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**TALON**  
T H E R A P E U T I C S

## ***Forward-Looking Statements***

This material contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are often, but not always, made through the use of words or phrases such as "anticipates," "expects," "plans," "believes," "intends," and similar words or phrases. These forward-looking statements include without limitation, statements regarding Talon's ability to obtain accelerated approval of Marqibo for the treatment of adult Ph- ALL from the FDA, the potential of Marqibo to be a safe and effective alternative for the treatment of adult relapsed ALL compared to existing therapies, and other statements that are other than statements based on historical fact. Such statements involve risks and uncertainties that could cause Talon's actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Such risks and uncertainties include: that the existing data from clinical trials of Marqibo conducted to date will not be adequate to demonstrate the safety and efficacy of Marqibo for the treatment of adult relapsed ALL, or otherwise sufficient to support FDA approval of our pending NDA or support European approval; that, even if approved, Talon may lack the financial resources and access to capital to support its future operations, including the potential commercialization of Marqibo if approved for marketing. Additional information concerning these and other risks are described in the company's Annual Report on Form 10-K for the year ended December 31, 2011. Talon assumes no obligation to update these statements, except as required by law.

## ***Marqibo Receives Positive ODAC Vote***

**March 21, 2012**

Marqibo<sup>®</sup> received a positive endorsement from the FDA Oncologic Drugs Advisory Committee (ODAC) indicating a favorable benefit/risk assessment for the use of Marqibo for the treatment of adults with Philadelphia chromosome negative acute lymphoblastic leukemia (ALL) in 2<sup>nd</sup> or greater relapse or that has progressed following 2 or more lines of anti-leukemic therapy

The FDA is anticipated to make an accelerated approval decision for Marqibo by August 12, 2012

## *Talon's Near-term Value Proposition*

### Marqibo®

- 2012: Enrollment initiation in Phase 3 frontline adult ALL confirmatory HALLMARQ trial (under SPA)
- 2012: US accelerated approval and potential launch in advanced, relapsed/refractory adult ALL
- 2012: Continue robust label expansion programs in ALL, NHL, and pediatric cancers
- 2012: EU marketing authorization application
- 2013: EU approval and potential launch

### Menadione Topical Lotion

- 2012: Enrollment of randomized Phase 2 trial for EGFR inhibitor rash prevention (Mayo Clinic as lead)
- 2013: Initiate Pivotal Phase 3 study

## Recent and Near Future Value Catalysts

Enrollment initiation of Marqibo Phase 1/2 Pediatrics Trial at NCI	✓
Submission of Complete Original Marqibo NDA to FDA	✓
SPA from FDA on Marqibo Phase 3 ALL Confirmatory (HALLMARQ) Study	✓
Acceptance of Marqibo NDA for Filing	✓
Activation of Marqibo Phase 3 ALL Confirmatory (HALLMARQ) Study	✓
Enrollment initiation of Marqibo Phase 3 Frontline NHL Trial with DSHNHL	✓
Activation of MTL Phase 2 EGFR Inhibitor Rash Prevention Trial at Mayo Clinic	✓
Marqibo EMA Protocol Advice and Exceptional Circumstances Discussion	✓
Enrollment initiation of MTL randomized Phase 2 trial at Mayo Clinic	✓
Positive Marqibo FDA ODAC Meeting	✓
HALLMARQ Study First-Patient-In	1H12
Marqibo FDA Accelerated Approval	1H12

NHL = non-Hodgkin's lymphoma

DSHNHL = German High Grade NHL Group

NCI = National Cancer Institute

NDA = new drug application

FDA = Food and Drug Administration

ALL = Acute Lymphoblastic Leukemia

SPA = Special Protocol Assessment

MTL = Menadione Topical Lotion

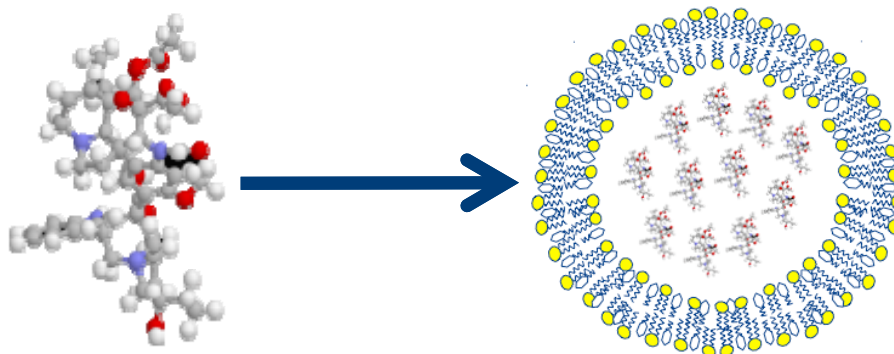
EGFR = Epidermal Growth Factor Receptor

EMA = European Medicines Authority

ODAC = Oncology Drug Advisory Committee

# Marqibo Is Intended to Replace Standard Vincristine

Standard vincristine is widely and globally prescribed to treat blood and solid cancers in adults and children

