JOHN WAYNE CANCER INSTITUTE
at Providence Saint John's Health Center

CLINICAL TRIAL ANNOUNCEMENT

Dose-Escalation Study of RRx-001 in Combination With Whole Brain Radiation in Subjects With Brain Metastases (BRAINSTORM)

The purpose of this research study is to test the safety and activity of whole brain radiation therapy with RRx-001, an experimental radiation sensitizer, in participants with brain metastases. As a radiation sensitizer, RRx-001 may increase the effect of whole brain radiation, the standard of care for brain metastases, on cancer cells in a specific target area while reducing damage to normal healthy cells. The ability to sensitize the cancer cells to radiation sets off a 'domino effect' of free radical damage in the tumor from a given amount or dose of radiation.

In this dose-escalation study, the safety and tolerability of escalating dose levels of RRx-001 administered intravenously twice a week in subjects with brain metastases receiving whole brain radiation therapy (WBRT) will be assessed. Once a maximum tolerated dose is identified, further (up to approximately 30) participants will be recruited. The study will use MRI to monitor changes in tumor blood flow associated with RRx-001.

Inclusion Criteria:

- Written informed consent
- Age ≥18 years
- Eastern Cooperative Oncology Group (ECOG) performance status 0-2
- One or more brain metastases
- Prior radiation therapy to the brain is allowed with the exception of whole brain irradiation
- Subjects must be neurologically stable for at least 14 days prior to first dose of study drug;
- Male and female subjects who are not surgically sterile or post-menopausal must agree to use reliable methods of birth control for the duration of the study and for 90 days after the last dose of study drug administration; male partners of female subjects should use condoms for the duration of the study, and for 90 days after the last dose of study drug administration

Please feel free to contact the clinical trial team to learn more about this study.

For more information, please contact the Neuro-Oncology Clinical Trial Team at:
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Sponsor

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