

# Marqibo<sup>®</sup> (Vincristine Optisome<sup>™</sup>)



## A combination of modern nanoparticle technology and a potent, widely-used, cell cycle-specific chemotherapy

Vincristine (VCR) is widely used in the treatment of leukemias, lymphomas, and multiple myeloma. Limited efficacy stems from cell cycle-specific (M-phase) activity combined with a short plasma half-life and routine dose-capping at 2 mg due to peripheral neurotoxicity at the approved 1.4 mg/m<sup>2</sup> dose level. Marqibo<sup>®</sup> is VCR encapsulated in sphingomyelin and cholesterol nanoparticles called Optisomes<sup>™</sup>. Optisomal encapsulation facilitates VCR delivery at 2.25 mg/m<sup>2</sup> without dose-capping and provides the potential to overcome the limitations of conventional VCR.

### Preclinical data demonstrates the value of Marqibo over VCR

- 100-fold increased circulation time and plasma AUC
- Up to a 7.4-fold greater tissue (bone marrow, lymph node, implanted tumor, spleen, and liver) vincristine exposure
- Increased therapeutic index in xenograft models compared to VCR in other liposomes or unencapsulated

### Clinical data demonstrate promising anti-cancer activity

- 24% CR/CRp rate in relapsed/refractory adult ALL
- 31% ORR in metastatic melanoma (25% CR in uveal subset)
- 36% ORR in relapsed/refractory Hodgkin's Disease
- 93% CR rate in front-line aggressive NHL
- 27% ORR in relapsed/refractory aggressive NHL

### Ongoing and pending clinical trials will support accelerated approval

- Global registration-enabling, Phase 2 trial in second relapse Ph(-) adult acute lymphoblastic leukemia (rALLy)
- Interim data analysis indicates 5 CR/CR<sub>p</sub>/CR<sub>i</sub> among first 20 patients receiving Marqibo, including 3 patients with extramedullary leukemia
- Confirmatory Phase 3 trial in newly diagnosed elderly (≥ 60 yrs) Ph(-) adult lymphoblastic leukemia (ALLY)
- Phase 2 trial in metastatic uveal melanoma

|                  | rALLy  | ALLY  |
|------------------|--|---|
| Study Design     | Multi-center, single-arm, open-label                     | Randomized, double-blinded, active-controlled |
| Study Treatment  | Weekly Marqibo 2.25 mg/m <sup>2</sup> without a dose cap | Multi-agent treatment with Marqibo or VCR     |
| Primary Endpoint | Confirmed CR/CRp rate                                    | Event-free survival                           |

Significant commercial value based on the potential for wide-spread replacement of VCR and the opportunity for premium pricing

#### HANA BIOSCIENCES

Gradon Knotts  
Vice President-Business Development  
7000 Shoreline Court, Suite 370  
South San Francisco, California 94080

Main Phone: 650-588-6404  
Direct Phone: 650-228-5048  
Cell Phone: 650-823-0509  
Fax: 650-228-5049

Email: gradon.knotts@hanabiosciences.com