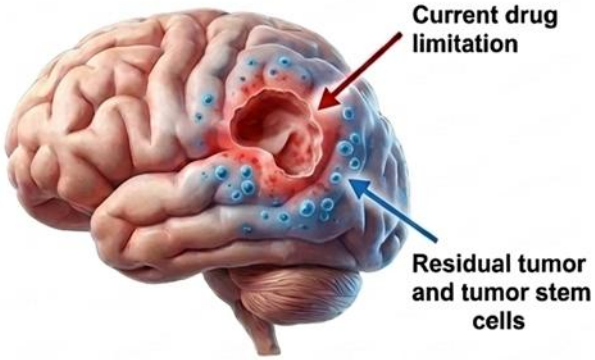
Cerebraca® Wafer: Redefining Localized Therapy for Glioblastoma

EFBHC EVERFRONT BIOTECH HOLDING COMPANY

Differentiated glioblastoma therapy entering pivotal study

Late-clinical CNS oncology asset positioned for strategic partnership

The Unmet Need



1. In glioblastoma, infiltrative residual tumor can extend 2–3 cm beyond the resection margin, while current local wafer therapy reaches only about 2–3 mm.
2. This spatial mismatch leaves deep residual tumor cells unreached and contributes to continued recurrence risk after surgery.

	Current Drug	Cerebraca® Wafer
Mechanistic rationale	1. BCNU alkylating therapy 2. MGMT-associated resistance	1. Multi-target modulation 2. RTK-network positioning
Drug penetration	2-3mm	20-30mm
Safety profile	High Toxicity. Significant adverse events: Seizures 37% Convulsions 19% Hemiplegia 19% Abnormal Healing 14%	Excellent Biocompatibility. FDA-approved biodegradable material. No ≥ Grade 3 adverse reactions in Phase I/IIa. adverse events: Seizures: 15% Convulsions: 0% Hemiplegia: 0% Abnormal Healing: 8%

Pivotal Phase IIb/III Study: Clinical Stage & Value Inflection Points

Clinical Stage Summary

- Recurrent Glioblastoma, Resection-Eligible
- N = 165 Patients
- 2:1 Randomization
- Primary Endpoint: Median Overall Survival (mOS)

Study design informed by FDA Type C meeting interactions, supporting a registrational path.

Trial Design & Treatment Arms

Stratification Factors: IDH mutation, MGMT promoter status, 5-ALA use, tumor size (< 5 vs. > 5 cm)

Treatment Arm (N=110)	Comparator Arm (N=55)
Resection	Resection
6 Cerebraca Wafers	Temozolomide
Temozolomide	

Pivotal Milestones Toward BTD & Registration

- **24 Events** → Safety / Futility Check → Continue Trial
- **84 Events** → Interim Analysis / BTD-Enabling Package → Breakthrough Therapy Designation (BTD) Potential
- **Final Analysis** → Registrational Readout → Potential NDA Submission

Strategic Opportunity in Recurrent Glioblastoma

- Phase IIa highlights mOS of 15.7 months (n=7) in recurrent glioblastoma and 26.2 months (n=5) in a biomarker-defined subgroup with EGFR, AXL-1, and cMET features.
- Robust IP protection beyond 2041 and Orphan Drug Designation provide strong commercial exclusivity for global partners..

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