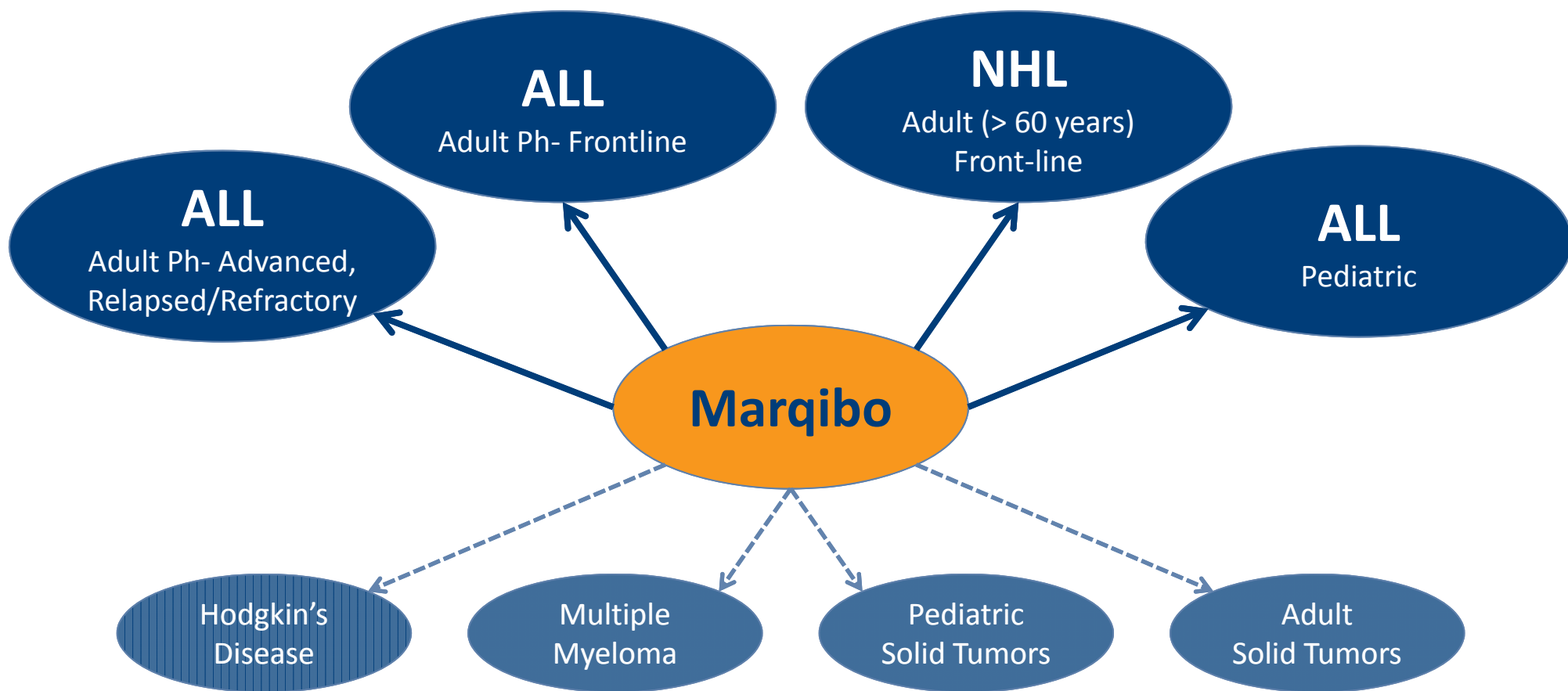


Marqibo is high concentration vincristine delivered by unique sphingomyelin and cholesterol liposomes (Optisomes™)

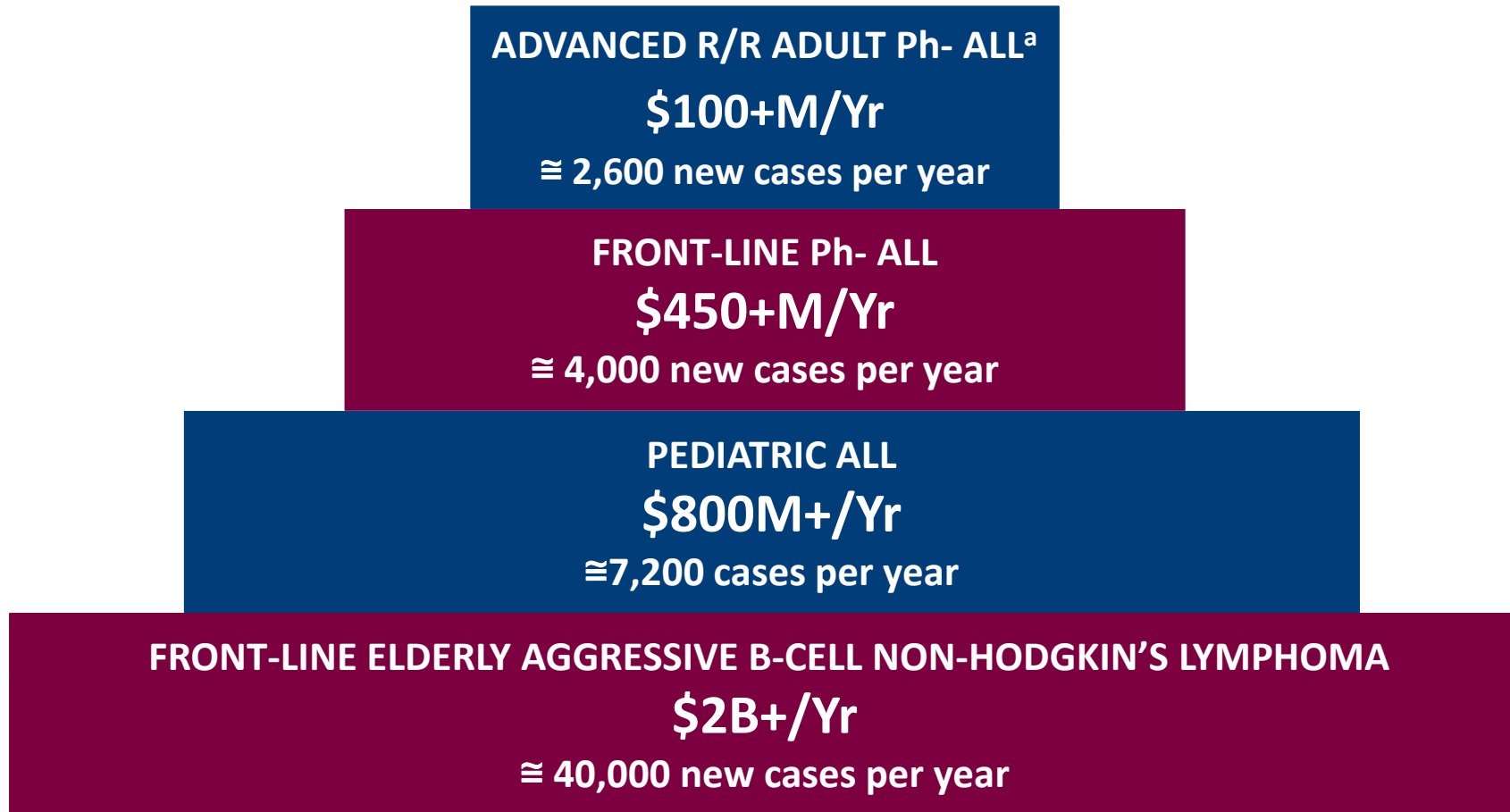
Standard Vincristine Limitation	Overcome by Marqibo
Short plasma circulation half-life	✓
Narrow therapeutic index	✓
Limited cancer tissue exposure duration	✓
Rapid and diffuse tissue distribution	✓
Dose cap at 2 mg regardless of patient size	✓

