Adaptive Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Single Ascending Doses of Kratom in Healthy, Nondependent, Adult Recreational Polydrug Users with Opioid Experience

ClinicalTrials.gov ID: NCT06072170

Protocol Number: 75F4012C00199 (FDU-P4-117)

Informed Consent Form: Version 1.0, 7-JUN-2023 (Pregnant Partner)

PREGNANT PARTNER INFORMATION AND AUTHORIZATION FORM AND AUTHORIZATION FOR RELEASE OF PROTECTED HEALTH INFORMATION

TITLE: Adaptive Study to Evaluate the Safety, Pharmacokinetics, and Pharmacodynamics of Single Ascending Dose of Kratom in Healthy, Non-Dependent, Adult Recreational Polydrug Users with Opioid Experience

PROTOCOL NO.: 75F40121C00199
Altasciences Protocol No.: FDU-P4-117
IRB Protocol No.:

SPONSOR: Food and Drug Administration (FDA), USA

STUDY DOCTOR: Debra Kelsh, MD
Altasciences Clinical Kansas, Inc.
10103 and/or 10203 and/or 10183 Metcalf Avenue
Overland Park, Kansas 66212
United States

PHONE NUMBER(S): 913-696-1601 (24 hours)

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

PURPOSE OF THE PREGNANT PARTNER INFORMATION AND AUTHORIZATION FORM

You became pregnant while your male partner (the biological father of your baby) was taking part in a research study.

The name of the investigational drug that your partner received in this study is kratom. The investigational drug has been administered 1 time. Investigational means that the drug has not been approved by the Food and Drug Administration (FDA).

Chronic (long-term) use of kratom during pregnancy may cause withdrawal symptoms in newborns. Studies of kratom use in pregnant animals suggested that kratom may potentially cause fetal abnormalities. However, the effect of kratom on a pregnant woman, an embryo, fetus (unborn baby), or nursing infant is not fully known at this time.

With this form, we are asking for your permission to collect medical information about your pregnancy, its outcome, and if appropriate, the birth and health of your baby. We

want to see if the study drug(s) your partner was given have any effect on your pregnancy and/or the health of your baby.

This form may contain words that you do not understand. Please ask the staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this form to think about or discuss with family or friends before making your decision about the collection of your pregnancy information.

If you agree, we will collect information about your pregnancy, the outcome of your pregnancy, and if appropriate, the birth and the health of your baby. We will give you a signed and dated copy of this form to keep for your records.

RISKS TO YOU

The risk to you from allowing us to collect this information is possible loss of confidentiality of your/your baby's medical records information.

BENEFITS TO THE COLLECTION OF YOUR INFORMATION

You will not receive any direct benefit from allowing the collection of information about your pregnancy and its outcome. However, what we learn from your information might lead to better understanding of the effect on pregnant women and their unborn babies who are exposed to the study drug taken by the baby's father during a research study.

COSTS TO YOU

There will be no cost to you for allowing us to collect this information about your pregnancy.

The regular medical care costs related to your pregnancy and the birth and care of your baby will be billed to you and/or your health insurance in the usual way.

YOUR ALTERNATIVE

Your alternative is to not allow us to collect and use this information for follow-up purposes.

YOUR DECISION IS VOLUNTARY

Your decision to allow us to collect and use information about your pregnancy and the birth and health of your baby is completely voluntary. If you decide to allow us to collect this information, you can change your mind at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.

If you decide not to allow the collection and use of the information, this will not affect medical care for either you or your baby.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR DATA COLLECTION PURPOSES

This section of the form is called an "authorization." It describes the information that we will collect, why we will collect it, and with whom we will share it.

WHAT INFORMATION ABOUT YOU AND YOUR BABY MIGHT BE USED AND GIVEN TO OTHERS?

The staff will get personal and medical information about your pregnancy and the birth and health of your baby.

WHO MIGHT USE AND GIVE OUT INFORMATION ABOUT YOU AND YOUR BABY?

The staff.

WHO ELSE MIGHT GET THIS INFORMATION?

Unless required by law, your name and pregnancy follow-up information will not be disclosed outside the research clinic. Your name will be available only to the following people or agencies:

- The study doctor and study staff, and authorized representatives of the study doctor;
- The Institutional Review Board (IRB) that reviewed this study and any other committees responsible for overseeing the research;
- Health authority inspectors, such as the U.S. Food & Drug Administration;
- Study monitors and auditors;
- Authorized Clinical Research Organization representatives.

