HAVE YOU HAD A **BABY** IN THE LAST **12 MONTHS**?

Are you experiencing symptoms of **depression** such as **sadness**, **anxiety**, or feelings of being **overwhelmed**?

If so, you may have **postpartum depression**. Find out if participating in our medical research study of a new single-dose investigational drug for postpartum depression may be an option for you.

Thank you for your interest in our research study. We understand the serious challenges that come with being a new mother and appreciate your attention.

After having a baby, some women get the "baby blues," or feel sad, worried, or tired within a few days of giving birth. For many women, the baby blues go away in a few days. However, if any of the following symptoms persist for more than 2 weeks, this may be a sign of PPD.

- Depressed mood is present most of the day
- Loss of interest or pleasure, most of the day
- Insomnia or sleeping too much
- Unusually slow or fast movements
- Feelings of worthlessness or guilt
- Loss of energy or fatigue
- Suicidal thoughts
- Impaired concentration or indecisiveness
- Change in weight or appetite

Postpartum depression is a serious mental health condition that affects behavior and physical health. If you have PPD, the sad and hopeless feelings do not go away and may interfere with your day-to-day life. Medical researchers continue to look for treatments to help.

This research study is evaluating RE104, an investigational drug, as a potential new treatment for mental health conditions including PPD. RE104 belongs to a class of drugs called psychedelics. RE104 is "investigational" because it is still being studied and is not yet approved by the US FDA for treatment of any condition. The FDA and ethics review board have, however, reviewed this study.

Before the FDA can approve any drug, it must be evaluated in clinical trials like this one and for that we need study volunteers like you to participate.

This study will compare a single dose treatment of 2 different strengths of RE104, a low dose (1.5 mg) and a high dose (30 mg). Study participants will be randomly assigned (like the flip of a coin) to receive one of the doses and neither they nor the Study Doctor will know which dose is given.

This study consists of the following parts.

Screening and Baseline Period

Women who may qualify for and are interested in participating in this study will be asked to visit with study staff for a Screening Visit up to 3 weeks before the Treatment Period. Before a potential participant decides to proceed with this study, the study staff will review with her a document called the informed consent form. This document will provide a detailed explanation of the study and its potential risks and benefits. After the potential participant reads the form, the study staff will answer any questions she may have. Then, if the participant wishes to proceed, she will sign the informed consent form to confirm that she understands what it means and is willing to participate in the study. Study participation is completely voluntary at all times.

During the Screening Visit, participants will discuss their symptoms with study staff and complete several assessments and tests to confirm eligibility to be in the study. Participants will also be asked to identify a caretaker who can look after their baby for a full day while they are undergoing study treatment (called a dosing session) and for 24 hours after dosing.

During screening, the specially trained and qualified site staff members, called Session Monitors, will prepare and teach the participant about the treatment and dosing experiences and management for the effects of RE104 during the dosing session.

Study Treatment/Dosing Session

After all tests are completed and when the Study Doctor determines a participant is ready for dosing, 1 injection of RE104 will be given in the upper arm. The visit will last at least 8 hours after receiving RE104 or until the effects of RE104 have worn off.

The dosing will take place in a comfortable room, where participants can lie on a bed or couch, listen to music, and relax. At least one of the Session Monitors familiar to the participant will always be in the session room to provide support.

Follow-up

Participants will take part in 7 Follow-up visits which will begin the day after receiving RE104 to monitor health and the effect of the study drug. 4 of these visits will be at the study center and up to 3 may be remote visits by telephone.

Two of the Follow-up visits will include Integration Sessions. During these, participants and their Session Monitor will discuss the experience with RE104 during the Dosing Session and address any safety concerns, if present.

Minimum Requirements to Participate

You may be eligible to join this study if:

- You are a female 18 to 45 years of age
- You had your baby sometime in the last 12 months
- You are experiencing signs of depression
- You have a caretaker who can look after your baby during the Dosing Session and for 24 hours after dosing

This is not a complete list of study requirements. The study staff will explain the complete list of requirements.

Costs and Expenses

There is no charge to participate in the research study. Participants who satisfy applicable requirements will be compensated for study-related time and expenses. Please ask the study staff for details.

Risks and Benefits

All drugs and medical procedures carry a risk of side effects. Therefore, it is possible that participants may experience some discomfort or other reactions from the use of RE104 (the study drug) or from the study procedures or tests. The study staff will explain these risks before potential participants decide whether to participate in the study. The safety of participants will be closely monitored throughout the study.

The information learned from this study may help find treatment options in the future for women suffering from postpartum depression. Participants will help contribute to the research of RE104. There is no guarantee that study participants will receive any direct benefit from their participation.

Next Steps

If you are interested to learn more about this study, please contact us using the information on the back of this brochure. If you contact us, you will not be obligated to participate in this study. Participation is entirely voluntary. Should you qualify for participation and decide to participate in the study, you may stop your participation at any time with no adverse impact to the care you receive outside of the study.

For more information about this research study, please contact:

ppdreconnectstudy.com

RECONNECT | Phase 2 Clinical Trial

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