# Marqibo

## A Portfolio in a Product



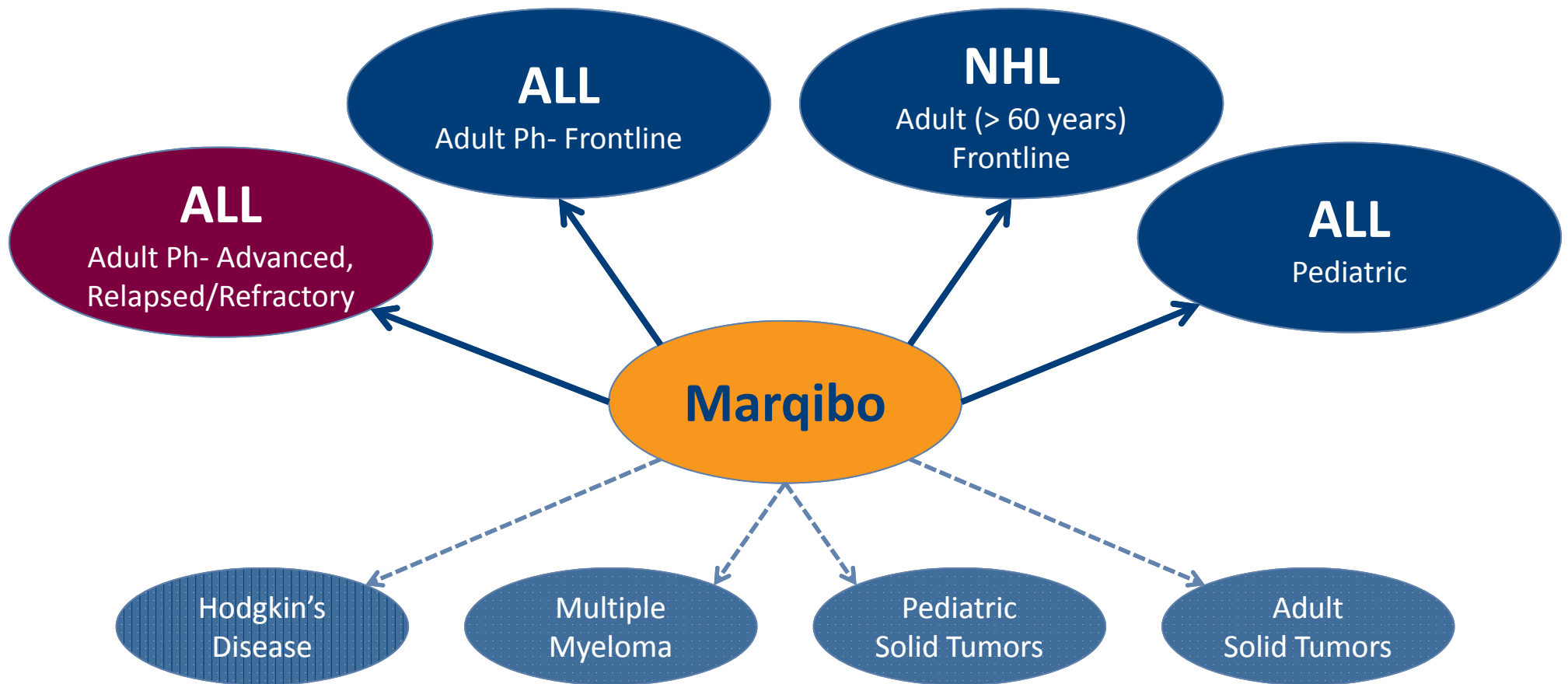
# Marqibo has Significant Global Market Potential



Source: Cancer Facts and Figures 2010. Atlanta, GA; American Cancer Society: 2010. and Decision Resources Spectrum 2010  
Incidence rates for US plus EU represent a doubling of published US incidence rates. ROW equals 20% of US and EU  
a = age 15 and greater

# Marqibo

## Targeting an Underserved Population as our 1<sup>st</sup> Indication



# ***Advanced, Relapsed/Refractory Ph- Adult ALL has a Grave Prognosis and No Standard Treatment Options***

- The prognosis is comparable to metastatic melanoma, pancreatic cancer, and gastric cancer <sup>1,2</sup>
- Third-line, single-agent therapies induce few responses ( $\leq 4\%$ ), result in a 2 month median OS, and are highly toxic (20-30% early and induction mortality)<sup>3</sup>
- Fourth-line or greater, single-agent therapies have not been studied and are expected to induce rare responses ( $< 1\%$ ) and produce unacceptable toxicity ( $> 30\%$  30-day mortality)
- Ph- ALL in 2<sup>nd</sup> or greater relapse and that has progressed following 2 or more lines of anti-leukemia therapy represents a dramatic unmet medical need and untapped commercial opportunity

<sup>1</sup> Tavernier E et al. *Leukemia* 2007; 21:1907-1914.

<sup>2</sup> *Cancer Facts and Figures 2010, Atlanta, Georgia, American Cancer Society: 2010.*