The above-mentioned individuals will use the personal information collected as part of this study, including your medical records ("study information") to check that the study is conducted correctly and to ensure the accuracy of the study information. These people are all obligated to maintain confidentiality by the nature of their work or are bound by confidentiality agreements. **Your health information may be further shared by the entities listed above. If shared by them, the information will no longer be covered by the Privacy Rule.**

The Privacy Rule was issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA) in order to protect the privacy rights of patients. The Privacy Rule is designed to protect the confidentiality of your health information and requires your written permission for your health information to be used in this follow-up. By signing this form, you allow the doctor to use your Personal Health Information to carry out this follow-up and the sponsor to use information related to you for research conducted with your personal health information.

WHY WILL YOUR/YOUR BABY'S INFORMATION BE USED AND/OR GIVEN TO OTHERS?

Your/your baby's information might be used by the staff or others to see if the study drug affects you and your baby.

If the results of the follow-up are made public, information that could identify you or your baby will not be used.

WHAT IF YOU DECIDE NOT TO GIVE PERMISSION (AUTHORIZATION) TO USE AND GIVE OUT (DISCLOSE) YOUR/YOUR BABY'S INFORMATION?

Your information and/or your baby's information will not be collected or included in the follow-up.

CAN YOU REVIEW OR COPY YOUR/YOUR BABY'S INFORMATION?

Yes. You do this by writing to the doctor whose name and address are listed on the first page of this form.

CAN YOU WITHDRAW OR REVOKE (CANCEL) YOUR PERMISSION?

Yes, but this permission will not stop automatically.

You can withdraw your permission to use and disclose your/your baby's health information at any time. You do this by writing to the doctor whose name and address are listed on the first page of this form.

When you withdraw your permission, no new information that identifies you or your baby will be collected. Information that has already been collected for the follow-up might still be used and given to others.

If you do not withdraw this Authorization, it will remain in effect. There is no expiration of this authorization.

IS YOUR/YOUR BABY'S HEALTH INFORMATION PROTECTED AFTER IT HAS BEEN GIVEN TO OTHERS?

There is a risk that your health information and your baby's health information will be given to others without your permission.

IF YOU HAVE QUESTIONS

You can contact the doctor at the numbers listed on page 1 of this form for any of the following reasons:

- you have questions about the collection of your/your baby's information or you have questions about the research study that your baby's father is in
- you think you or your baby have a problem related either to the collection of your information or to the research study
- you have questions, concerns, or complaints to report about the collection of your/your baby's information

If you have questions about your/your baby's rights or if you have questions, concerns, or complaints about the research study your male partner is in, you can contact the Institutional Review Board (IRB):

Advarra Institutional Review Board (Advarra IRB)

- By mail:

Study Subject Adviser

Advarra IRB

6100 Merriweather Dr., Suite 600

Columbia, MD 21044

- or call toll free: 877-992-4724
- or by email: adviser@advarra.com

This follow-up is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at the phone number and/or email address listed above if:

- You have questions, concerns, or complaints that are not being answered by the follow-up team.
- You are not getting answers from the follow-up team.
- You cannot reach the follow-up team.
- You want to talk to someone else about the follow-up.
- You have questions about your rights as a subject participating in this follow-up

The IRB will not be able to answer some questions, but you can contact the IRB if the staff cannot be reached or if you want to talk to someone other than the study staff.

Do not sign this release form unless you have had a chance to ask questions and you have received satisfactory answers to all your questions.

If you agree to the collection of information about your pregnancy and the birth and health of your baby, you will receive a signed and dated copy of this form for your records.

LEGAL RIGHTS

You will not lose any of your legal rights to which you are otherwise entitled by signing this form.

AUTHORIZATION

- I have read the information in Pregnant Partner Information and Authorization Form (or someone read it to me).
- I have had an opportunity to discuss the collection of this information with the study staff. My questions have been answered to my satisfaction.
- I agree to allow the collection of information about my pregnancy and the birth and health of my baby. Your agreeing to participate is completely voluntary.
- I authorize the use and disclosure of my information and my baby's information to the parties listed in the authorization section of this form for the purposes described.

You will receive a copy of this signed and dated Pregnant Partner Information and Authorization Form for your records.

__ __/__ __ __/__ __ __ __	_____	_____	___ ___:___ ___
D D M M M Y Y Y Y	Pregnant Partner's Name (Print)	Pregnant Partner's Signature	Time

__ __/__ __ __/__ __ __ __	_____	_____	___ ___:___ ___
D D M M M Y Y Y Y	Person Conducting Authorization (Print)	Person Conducting Authorization Signature	Time