CELERION
621 ROSE ST
LINCOLN, NE 68502-2040

000027

119 pgs

01190000027K0/

ATTENTION

Confidential Information enclosed.
To be viewed by authorized persons only.

If you have questions regarding any information you have requested, please call the phone number on the enclosed invoice.

To Whom It Concern:

CIOX has provided to you protected health information that may contain information that falls under the 42 C.F.R. Part 2. The federal rules prohibit you from making any further disclosure of information in this record that identifies a patient as having or having had a substance use disorder either directly, by reference to publically available information, or through verification of such identification by another person unless further disclosure is expressly permitted by written consent of the individual whose information is being disclosed or as otherwise permitted by 42 CFR part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose (see 42 CFR §2.31). The federal rules restrict any use of the information to investigate or prosecute with regard to a crime any patient with a substance use disorder, except as provided at 42 CFR §§ 2.112(c)(5) and 2.65.

If the enclosed record pertains to HIV/AIDs, it has been disclosed to you from records whose confidentiality is protected by federal and perhaps, state law, which prohibits you from making any further disclosure of such information without the specific consent of the person to whom such information pertains or as otherwise permitted by state law. A general authorization for this release of health or other information is not sufficient for this purpose.

If the information requested is from a facility located within the Washington State area then this information will fall under the RCW 70.02.300 which states that this information has been disclosed to you from records who confidentiality may be protected by state law. State law prohibits you from making any further disclosure of it without the specific written authorization of the person to whom it pertains, or as otherwise permitted by state law. A general authorization for the release of this protected information is not sufficient for this purpose.

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Ciox Health
P.O. Box 1812
Alpharetta, GA 30023-1812
Fed Tax ID 58 - 2659941
1-800-367-1500

Date
11/8/2018
Request ID #
0259819282

Ship to:

CELERION
CELERION
621 ROSE ST
LINCOLN, NE 68502-2040

Requested By: CELERION
Patient Name: [redacted]

Records from:

NEBRASKA MEDICINE
989100 NEBRASKA MEDICAL CENTER
OMAHA, NE 68198-9100

Ciox Health is the largest provider of release of information(ROI) services and technology. We ensure the compliant exchange of protected health information for over 18,000 healthcare facilities nationwide. To learn more about our flexible ROI solutions, go to www.CioxHealth.com

Get future medical records as soon as they are processed, by signing up for secure electronic delivery. Register at: edelivery.cioxhealth.com

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Request for Release of Medical/Dental Records to Celerion

Participant Name [redacted] Date of Birth (b) (6) Study Number CA24914_2

As a participant in a clinical research investigation, I [redacted]
(Printed Participant Name)

authorize UNMC Omaha to release

- ☑ Medical Records
- ☐ Medical Records containing sensitive information including but not limited to HIV and/or hepatitis C test results, past psychiatric history/involuntary psychiatric admission, etc.

related to my participation in the above mentioned medical research study at Celerion. Please forward documentation to:

Celerion
621 Rose St.
Lincoln, NE 68502
Fax: +1 402 930 0428

MCH

Please send or fax all records from _____ including the following:

- ☑ Admission/Discharge Summary
- ☐ EG
- ☑ ER Report
- ☑ Lab Work
- ☐ Medication Report
- ☑ Physician Progress Notes
- ☑ X-Ray Report
- ☐ Copy of Film(s)
- ☐ Other _____

My medical records will assist the research investigators in compiling complete information as a part of the approved clinical protocol in which I am participating. If you have any questions, you may contact the Investigator at **CELERION** for further details. A photo copy or faxed version of this authorization shall be considered as effective and valid as the original.

I understand that I may revoke this authorization in writing at any time, except to the extent that action based on this authorization has already been taken. Unless I revoke this authorization earlier, it **will expire 1 year from the date requested** or on the specified date of 10/12/18.

Your assistance is appreciated.