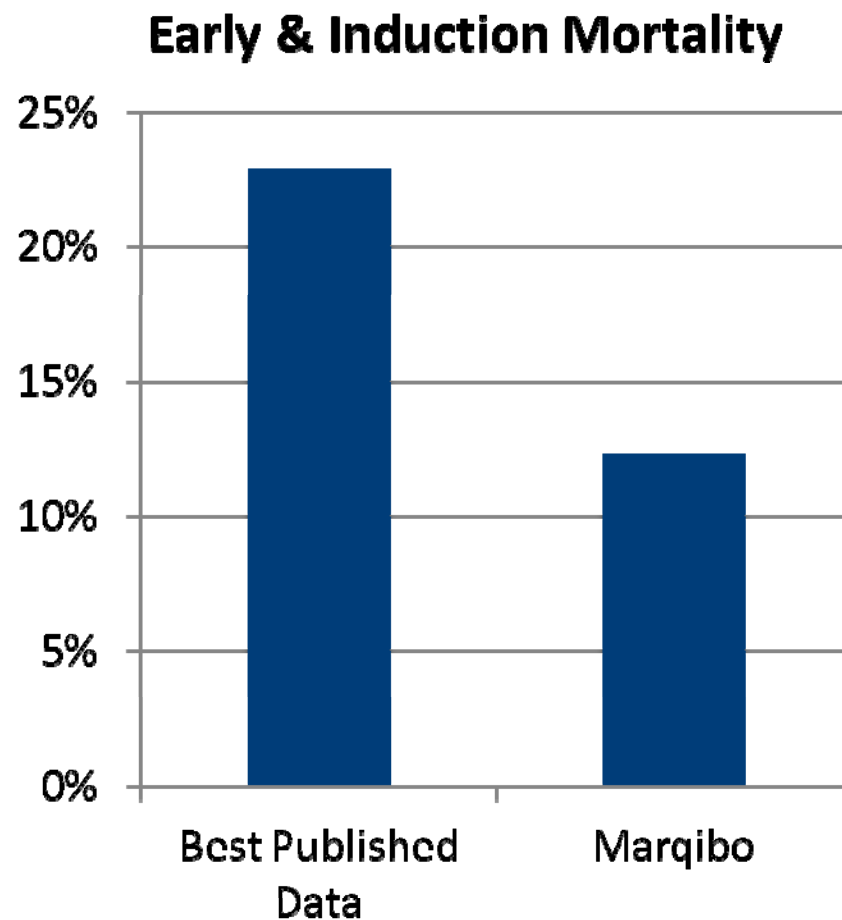
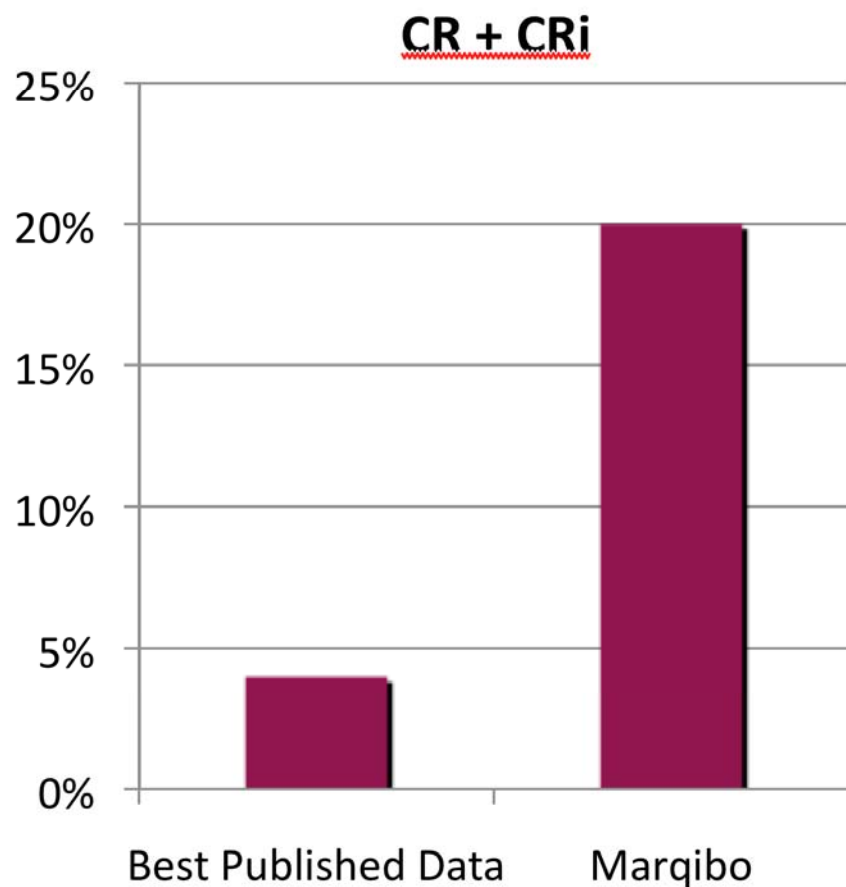
<sup>3</sup> O'Brien S et al. *Cancer* 2008; 113:3186-91.

# ***Marqibo as a Single-Agent Produced Encouraging Efficacy in Adults with Advanced, Relapsed/Refractory Ph- ALL***

<b>Outcome Measure ITT Analysis/PI Assessment</b>	<b>Phase 2 Study HBS407 (RALLY) Marqibo 2.25 mg/m<sup>2</sup> N = 65</b>
Overall Response Rate (CR, CRi, PR, BMB)	35.4% (23/65)
Overall Remission Rate (CR/CRi)	20.0% (13/65)
CR/CRi Rate by Line of Treatment	Third line – 18.8% (6/32) Fourth line – 20.8% (5/24) Fifth line – 25.0% (2/8) Seventh line – 0% (0/1)
Median CR/CRi Duration	5.4 mos (range 1.1 – 15.4)
Median Overall Survival of CR/CRi Patients	7.67 mos (range 2.4 – 23.3+)
Median Overall Survival	4.6 mos (range 0.4 – 22.0+)

O'Brien S et al. *J Clin Oncol*, 2010 ASCO Annual Meeting Proceedings 2010; 28:6507.

# Marqibo is Differentiated from Published Single-Agent Therapies



O'Brien S et al. *J Clin Oncol*, 2010 ASCO Annual Meeting Proceedings 2010; 28:6507.  
O'Brien S et al. *Cancer* 2008; 113:3186-91.

## ***Marqibo Produced Meaningful Outcomes in RALLY***

- 12 (18.5%) patients in the RALLY study were able to “bridge” to a stem cell transplant following Marqibo treatment
- 5 patients in the RALLY study had survival greater than 1 year
- 70% of CR/CRi patients in RALLY had a response duration longer than the response duration to their most recent therapy
- 44.4% of patients with clinically notable leukemic infiltration of vital organs had rapid reversal of organ dysfunction and achieved CR/CRi
- Marqibo induced remissions even in patients refractory to multi-agent chemotherapy containing a vinca alkaloid and to clofarabine

*Schiller G et al. J Clin Oncol, 2011 ASCO Annual Meeting Proceedings 2011; 29:2011.*

