



GALLISTA™ (oral gallium maltolate)

Executive Summary

OVERVIEW

Today, millions of cancer patients receive treatments that cause severe side effects and yet have little efficacy. GALLISTA™ is a new orally administered compound that has the potential to fundamentally improve the lives of many of these patients by providing **effective treatment without serious side effects**. GALLISTA™ (oral gallium maltolate) is being developed as **an orally active formulation of gallium, a drug already approved by the FDA in intravenous form** (gallium nitrate; Ganite®). Clinical and preclinical studies have repeatedly shown gallium to have efficacy against cancer, inflammatory disorders, infectious disease, and bone loss. Gallium is a particularly exciting new therapeutic because it naturally targets diseased tissue while sparing healthy tissues.

A FEW COMPETITIVE ADVANTAGES OF GALLISTA™

- Easy to use oral drug designed for once-per-day dosing
- Intended as a safer and more convenient form of an existing FDA-approved gallium drug (intravenous gallium nitrate, administered continuously over five days in a hospital)
- **Oral gallium maltolate has successfully completed several Phase I clinical trials for safety, in a total of 96 patients:** no serious toxicity was observed at daily doses of up to 3,500 mg per day for repeated 28-day periods
- Oral gallium maltolate has demonstrated apparent anecdotal efficacy in liver cancer, lymphoma, multiple myeloma, colon cancer, metastatic breast cancer, pediatric brain cancers (gliomas), and metastatic prostate cancer
- The potential exists to treat brain cancers: unlike most drugs, gallium can cross the blood-brain barrier
- Personalized medicine: the drug can be paired with an FDA-approved diagnostic method
- [Published efficacy results in a medical journal](#)
- Technology protected by patents and patent applications owned and controlled by the inventor
- Research collaborations with major medical centers

DEVELOPMENT PLAN FOR THE NEXT TWO YEARS

Seven million dollars is being sought to fund the development of GALLISTA™ through proof-of-concept Phase I/II clinical trials to demonstrate efficacy in cancer patients. Two initial, parallel trials are planned: in refractory lymphomas and in primary liver cancer. These initial trials would enroll about 30 to 50 patients each, and would last about a year. If significant extension of life is found in either trial, it is possible that provisional FDA approval could be obtained for treatment of these rapidly lethal cancers. The \$7 million would cover the costs of the trials themselves (\$3 million), plus drug manufacture and formulation (\$750,000), non-clinical research that may be required (\$1,250,000), patent expenses (\$200,000), personnel/consultants (\$1,000,000), and rent, insurance, legal, and travel costs (\$800,000).



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MARKETS

The major potential U.S. markets for oral GALLISTA™ in the cancer field are summarized below (annual sales based on \$10,000 per patient); **worldwide markets are several times larger**. Infectious disease use may also be possible.

Indication	Annual Incidence	Annual Deaths	Estimated Prevalence in the U.S.	Market Share (%)	Estimated Annual U.S. Sales (\$million)
Colorectal cancer	136,830	50,310	440,000	10	440
Liver cancer	33,190	23,000	33,000	50	165
Pancreatic cancer	46,420	39,590	48,000	10	48
Breast cancer	235,030	40,430	850,000	5	425
Prostate cancer	233,000	29,480	780,000	5	390
Bladder cancer	74,690	15,580	250,000	10	250
Non-Hodgkin's lymphoma	70,800	18,990	175,000	25	438
Multiple myeloma	24,050	11,090	35,000	25	86
Brain, nervous system	23,380	14,320	36,000	10	36
Totals	877,390	242,790	2,647,000	9	2,278
Bone metastasis (estimated)	400,000	120,000	1,200,000	15	900

Figures are derived from data in *Cancer Facts and Figures 2014* (American Cancer Society, 2014).

UNIQUE OPPORTUNITY WITH HUGE POTENTIAL

- GALLISTA™ (gallium maltolate) is ready to enter Phase I/II trials in patients with lymphoma, liver cancer, multiple myeloma, or other cancers: trials could start within a few months of funding
- Potential to supersede an FDA-approved drug (intravenous gallium nitrate) with a safer, more convenient, and less expensive option
- Efficient, low-cost manufacturing of gallium maltolate for Phase II clinical trials is already established
- Only \$7 million needed for Phase II proof-of-concept testing (which may be sufficient for provisional FDA approval in advanced, lethal cancers such as liver cancer, lymphoma, and brain cancers)
- Efficacy likely to be determined within only 6 to 18 months

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