopez@lopezmchugh.com)
Subject: Incretin Mimetics 30b6 Deposition Notices
Attachments: Incretin Mimetics 30b6 Deposition Notices v 1.docx; Incretin Mimetics AER 30b6 Deposition Notice v 1.docx

All:

Attached is Plaintiffs' attempt to narrow the 30(b)(6) deposition notices originally served on Merck, Amylin and Lilly back in April. We originally served 7 notices. We've attempted to narrow this down to 5 at this point. The subject areas on Corporate Structure, Study Management, Records Management and Outside Contractors/Consultants are addressed in the first attachment. The blanks in the document relate to the drug and defendant, which we will obviously include once these are finalized. Adverse Events Reporting is the fifth notice addressed in the second attachment. This is one we feel that we cannot narrow.

I suggest we set a call Thursday afternoon – I propose 4:00CST – to discuss these. We would like to be in a position to discuss any scope differences (hopefully there will be none) and to begin scheduling these depositions by the first hearing next hearing.

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EXHIBIT A – CORPORATE STRUCTURE AND ORGANIZATION

1. The identity of _____'s parent, subsidiary and affiliate companies involved with the development of _____.
2. _____'s corporate organization and structure, including:
 - a. The internal organizational structure of _____'s individual departments, groups, regions, divisions, committees and/or task forces;
 - b. The organizational structure within each of _____'s departments, groups, regions, divisions, committees and/or task forces; and
 - c. The functions, duties and responsibilities of each department, group, region, division, committee and/or task force.
3. The corporate organization and structure of all _____ employees relating to _____ from the date _____ first started developing _____ until the present, including:
 - a. All persons, organizations, departments, entities, committees and/or task forces involved in the research, development, marketing and production of _____.
 - b. All persons, organizations, departments, entities, committees and/or task forces involved in regulatory approval and compliance of _____ with U.S. and foreign regulation; and
 - c. All persons, organizations, departments, entities, committees and/or task forces involved in communicating with regulatory officials with the FDA or any foreign regulatory body.

EXHIBIT A – RECORDS MANAGEMENT

1. The standard operating procedures or polices (as used by each department or division) that existed at any time regarding document retention, collection, storage and management that would encompass documents relating to _____.

2. The manner in which _____ (as used by each department or division) has actually retained, collected, stored, and managed documents relating to _____ from the date _____ first started developing _____ until the present.

3. The nature, location, storage and organization of all documents related to any meetings or activities of _____'s boards of directors and board of director committees and subcommittees, including but not limited to meeting minutes, reports, handouts and investigational documents from the date _____ first started researching and/or developing _____ until the present.

4. The nature, location, storage and organization of all documents related to any meetings or activities of each department, group, region, division, committee and/or task force related to the development of or work with _____.

5. With respect to all computers, computer systems, electronic media, networks and other technology assets currently or previously in operation that would in any way house electronic documents or information pertaining to _____,
 - a. the operating systems used and any applications installed;
 - b. how electronic documents are maintained, archived, and indexed;
 - c. the hardware and software, including upgrades or replacements, and utility programs used; and
 - d. the types of databases used, including how the database is accessed, and any standard reports prepared.

6. The identity, system parameters, description and function of all software programs or utilities used for email, electronic peer-to-peer messaging, and/or instant messaging, including the identity of servers and departmental servers where e-mail and messaging is stored and the identity of any remote systems used to access e-mail and/or messaging.

7. The policies and procedures for archiving and journaling e-mail messages, electronic peer-to-peer messaging, and instant messaging.

8. The policies and procedures related to the synchronization and backup/storage of data to the email and/or messaging server with the use of other systems and devices including accessing e-mail and messaging via the internet and via Blackberry/PDA.

9. The identity and function of any information technology or management information systems department, division, or equivalent functional group within your company or provided to you through any outsource service provider, and the identity of the person(s) within it responsible for electronically stored information (ESI) related to _____.

10. The policies and practices concerning the deletion, backup, and preservation of _____ ESI in the normal course of business.

11. The description and location of any system, terminal, database and platform shared with any third party, including but not limited to Contract Research Organizations and other outside contractors and consultants.

12. A description of any and all documents or information related to _____ that was destroyed pursuant to any data retention and destruction policies or that was otherwise destroyed, erased, wiped, deleted, corrupted, damaged, lost, or overwritten.