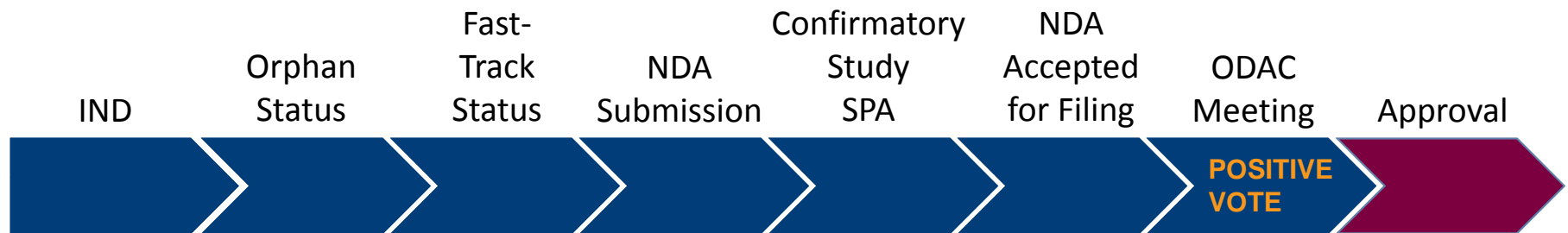
*O'Brien S et al. J Clin Oncol, 2010 ASCO Annual Meeting Proceedings 2010; 28:6507.*

## ***Marqibo 2.25 mg/m<sup>2</sup> was Generally Safe and Well-Tolerated in Heavily Pre-Treated Adults with ALL***

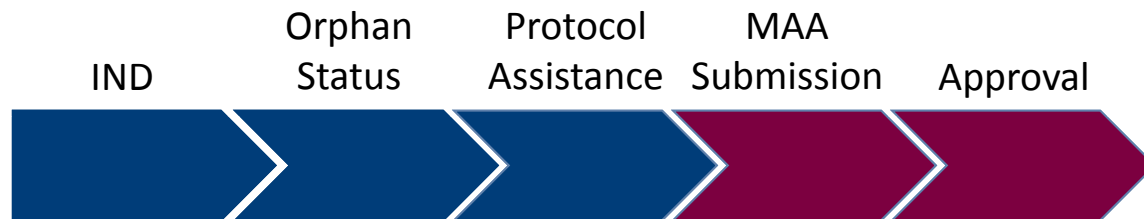
- Low incidence of Grade  $\geq$  3 Adverse Events of special interest:
  - Peripheral neuropathy = 12% (despite universal prior vincristine exposure)
  - Constipation = 4.8% (despite universal prior vincristine exposure)
  - Chemical cellulitis = 0%
- No new or unexpected toxicities
- No toxicity attributed to the liposome encapsulation
- Relatively low 14-day (4.6%) and 30-day (12.3%) mortality rates
- Toxicity was predictable and manageable

