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April 29, 2011

RE: IND 101,825; Serial No. 0005

Annual report for LSD-Assisted Psychotherapy for Anxiety associated with advanced-stage life threatening diseases

Attention: Ann Sohn, Pharm.D. LT USPHS, Regulatory Project Manager

Dear CDER Staff:

Enclosed is the annual report for IND 101,825, LSD-Assisted Psychotherapy for anxiety associated with advanced-stage life threatening diseases. This report contains a brief summary of the clinical, nonclinical, and CMC issues that have occurred during the reporting period of February 28, 2010 to February 28, 2011 for MAPS' protocol investigating LSD-Assisted Psychotherapy.

Please do not hesitate to call me if you have questions or need additional information. Thank you very much for your assistance.

Sincerely,

Rick Doblin
MAPS Executive Director

Enclosures:

Annual report, dated April 29, 2011

Amendment 5

Summary of Changes for Amendment 5

Summary of Changes for Amendment 6

Amended 1572

Form 1571

Multidisciplinary Association for Psychedelic Studies
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Multidisciplinary Association for Psychedelic Studies (MAPS)

d-lysergic acid diethylamide (LSD)

IND 101,825

Serial Number: 0005

ANNUAL REPORT

February 28, 2010 through February 28, 2011

April 29, 2011

MAPS

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ANNUAL REPORT

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1. INDIVIDUAL STUDY INFORMATION

This annual report covers the period from February 28, 2010 through February 28, 2011. The following is a cumulative listing of all studies using LSD under US-IND. There were no MAPS studies for LSD conducted that were not under US-IND.

Protocol, Study Title, Phase, Country, Subject Population, Number of Subject Planned/Entered Treatment/Completed Treatment/Dropped Treatment, Relevant Product and Status During Reporting Period can be found in the Table 1.1 Summary of Clinical Trials.

Table 1.1: Summary of Clinical Trials

Protocol	Study Title	Phase	Subject Population	No. of Subjects Planned/Entered/Completed/Dropped	Relevant Product	Status During Reporting Period
LDA-1	LSD – assisted psychotherapy in persons suffering from anxiety associated with advanced-stage life threatening diseases: A Phase-2, double-blind, placebo-controlled dose-response pilot study	2	Women and men 18 YO or older diagnosed with the advanced stage of an illness with a substantially reduced life expectancy	12 planned 12 entered 8 completed 0 dropped	4 Subjects at 20 μ g LSD and 8 subjects at 200 μ g LSD	Ongoing, completed enrollment

1.1 Protocol LDA-1

Title: LSD – assisted psychotherapy in persons suffering from anxiety associated with advanced-stage life-threatening diseases: A Phase 2, double-blind, placebo-controlled dose-response pilot study.

Purpose: To develop a treatment method for LSD-assisted psychotherapy for people confronting anxiety relating to advanced-stage illnesses and to gather preliminary evidence on the safety and efficacy of this treatment in this population using current scientific standards.

Amendments During the Reporting Period:

There have been two amendments during the reporting period.

Amendment 5: Addition of audio/video recording to preparatory , experimental and integrative sessions, increasing visit windows for flexibility of scheduling due to subject population needs, clarification of when outcome measures will be administered, and clarification that follow-up will be conducted as a separate extension protocol, submitted to the local Ethics Committee on 3 May, 2010 and approved 27 May, 2010.

Amendment 6: Change in data analysis statistician submitted to the local Ethics Committee on 28 February, 2011 and approved 22 March, 2011.

Subject Population: Males and females suffering from anxiety associated with advanced-stage life-threatening diseases 18 years of age or older. The number of subjects reported below is the cumulative number for the reporting period.

Number of Subjects Planned	12
Number of Subjects Enrolled	12
Number of Subjects Dropped	0
Number of Subjects Completed Experimental Sessions	9
Number of Subjects Completed Stage 1	7
Number of Subjects Completed Stage 2	3
Number of Subjects Completed Follow Up Extension study	2

Demographics: See Appendix A for summary of subject enrollment by demographic factors based on preliminary non-QA'd data collected during the reporting period.

Status: The study started enrollment on March 28, 2008. All planned subjects have been enrolled and the study is ongoing.