13. The policies for responding to litigation hold orders, executing litigation hold orders and collection of potentially discoverable documents.

14. The company employees responsible for complying with litigation hold orders.

EXHIBIT A – STUDY MANAGEMENT

1. Animal Studies (Pre-Clinical)

- a. Individuals responsible for the management of Animal Studies associated with _____.
- b. Policies and procedures for providing data from animal studies to the FDA and other world health regulatory agencies.
- c. Policies and procedures for the maintenance of animal study data including:
 - i. Cageside observations
 - ii. Pathology slides
 - iii. Any other data associated with a given study.
 - iv. Preliminary and Final study reports
- d. Databases and computer systems used in the conduct and maintenance of animal studies.
- e. Identification and location of materials for animal studies related to _____.

2. Human Studies

- a. Individuals responsible for the management of human studies associated with _____.
- b. Policies and procedures for providing data from human studies to the FDA and other world health regulatory agencies.
- c. Policies and procedures for the maintenance of human study data including:
 - i. Case report forms
 - ii. Pathology slides
 - iii. Clinical trial master files
 - iv. Any other data associated with a given study.
 - v. Preliminary and final study reports.
- d. Databases and computer systems used in the conduct and maintenance of human studies.
- e. Identification and location of materials for human studies related to _____.

EXHIBIT A – OUTSIDE CONTRACTORS/CONSULTANTS

1. The identity (including the name, employer or the corporate entity the person is associated with, the time period in which the relationship existed, the title, role, function of the individual or entity, and a general description of the nature of the consultation or discussion) of all persons or entities that

_____ consulted with or retained concerning _____ from the date _____ first started developing _____ until the present. Areas of inquiry

related to the identity of these consultants will include but will not be limited to the following:

- a. Pre-Clinical Trials- design, preparation, conducting, monitory, analysis and submission;
- b. Clinical Trials- design, preparation, conducting, monitoring, analysis and submission;
- c. Public Relations;
- d. Media-Training;
- e. Press Releases - design, preparation, drafting and distribution;
- f. Marketing Materials - design, preparation, drafting and distribution;
- g. FDA Consultants;
- h. Firms and/or Individuals, who held themselves out to be experts in the area of FDA and other regulatory matters;
- i. Firms and Individuals, who held themselves out to be experts in the area of foreign government and/or regulatory matters;
- j. Package Insert and any other labeling design, preparation, drafting, printing, translation and distribution;
- k. Warnings - design, preparation, drafting and distribution;
- l. Dear Doctor Letters - design, preparation, drafting and distribution;
- m. Doctors, Ph.D.s, consultants and other experts in the area of the use of GLP-1 agonists and DPP-4 inhibitors;
- n. Salespersons and contract sales representatives;
- o. Scientific consultants;
- p. Adverse event evaluations, assessments, reporting, databases, or other expertise related to adverse events;

q. Scientific studies and testing;

r. Animal Studies conducted; and

s. Drafting of manuscripts and other scientific literature for purposes of publication in any forum, including but not limited to peer-reviewed publications, abstracts, presentations and editorials.

2. The identity of those individuals responsible for interacting with each person or entity identified above.

EXHIBIT A – ADVERSE EVENT REPORTING DEPOSITION SUBJECT MATTER

1. The organization of any division, segment, or office of Defendant that participates in the receipt, collection, evaluation, analysis, or reporting of information to any regulatory agency regarding serious adverse events (SAEs) and/or adverse events (AEs) in patients who have taken or received _____ manufactured by _____.

2. A complete description of any database, computer program or other means used to track any and all reports of adverse events in patients prescribed _____ from pre-marketing clinical trials to present.

3. All colleagues, entities and/or third parties with whom Defendant contracts, including, but not limited to, Functional Service Providers [FSPs], Contract Research Organization [CROs], vendors and/or consultants and/or other third parties related to the collection, processing, evaluating, analysis of, reporting, and/or publication of SAEs and/or AEs.

4. Procedures by which Defendant ensures appropriate communication of relevant information related to SAEs and AEs to interested parties in a timely manner, whether or not reported to regulatory authorities.

5. Post Market reporting and/or Post Marketing Surveillance documents and materials including all Medwatch forms, all SAE and AE reports, including, but not limited to, any and all corresponding documents, materials, notes, written and electronic data, medical records, correspondence, follow up communications, investigations and memoranda relating to every and all adverse experiences and/or events concerning the use _____, reported to, aware of and/or known by, _____.