# *Special Approval Processes Remain Essential in Rare Hematologic Cancers Like ALL*

## Pathway to US Accelerated Approval



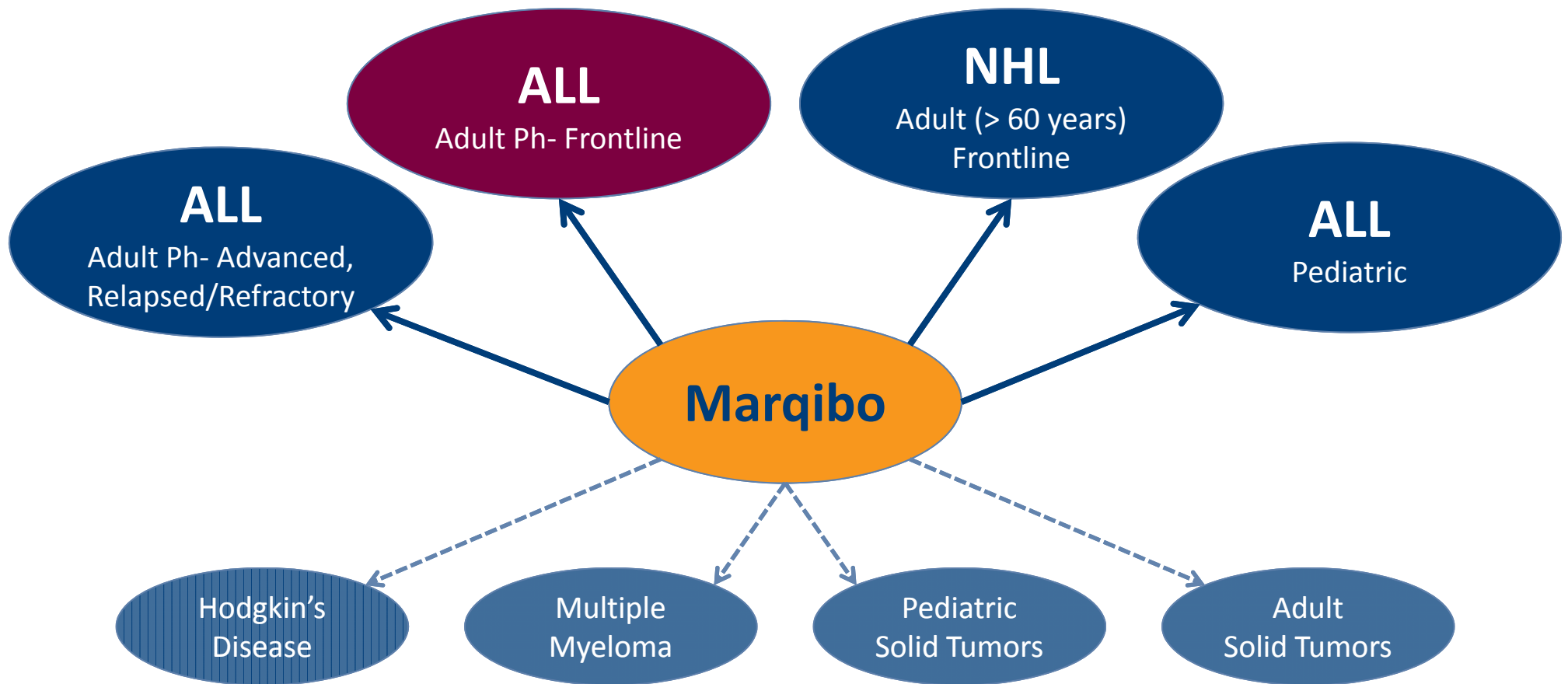
## Pathway to EU Conditional Approval



 completed  imminent

# Marqibo

## Expanding to Newly Diagnosed Adult ALL

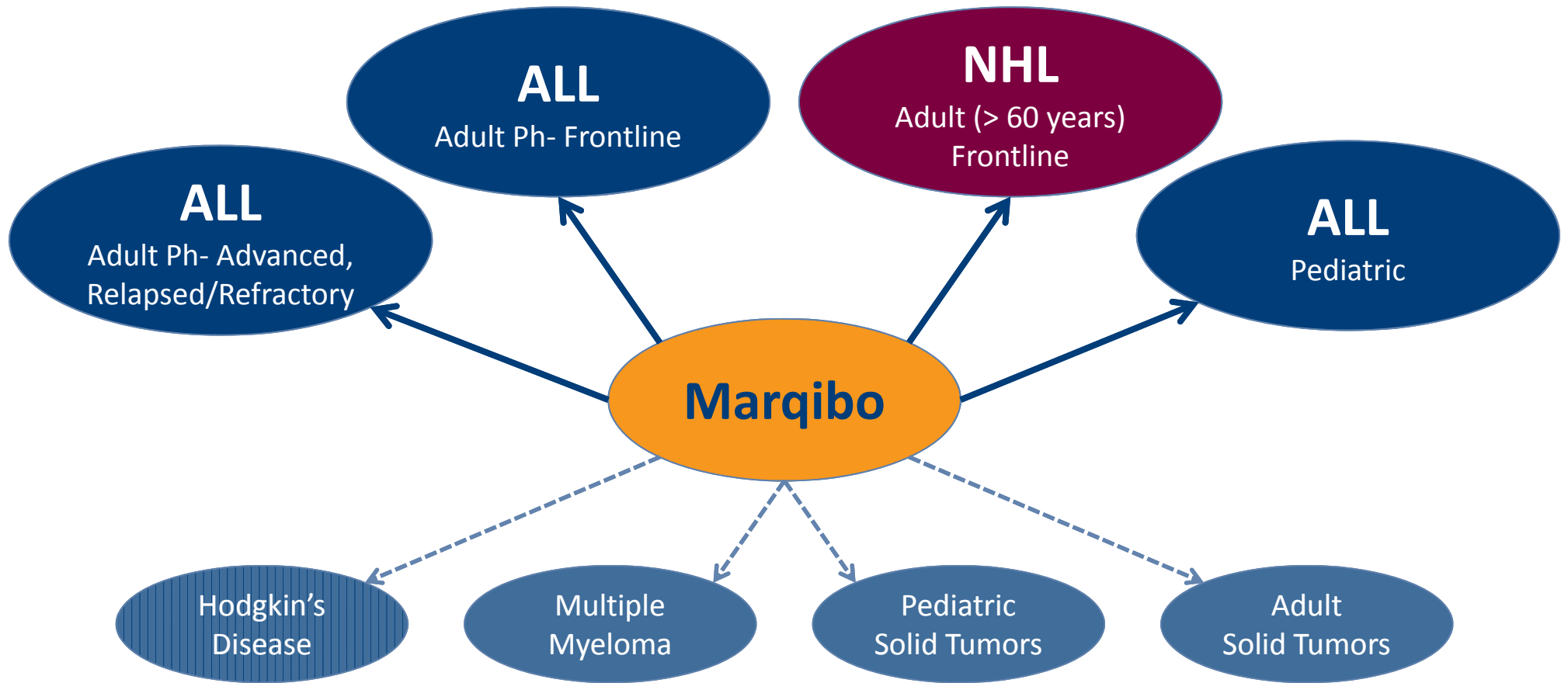


# ***Front-Line Adult Ph- ALL Represents an Important Clinical Need and Commercial Opportunity***

- Phase 3 “confirmatory” study in elderly adults with untreated Ph- ALL
  - Standardized multi-agent therapy including Marqibo versus standard vincristine
  - Powered for superiority of overall survival primary endpoint
  - Global trial sponsored and run by Talon with CRO support
  - Open to enrollment with First-Patient-In anticipated in 1H 2012 in US
  - Full design agreement with FDA as reflected by granted SPA
  - Potential to support an sNDA and expanded label
- Phase 2 study in adults with untreated Ph (-) ALL
  - Substituting Marqibo for vincristine in Hyper-CVAD to create Hyper-CMAD
  - Being conducted by MD Anderson Cancer Center

