

Brakiva™ (Topotecan Optisome™)

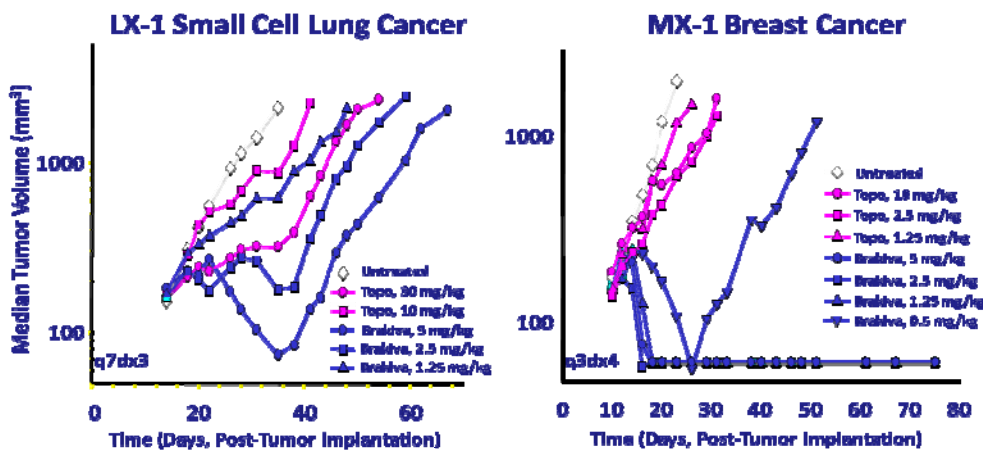


A combination of modern nanoparticle technology and a potent lung and ovarian cancer chemotherapy

Topotecan (Topo) is widely used as a single-agent in the treatment of small cell lung and ovarian cancers after failure of initial therapy. Topo has also demonstrated activity in patients with relapsed/refractory AML and MDS. Topo therapy is limited by its cell cycle-specific (S-phase) activity combined with a short plasma half-life; an inconvenient, but critical, dosing schedule; and rapid drug hydrolysis and inactivation when exposed to the basic pH of plasma. Brakiva™ is Topo encapsulated in sphingomyelin and cholesterol nanoparticles called Optisomes™. Optosomal encapsulation has the potential to facilitate convenient, full-dose Topo delivery in a manner that can overcome the limitations of conventional Topo.

Preclinical data demonstrate the value of Brakiva over Topo

- Prolonged circulation time and increased plasma AUC
- 10-fold increased Topo delivery to tumor sites
- 10 to 20-fold increased activity in nonclinical models
- Optisome core pH of 4.0 maintains lactone ring integrity so that most Topo delivered to tumor is in its fully active form



Manufacturing technology transfer is ongoing and clinical batch production slated for completion in 2Q08

FDA IND activated and Phase I trial design approved

Two-arm Phase I dose-escalation trial in patients with relapsed and/or refractory solid tumors to evaluate every 21 day as well as day 1+8 every 21 day dosing is scheduled to start in 2H08

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