Study Snapshot

Key Conclusions

- CNSide™ identified tumor cells and pathogenic/actionable mutations in patients with MBC and LM, including cases with negative CSF cytology
- Variable concordance and discordance between CSF and extracranial NGS supports the clinical rationale for directly evaluating the CSF compartment to uncover CNS-specific targets and resistance mechanisms

Background

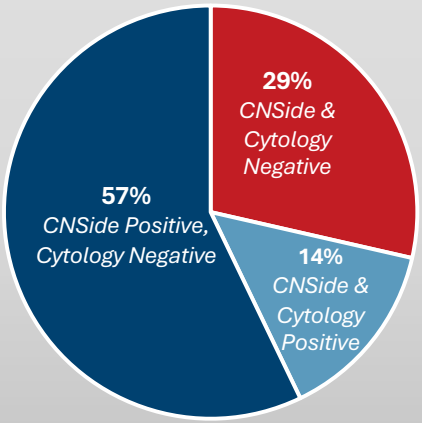
This single-center, non-therapeutic prospective observational study evaluated the frequency and concordance of actionable mutations in the CSF versus extracranial sites in patients with metastatic breast cancer (MBC) and leptomeningeal metastases (LM).

Methods

- Single-center, prospective, non-therapeutic observational study of 15 patients with MBC and known or suspected LM treated at UCSF between 2020–2024
- CSF, blood, and archival tumor samples were collected when available; CSF tumor cells (CTC-TCs) were enumerated and CSF circulating tumor DNA (ctDNA) was analyzed by NGS using the CNSide technology
- CSF NGS results were compared with available matched blood and/or tumor tissue NGS to evaluate concordance and discordance of actionable mutations across CNS and extracranial compartments

Results

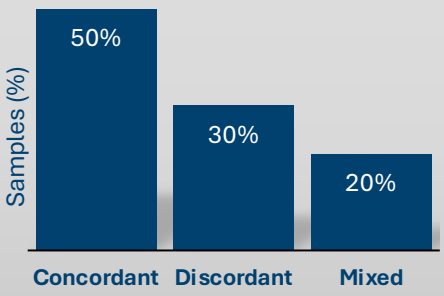
1. Improved sensitivity to detect LM: CNSide detected CSF-TCs in 71.4% of tested patients (5/7) with MBC



2. CSF NGS detected molecular alterations in 50% of patients with confirmed LM (7/14)

	n (%)
ERBB2 amplification	1 (6.7)
ESR1	1 (6.7)
PIK3CA	4 (26.7)
TP53	4 (33.3)

3. CSF vs extracranial NGS demonstrated variable genomic concordance (N=10)



CNSide®

During the time of data analysis and manuscript writing, CNSide was run as a Laboratory Developed Test at Biocept, Inc. in a California CLIA-certified and CAP-accredited laboratory. CNSide was acquired by Plus Therapeutics in May 2024, and the test was made commercially available in March 2026 by CNSide Diagnostics LLC, a wholly owned subsidiary of Plus Therapeutics, Inc.

Disclosure

None of the authors were employed by, or consultants for, Biocept during the time of data analysis and manuscript writing.

Study

This was a prospective, non-interventional study performed at a single institution on patients treated between 2020 and 2024 under an IRB approved protocol where the IRB agreed to waive consent.

Study Snapshot

This Study Snapshot was developed by CNSide Diagnostics, LLC. The source data for this Study Snapshot is a peer-reviewed publication by Huppert et. al. (Reference: "Detection of actionable mutations in the cerebrospinal fluid and concordance/discordance with extracranial mutations in patients with metastatic breast cancer and leptomeningeal disease". *Ther Adv Med Oncol.* 2026;18:17588359261424678.)

Regulatory Status

CNSide is a Laboratory Developed Test (LDT) for which safety and effectiveness have not yet been established. The test is labeled as RUO-Research Use Only. Not for diagnostic purposes.

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