Multidisciplinary Association for Psychedelic Studies (MAPS)

d-lysergic acid diethylamide (LSD)

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ANNUAL REPORT

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MAPS

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ANNUAL REPORT

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1. INDIVIDUAL STUDY INFORMATION

This annual report covers the period from February 28, 2011 through February 28, 2012. 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	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 or older diagnosed with the advanced stage of an illness with a substantially reduced life expectancy	12 planned 12 entered treatment 12 completed treatment 0 dropped treatment 10 entered follow-up 2 dropped follow-up 2 completed follow-up 6 ongoing in follow-up	4 Subjects at 20 μg LSD and 8 subjects at 200 μg LSD	In follow-up

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 has been one amendment during the reporting period.

Amendment 6: Change in statistician conducting data analysis submitted to the local Ethics Committee on 28 February, 2011 and approved on 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	12
Number of Subjects Entered Follow-Up Extension	10
Number of Subjects Dropped Follow-Up Extension	2
Number of Subjects Completed Follow-Up Extension	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 has completed the treatment period and is currently in follow-up.

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 cumulative preliminary data on SAEs reported to MAPS from studies conducted under US-IND.

2.1.2 Summary of Adverse Events

In the ongoing study, no adverse events occurred during the reporting period.

See Appendix C for cumulative preliminary data on severe Adverse Events reported to MAPS from studies conducted under US-IND.

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 cumulative preliminary data reported to MAPS from studies conducted under US-IND.

2.1.5 Summary of Dropouts

Two subjects dropped the follow-up 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 reporting period. Drug administration has been completed for this study. The final LSD treatment session took place on May 26, 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 for its potential to lessen anxiety associated with advanced-stage life-threatening diseases. An additional outcome to be 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 most recent version of the Investigator's Brochure has been submitted to FDA.

5. SIGNIFICANT PROTOCOL MODIFICATIONS

There have been no significant protocol modifications during the reporting period.

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 Cumulative 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	Full	Breast Cancer
LDA-1	108	39	F	174	92	White European	Full	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	Full	Breast Cancer
LDA-1	112	46	M	174	58	White European	Full	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 CRFs 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

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Appendix C: All Studies Cumulative 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	Procedure, Hospitalization	None	Persists diminishing	None
111	Full dose	Tumor progression	N	2-Dec-11	UNK-Jan-11	Ongoing	Continuous	Delayed treatment	Procedure, Prescription Medication	None	Persists, worsening	None

Appendix D: All Studies Cumulative 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	Procedure, Hospitalization	Death	Not related