2. SUMMARY INFORMATION

2.1 Clinical Safety

2.1.1 Summary of Serious Adverse Events (SAEs)

No SAEs occurred during the reporting period. See Appendix B for preliminary data on SAEs reported to MAPS from studies conducted under US-IND during the reporting period.

2.1.2 Summary of Adverse Events

In the ongoing study, two severe adverse events occurred during the reporting period. Neither were found to be related to the study drug.

Subject 109, who suffered from non-Hodgkin's lymphoma, was found to have secretions from a skin lesion in the right ear canal at baseline. During the study, this condition was exacerbated and became a severe skin lesion, but this was unrelated to the study drug. The condition decreased in severity and resolved after radiation therapy.

Subject 111, who suffered from breast cancer, experienced exacerbation of the original cancer present at baseline. The condition persists and is worsening. However this is an expected adverse event that is unrelated to drug administration.

See Appendix C for preliminary data on severe Adverse Events reported to MAPS from ongoing studies conducted under US-IND during the reporting period.

2.1.3 Summary of IND Safety Reports

There have been no IND Safety Reports during the reporting period.

2.1.4 Summary of Deaths

There have been no deaths during the reporting period. See Appendix D for a cumulative data summary.

2.1.5 Summary of Dropouts

There were no subject dropouts during the reporting period.

2.1.6 Brief Description of Findings

Data has not been analyzed to provide a description of findings. There have been no significant events (SAEs related to drug administration or withdrawals caused by AEs) that have occurred during the reporting period. The study is showing promising results, but only when an outlier in the placebo group is removed from the data. This subject received positive news about cancer progression that caused the STAI to drop dramatically, independent of the treatment.

2.2 Nonclinical

No new nonclinical studies were performed during the reporting period.

2.3 Chemistry, Manufacturing, and Controls

There have been no manufacturing changes made during the past year. Due to consistent demonstrated stability of the drug, further stability testing was not found to be necessary by the supplier and the updated expiration date is now May 31, 2011.

3. NEW GENERAL INVESTIGATIONAL PLAN

Rationale for LSD research is to reevaluate the therapeutic potential of LSD-assisted psychotherapy and to develop a method that is safe and efficacious for patients with anxiety associated with an advanced-stage life-threatening illness. MAPS' goal is to obtain the prescription use of LSD-assisted psychotherapy by specially-trained and licensed psychiatrists and psychotherapists in specially regulated clinics.

LSD is currently being studied to lessen anxiety associated with advanced-stage life-threatening diseases. An additional outcome explored is whether participants receiving LSD-assisted psychotherapy will experience dose-dependent improvements in quality of life. At this time there are no future studies planned.

4. REVISED INVESTIGATOR'S BROCHURE

The Investigator's Brochure has not been updated since its submission. The most recent version of the Investigator's Brochure has been submitted to FDA.

5. SIGNIFICANT PROTOCOL MODIFICATIONS

There has been one significant protocol amendment during the reporting period in the LDA-1 protocol.

Amendment 5: Addition of audio/video recording to preparatory, experimental and integrative sessions, increasing visit windows for flexibility of scheduling due to subject population needs, clarification of when outcome measures will be administered, and clarification that follow-up will be conducted as a separate extension protocol, submitted to the local Ethics Committee on 3 May, 2010 and approved 27 May, 2010.

6. SUMMARY OF SIGNIFICANT FOREIGN MARKETING DEVELOPMENTS

LSD is not currently approved for marketing authorization elsewhere in the world. There were no foreign marketing developments during the reporting period.

7. LOG OF ANY OUTSTANDING BUSINESS

None.