# Marqibo

## Addressing a Large Opportunity in NHL

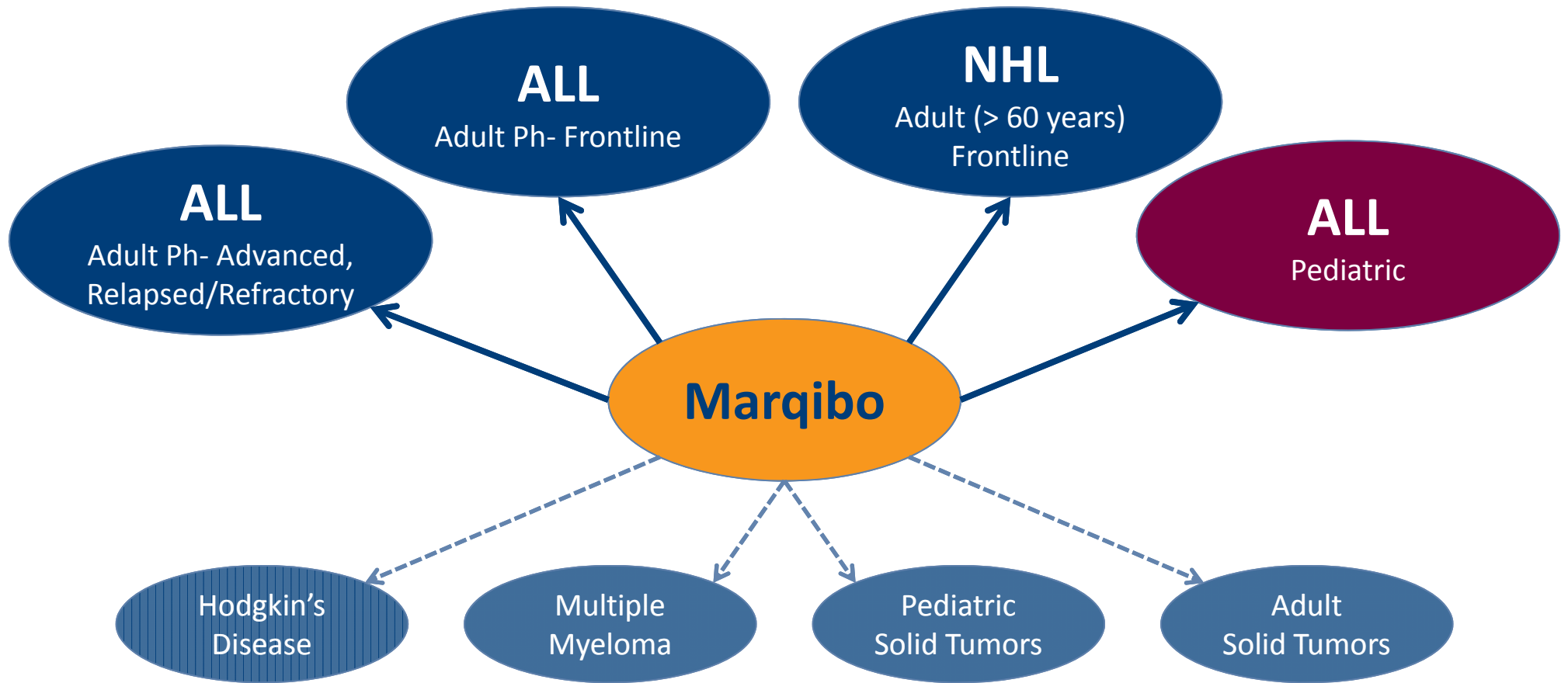


# ***Frontline Aggressive B-Cell NHL Represents a Large Clinical and Commercial Opportunity***

- Phase 3 study in elderly adults with untreated aggressive B-cell NHL
  - R-CHMP-14 versus R-CHOP-14
  - Approximately 1,000 patients to be enrolled ideally over 3 years
  - Primary endpoint is progression-free survival
  - Run by the German High-Grade Non-Hodgkin's Lymphoma Study Group
  - First-Patient-In achieved in 4Q 2011
  - Potential to support an sNDA and expanded label by 2017
- Phase 2 studies in frontline aggressive NHL (R-CHMP) and relapsed/refractory NHL (single-agent Marqibo) completed

# Marqibo

## Providing Pediatric Access

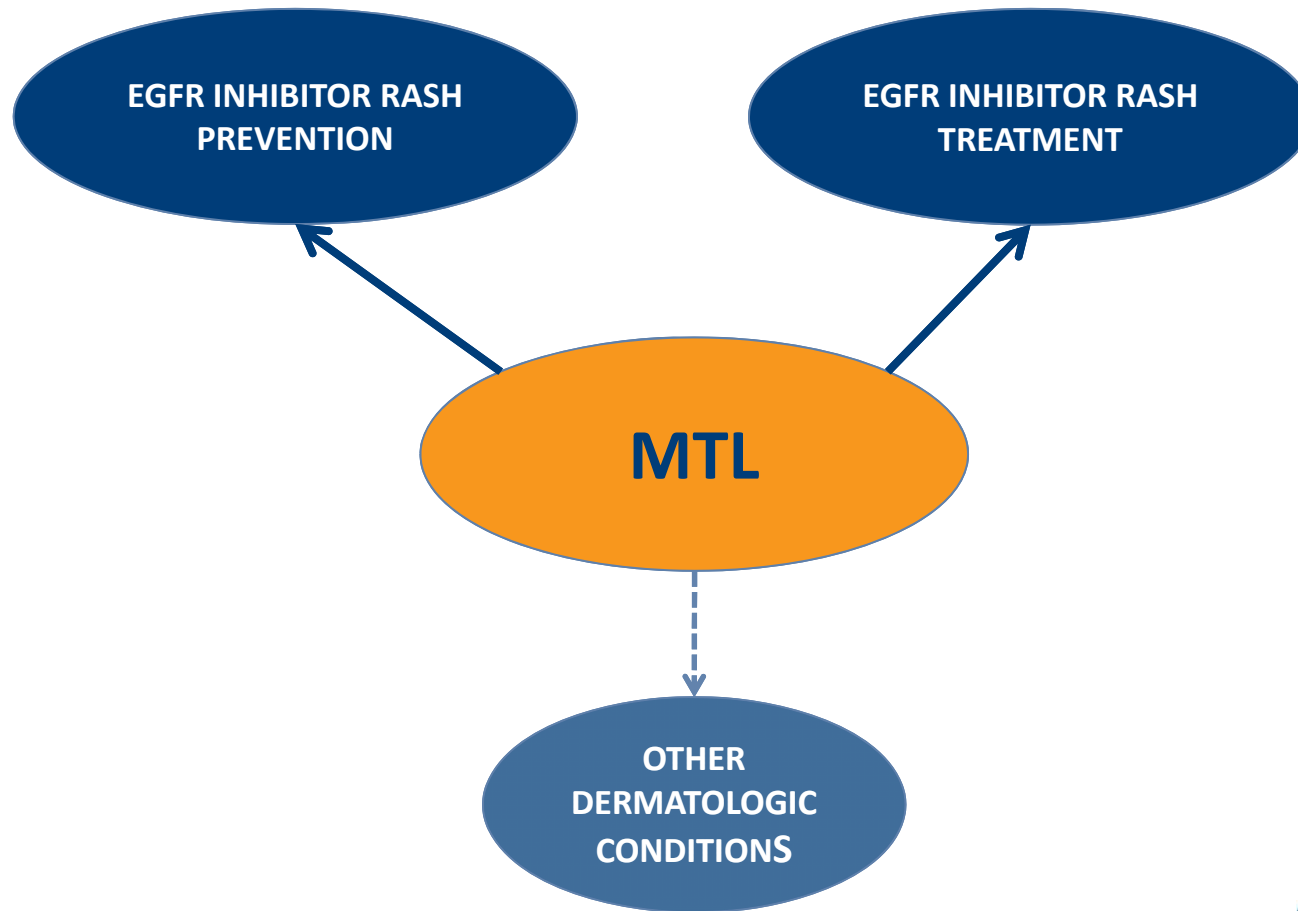


# ***Marqibo has the Potential to Benefit Children with Solid Tumors and Hematologic Malignancies***

- Standard vincristine is widely used in children with newly diagnosed and relapsed sarcomas, lymphomas, and ALL
- A Phase 1 dose-escalation trial is enrolling at the NCI
  - Primary objective to determine the maximum tolerated dose and toxicities
  - Open-label trial in up to 36 patients ages 2 to 20 years old
- A Phase 2 program in ALL at the pediatric MTD is planned

# ***Menadione Topical Lotion (MTL)***

*First-in-Class Compound for Treatment-limiting Skin Toxicity  
Associated with EGFR Inhibitors*