Sincerely,

[redacted]
Participant Signature

10/12/18
Date Requested

RECEIVED

OCT 23 2018

HEALTH INFORMATION MANAGEMENT

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Adverse Events

Study #: CA24914 **Group #:** 2 **Site:** LNK

Group #: All
Period: All
CLID: 43
PHID: All

Include Predose? Yes
Include PI Review? No
Include Initials? No
Include PHID? No
Include AE Term? No

SP Status: Dosed
Only SAEs: No
Screening AEs? Include SCR AEs

Sponsor: 22nd Century Group, Inc.
Protocol: CA24914
PI: Allen Hunt, M.D.
CSM: (b) (6)

* Adverse Event date is unknown ** Adverse Event time is unknown

CLID	SID	PER	TRT	Verbatim Term	PI INIT	Onset Date/Time	Resolved Date/Time	SEV	FRE	SER	OUT	ACT	REL	OTH	OTH1
43	23	2	D	TEMPORAL HEADACHE	PM11	16-AUG-2018 14:30	17-AUG-2018 15:00	2	3	7	1	5	3		
43	23	2	D	OCCIPITAL HEADACHE	PM11	19-AUG-2018 18:30	02-SEP-2018 13:30	1	2	7	1	1	3		
43	23	2	D	TENDERNESS AT RIGHT ANTECUBITAL VENIPUNCTURE SITE	PM11	14-SEP-2018 09:50	15-SEP-2018 14:00	1	2	7	1	5	5		
43	23	2	D	SUBARACHNOID HEMORRHAGE	PM11	(b) (6) **	02-OCT-2018 **	3	3	3	1	1	5		

Adverse Events

Study #: CA24914 **Group #:** **Site:**

Group #: All
Period: All
CLID: 43
PHID: All

Include Predose? Yes
Include PI Review? No
Include Initials? No
Include PHID? No
Include AE Term? No

SP Status: Dosed
Only SAEs: No
Screening AEs? Include SCR AEs

Sponsor: 22nd Century Group, Inc.
Protocol: CA24914
PI:
CSM:

* Adverse Event date is unknown ** Adverse Event time is unknown

SEV (Severity)

1	Mild
2	Moderate
3	Severe

FRE (Frequency)

1	Single Episode
2	Intermittent
3	Continuous

SER (Serious)

1	Death
2	A life threatening AE
3	Inpatient hospitalization or prolongation of existing hospitalization
4	A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
5	A congenital anomaly/birth defect
6	Important medical event
7	Not serious

OUT (Outcome)

1	Resolved
2	Improved
3	Unchanged
4	Worse
5	Fatal
6	Unknown/lost to follow-up

ACT (Action)

1	None
2	Drug discontinued due to A/E
3	Drug dosage adjusted
4	Drug stopped-restarted
5	Therapy
6	Hospitalization

REL (Relationship)

1	L kely
2	Probably
3	Possibly
4	Unlikely
5	Unrelated
99	Undetermined

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Participant Medical History

SID: 23

Study #: CA24914

PARTICIPANT HISTORY

1. Do you have a history of **DRUG ABUSE**? **No**

2. Do you have a history of **ALCOHOLISM**? **No**

3. Are you currently using or have you ever used **TOBACCO** or **NICOTINE** products? **Yes**

Condition	Start			End		
	DD	MM	YY	DD	MM	YY
1 Pack Cigarettes/day (20-29)			1990			

4. Do you have any difficulty **SWALLOWING** a capsule or tablet? **No**

5. Ethnicity

Non Hispanic or Latino

6. Race

White

FAMILY HISTORY

Have any of your immediate family members (mother, father, sister, brother) had diabetes, heart disease, cancer, prolonged QTc, high blood pressure, kidney disease, mental illness, or any other family related illness? **Yes**

Condition	Comments
Family History of Diabetes	

CURRENT MEDICATIONS

Have you taken any medication including (but not limited to) prescription (Rx), over-the-counter (OTC), birth control, vitamins, herbal supplements, vaccinations or topical creams in the last 30 days? **No**