6. Policies and/or procedures related to the content, maintenance and/or storage of all files containing or relating to all adverse event experiences, including but not limited to,

original source documentation, back-up files, complaint files, complaint records and/or receipts, forms, memoranda, e-mails, consultant reports and/or other material that supports any and all data collected by Defendant or its colleagues or contractors irrespective of whether the data were reported to regulatory agencies, or to third party consultants, and which files and material are available to those responsible for reviewing, analyzing, summarizing, investigating and reporting all Adverse Experiences to any source, including FDA.

7. Policies and procedures related to any language or algorithms used for causality and communication when adverse events including, but not limited to, death may be attributable to a product, including _____.

8. Policies and procedures for collecting information related to adverse event experiences including, but not limited to, the collection of follow-up information/data after the initial adverse event report/alert to any _____ employee and/or its agents or contractors.

9. Databases, computer programs or other means used to track any and all reports of adverse events in patients who received _____.

EXHIBIT B – ADVERSE EVENT REPORTING DOCUMENTS TO BE PRODUCED

1. Communications between _____ and the FDA concerning the review, analysis and summaries of post-marketing adverse event reports regarding _____.
2. The processes and procedures used by _____ in connection with processing of adverse event reports, including the identification of policy manuals, SOPs, and safety or pharmacovigilance manuals.
3. Policies, procedures, training material, instructions, protocols, definitions and other writings which in any way relate to the collecting, analysis, follow-up, investigation, grading and reporting of injuries and damages associated with, the use of _____.
4. Any and all Post Market reporting and/or Post Marketing Surveillance documents and materials including all Medwatch forms, all Adverse Experience (AE) reports, all corresponding documents, materials, notes, written and electronic data, medical records, correspondence, follow up communications, investigations and memoranda relating to every and all adverse experiences and/or events concerning the use of _____, reported to, aware of and/or known by, defendants.
5. Copies of each source file or back-up file that contains documentation, records, memoranda, emails, consultant reports and other material that supports any and all data reported to FDA, foreign regulatory agencies, third party consultants and company safety surveyors, and which files and material are available to those responsible for reviewing, analyzing, summarizing, investigating and reporting Adverse Experiences to any source, including FDA.
6. Databases, computer programs or other means used to track any and all reports of adverse events in patients who received _____.
7. Any and all information Defendants have presented to any Regulatory Agency,

including the FDA and any foreign regulatory agency, regarding the submission of any adverse events, including any and all documents provided to the Regulatory Agencies in reporting adverse events.

8. Any and all standard operating procedures used to identify which adverse events will be reported to any regulatory agency, and the manner and timeframe in which the adverse events will be reported.

9. Any and all data analysis or trends of adverse events that were reported to _____ in patients injected with _____, including any studies, research or documents prepared to reflect any analysis or trend.

10. Any and all writings which reflect, discuss and include adverse event reports evaluations, safety-related hypotheses and the use of techniques to evaluate these hypotheses.

11. Educational, promotional and instructive initiatives designed to emphasize the responsibility of Health Care Providers to identify and report adverse events related to the use of _____.

12. Databases, computer programs or other means used to report to FDA, senior management at your company, outside consultants and company representatives who interact and communicate with health care providers reports of adverse events in patients who received _____.

13. Written material, brochures, sales aids, training material, scripts and instructions provided to company representatives who interact and communicate with health care providers regarding reports of adverse events in patients who received _____.

14. Signal detection practices including any automated tools used to find, assess, and or review safety signals.

15. Scientific literature published by any employee of the company concerning adverse event reporting, pharmacovigilance, or signal detection practices.

16. Copies of presentations made by any employee of the company to any outside organization concerning adverse event reporting, pharmacovigilance, or signal detection.

17. Copies of posters presented by any employee of the company to any outside organization concerning adverse event reporting, pharmacovigilance, or signal detection.

18. Any and all writings which reflect, discuss or analyze the nature, scope, details, positions and results of any post-marketing investigation by any Regulatory Agency regarding _____, including, but not limited to, any investigation in preparation for, or as a result of, any FDA Advisory Panel or Committee meeting, or other FDA or foreign regulator meeting or inquiry relating to the safety, efficacy, marketing practices, adverse reports and/or labeling/instructions for use of _____.