# ***MTL Designed to Address a Growing Cancer Therapy Toxicity Challenge***

## **The Clinical Challenge**

- Treatment with all approved EGFR inhibitors (e.g., Erbitux<sup>®</sup>, Tarceva<sup>®</sup>, Tykerb<sup>®</sup>, and Vectibix<sup>®</sup>) causes a painful and treatment-limiting rash
- Rash occurs in up to 90% of patients within weeks of exposure and leads to treatment discontinuation in up to 30% of affected patients

## **Menadione Topical Lotion may be the Solution**

- First-in-class topical that may prevent or mitigate the rash
  - Phosphatase inhibition targets the underlying cause of toxicity
  - No currently approved treatments available
- Mechanism of action/use patents issued; formulation patents pending
- Phase 2 randomized trial sponsored by the Mayo Clinic and funded by NCI first patient enrolled in January 2012

# ***MTL Phase 1 Program Identified MTD And Confirmed Lack of Systemic Absorption***

	<b>HBS 701</b>	<b>HBS 702</b>
Study Population	Active Cancer Patients with or at risk for EGFR inhibitor rash	Healthy volunteers
Study Size	18	12
Study Treatment	Split-face and split-chest dosing with MTL 0.2% BID or placebo lotion as treatment or prophylaxis (dose reductions allowed)	0.0%, 0.05%, 0.1%, and 0.2% MTL applied to entire face, neck, chest, and upper arms BID for 3 days with a 2 day washout between lotion strengths
Pharmacokinetic Profile	No appreciable systemic absorption	No appreciable systemic absorption
Safety and Tolerability	MTD = 0.1% lotion	MTD = 0.1% lotion
Activity Signal	Visual evidence that MTL 0.1% lotion may prevent Grade 2 or greater EGFR inhibitor rash	Menadione detectable at skin dermal-epidermal junction

# *Commercial and Partnering Strategy*

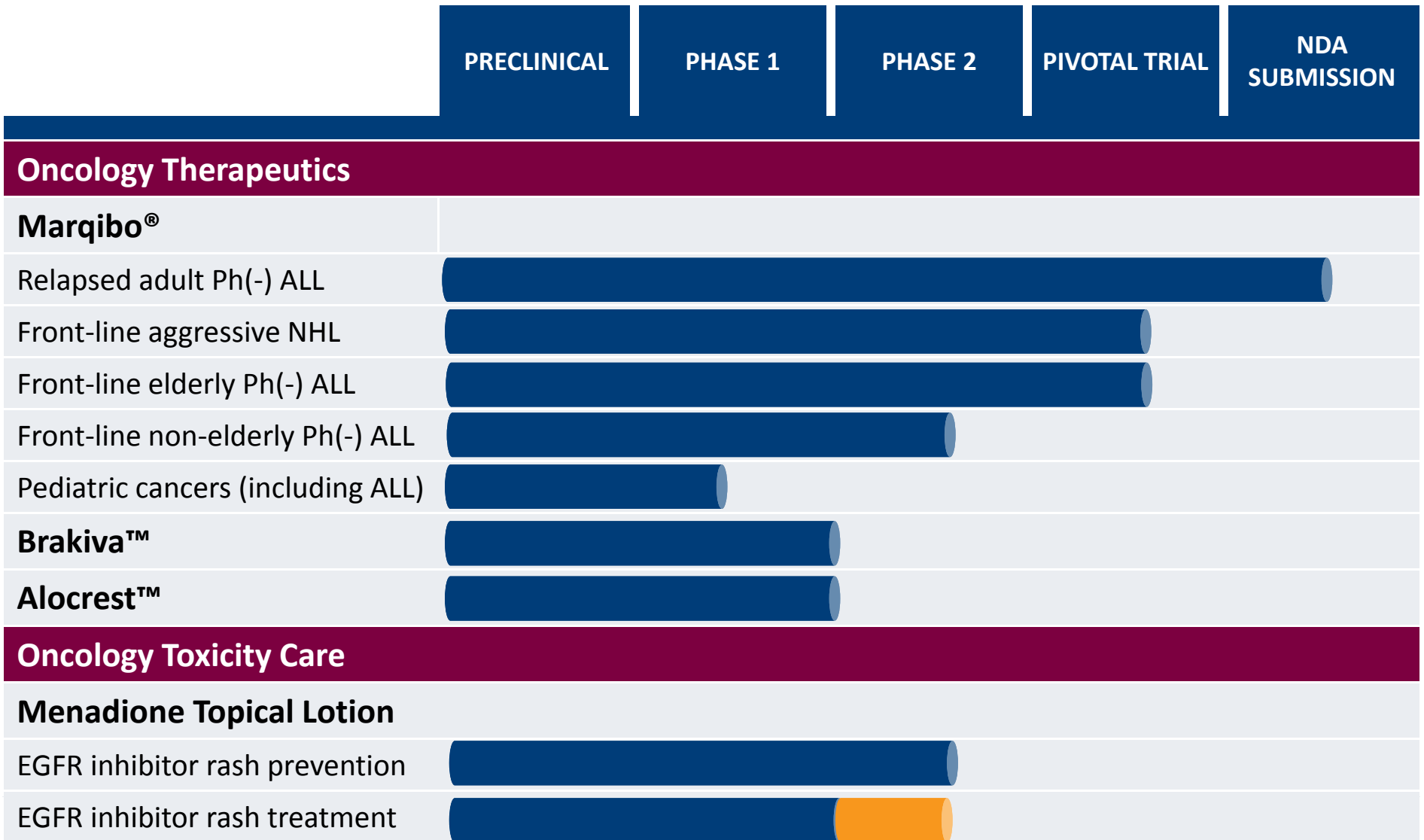
## **MARQIBO**

- Seeking ex-US partner
  - Regulatory and commercial support of initial ALL indication
  - Regulatory, clinical, and commercial support of the ongoing and planned label expansion programs
- Talon plans commercial launch in the US
  - Advanced relapsed/refractory ALL market ideal for an efficient Talon launch
  - Subsequent larger market launches may benefit from partnership and a larger commercial infrastructure

## **MENADIONE TOPICAL LOTION**

- Will seek partnerships for Phase 3 global development

# Talon Therapeutics Clinical Oncology Portfolio



 = planned

## *Talon's Near-term Value Proposition*

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