ALLERGIES, SENSITIVITIES, and REACTIONS

Do you have a history of **Allergies or Sensitivities**? **No**

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Participant Medical History

SID: 23

Study #: CA24914

PREVENTION OF PREGNANCY

1. What have you decided to consistently use to prevent you/your partner from getting pregnant in the last 6 months? *(Check all that apply)*	When did you/your partner start using this method to prevent pregnancy? Month	Year	Agree to use during study?
Lifestyle			
☐ **Abstinent** (Not sexually active with a partner of the opposite sex)			☐
☐ **Condom and Spermicide**			☐
☐ **Condom Only**			☐
☐ **Diaphragm and Spermicide**			☐
☐ **Diaphragm Only**			☐
☐ **Vasectomy / Partner With Vasectomy** (specify date of vasectomy)			☐
Females Only: I have been sexually active only with a **partner** with a vasectomy since:			☐
☐ **Other** (Specify) _____			☐
Hormonal and Device	**Month**	**Year**	
☐ Hormonal **IUD** (e.g., Mirena®)			☐
☐ Non-hormonal **IUD** (e.g., ParaGard®)			☐
☐ **Injection** Birth Control (e.g. Depo-Provera® or Lunelle®)			☐
☐ **Implant** (e.g. Implanon®)			☐
☐ **Oral Contraceptive** (pill)			☐
☐ **Non-surgical** Birth Control Procedure (e.g., Essure®)			☐
Has a confirmatory dye test been done? ☐Yes ☐No			
☐ Birth Control **Patch** (e.g., Ortho-Evra®)			☐
☐ Vaginal Ring (e.g. NuvaRing®)			☐
Surgical Methods and Menopause	**Month**	**Year**	
☐ **Tubal Ligation** (both tubes tied)			☐
☐ **Oophorectomy** (both ovaries removed)			☐
☑ **Hysterectomy** (full or partial removal of the uterus)		1995	☑ 7-17-18
☐ **Postmenopausal** (provide end date of last menstrual cycle)			☐

FEMALES ONLY - Males skip to the next section

	Onset DD	Onset MM	Onset YY	End DD	End MM	End YY
1. If you are **not** postmenopausal, when was your last menstrual period?			1995			1995
2. Are you currently nursing (breastfeeding or lactating)?						No

SYSTEM REVIEW

1. Do you or have you ever had any disorders of the **HEAD, EYES, EARS, NOSE, OR THROAT?**	No
2. Do you have or have you ever had any **CARDIOVASCULAR (Heart)** disorders?	No
3. Do you have or have you ever had any **RESPIRATORY (Breathing)** disorders?	No

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...icipant Medical History

SID: 23

Study #: CA24914

4. Do you have or have you ever had any **GASTROINTESTINAL** disorders?	No
5. Do you have or have you ever had any **GENITOURINARY** disorders?	① No Ye
6. Do you have or have you ever had any **MUSCULOSKELETAL** disorders?	No [redacted]
7. Do you have or have you ever had any **NEUROPSYCHIATRIC** disorders?	No 7/17
8. Do you have or have you ever had any **ENDOCRINE** disorders?	No
9. Do you have or have you ever had any **SKIN OR BREAST** disorders?	No
10. Do you have or have you ever had any **CANCER** occurrence?	No
11. Do you have or have you ever had any **HEMATOLOGIC, LYMPHATIC, or IMMUNE** disorders?	No
12. Do you have or have you ever had any condition or illness which has not been previously mentioned?	No

SURGICAL HISTORY – provide any surgeries not previously provided in the system review

Have you ever had any **Surgeries (other than vasectomy, tubal ligation, oophorectomy or hysterectomy)?** Yes

Operation	DD	MM	YY	Reason
Surgery, other		Mar	1999	Replaced right thumb joint.
Surgery, Carpal tunnel syndrome			1997	surgery to repair right carpal.

HOSPITALIZATIONS – provide any hospitalizations not previously provided in the system review

Have you ever been hospitalized (other than for surgery or natural childbirth)? No

I understand that assistance will be made available to me should I require it. I understand that false, incomplete, or misleading information about medical history could have very serious consequences (e.g., negative effects to my personal health, unforeseen adverse effects). The information in this packet is accurate and complete to the best of my knowledge.

[redacted] 7/12/18

Study Participant *Date*

For Internal Use Only

I have reviewed the content of this packet with the participant, and all entries are considered to be not clinically significant (NCS) unless otherwise indicated by me.

(b) (6) 17 Jul 2018

Investigator Signature *Date (dd-mmm-yyyy)*

My signature indicates that the data contained in the preceding pages for this participant has been reviewed for accuracy and

(b) (6) 17JUL2018

Admissions S... *Date (dd-mmm-yyyy)*

①Abnormal menstrual bleeding. Heavy bleeding after child birth Hysterectomy performed. 1995 (b) (6) 17JUL 2018