Appendix A: All Studies Demographics*

Study	Subject Number	Age	Sex	Height/ cm	Weight/ Kg	Ethnicity	Treatment Group	Diagnosis
LDA-1	101	45	M	189	97.5	White European	Full	Gastric Carcinoma, non metastatic
LDA-1	102	44	M	170	61	White European	Low	Renal Carcinoma, non metastatic
LDA-1	103	47	M	180	68	White European	Low	Very severe Migraine Disease**
LDA-1	104	57	M	173	57	White European	Full	Gastric Carcinoma, metastatic
LDA-1	105	62	F	175	69	White European	Low	Breast Cancer
LDA-1	106	47	M	180	65	White European	Full	Gastric Cancer
LDA-1	107	61	F	166	52	White European	UNK	Breast Cancer
LDA-1	108	39	F	174	92	White European	UNK	Breast Cancer
LDA-1	109	64	M	173	81	White European	Low	Non-Hodgkin Lymphoma
LDA-1	110	59	M	178	69	White European	Full	Parkinson's Disease
LDA-1	111	43	F	173	69	White European	UNK	Breast Cancer
LDA-1	112	46	M	174	58	White European	UNK	Bechterew's Disease

**Based on preliminary non-QA'd data received from the site.*

***This subject was enrolled as a protocol deviation based on previous history of suicidality caused by severe chronic pain. The severity of the migraine was such that a return to suicidal thinking was possible, although the subject was not suicidal at the time of enrollment. The investigator indicated that Swissmedic did not criticize enrollment of this subject and that since he was conducting a pilot study, it was appropriate to interpret life-threatening as either mental or physical.*

Appendix B: All Studies Cumulative Serious Adverse Events*

* Based on preliminary non-QA'd data received from the site.

Study	Dose	Subject No.	Adverse Event Diagnosis	Date of last LSD Admin.	Onset date	Resolution date	Severity	Frequency	Action taken for Study	Action taken-treatment	Action Taken Other Specify	Outcome	Relationship to Drug
LDA-1	Full dose	104	Metastatic esophageal cancer	29-Jan-09	UNK-Nov-08	26-Oct-09	Severe	Continuous	Delayed treatment	None	Chemotherapy, Hospitalization	Death	None
LDA-1	Low dose	105	Infection of left renal pelvis	1-Oct-09	UNK-Dec-09	Ongoing	Severe	Continuous	None	Prescription Medication	Hospitalization	Persisting	None
LDA-1	Full dose	106	Broken femur	Before dosing	UNK-Oct-09	UNK-Dec-09	Severe	Continuous	Delayed treatment	Procedure, Hospitalization	None	Full recovery	None

Appendix C: All Studies Severe Adverse Events*

* Based on preliminary non-QA'd data received from the site

Subject Number	Dose	Adverse Event Diagnosis	Serious	Date of last LSD Admin.	Onset date	Resolution date	Frequency	Action taken for Study	Action taken-treatment	Action Taken Other Specify	Outcome	Relationship to Drug
104	Full dose	Metastatic esophageal cancer	Y	29-Jan-09	UNK-Nov-08	26-Oct-09	Continuous	Delayed treatment	None	Chemotherapy, Hospitalization	Death	None
105	Low dose	Urinary Tract Infection	N	Before dosing	UNK-Aug-09	Ongoing	Continuous	None	Procedure Prescription Medication	Outpatient treatment	Persisting	None
105	Low dose	Infection of left renal pelvis	Y	1-Oct-09	UNK-Dec-09	Ongoing	Continuous	None	Prescription Medication	Hospitalization	Persisting	None
106	Full dose	Broken femur	Y	Before dosing	UNK-Oct-09	UNK-Dec-09	Continuous	Delayed treatment	Procedure, Hospitalization	None	Full recovery	None
109	Low dose	Skin lesion	N	8-Jul-10	26-Aug-10	Ongoing	Continuous	None	None	None	Persists worsening	None
111	UNK	Tumor progression	N	2-Dec-11	UNK-Jan-11	Ongoing	Continuous	Delayed treatment	Procedure, Prescription Medication	None	Persists, worsening	None

Appendix D: All Studies Deaths*

** Based on preliminary non-QA'd data received from the site.*

Study	Subject No.	Adverse Event Diagnosis	Serious	Date of last LSD Admin.	Onset date	Resolution date	Frequency	Action taken for Study	Action taken-treatment	Outcome	Relationship to Drug
LDA-1	104	Metastatic Esophageal Cancer	Y	29-Jan-09	UNK-Nov-08	26-Oct-09	Continuous	Delayed treatment	Chemotherapy Hospitalization	Death	Not related