

# DepYmed Inc.

A Joint Venture of  
Cold Spring Harbor Laboratory  
&  
Ohr Pharmaceutical

# Overview

- Joint venture between Cold Spring Harbor Laboratory and Ohr Pharmaceutical (Nasdaq:OHRP)
- Portfolio of PTP1B inhibitors for oncology, diabetes, and obesity applications
- Ongoing oncology research being conducted by Professor Nicholas Tonks of CSHL who discovered the PTP1B enzyme
- Lead molecule Trodusquemine (MSI-1436) to enter Phase I single agent trial in breast cancer 1Q 2015 (safety data demonstrated in >65 patients to date)
- Patent strategy underway with latest filings in 2013
- Raising a \$2 million for Phase 1 Clinical Trial, staff, oral formulations and working capital.

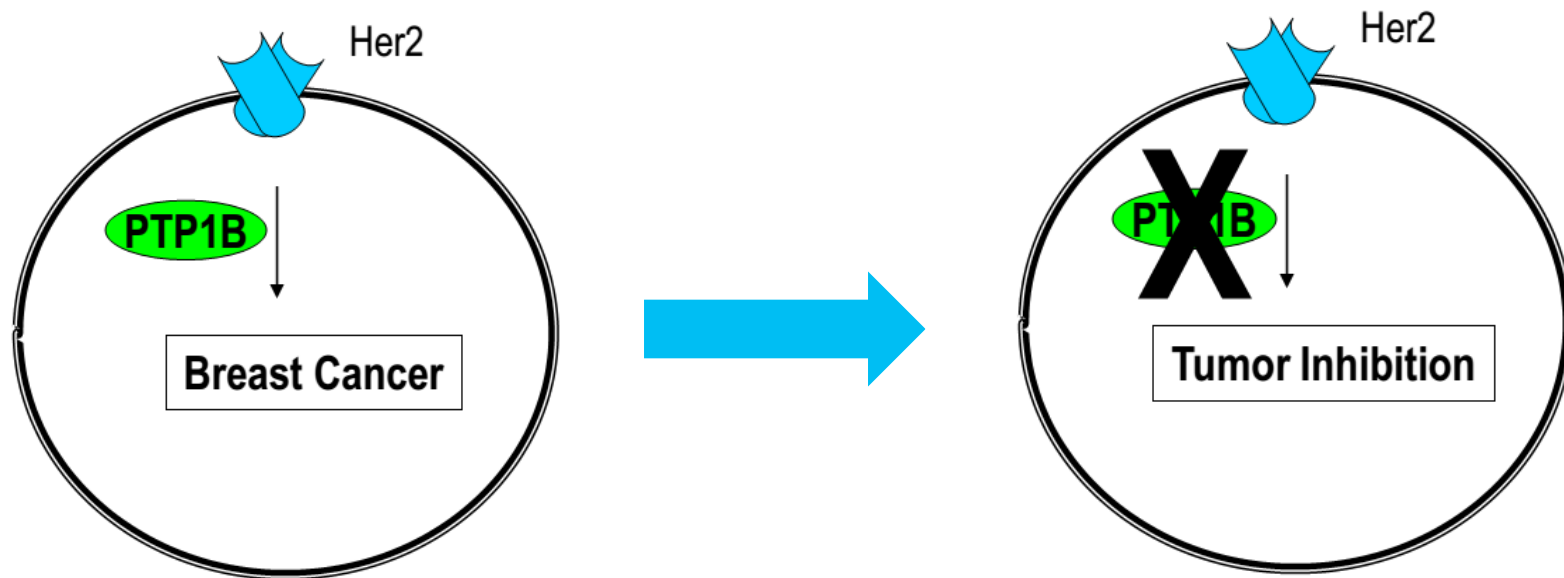
# Lead Program- Trodusquemine

- Potent and selective inhibitor of PTP1B
- Novel approach to targeting PTP1B
- PTP1B is a well recognized therapeutic target for oncology, obesity and diabetes
- Activity seen in multiple *in vivo* models
- Phase I Clinical studies conducted
  - Single and multi dose escalation studies
  - Acceptable safety profile

# Trodusquemine Inhibits Her2 Pathway Via PTP1B Inhibition

- PTP1B activates Her2 pathway
  - Accelerates tumor growth
  - Induces metastasis

- MSI-1436 inhibits Her2 pathway
  - Inhibits tumor growth
  - Inhibits metastasis



# PTP1B: an “oncogenic” function in breast cancer

- The PTP1B gene locus is frequently amplified in breast cancer and associated with poor prognosis
- Overexpression of PTP1B alone is sufficient to cause breast tumors
- Transgenic mice expressing activated forms of HER2/ErbB2 in mammary glands develop mammary tumors and lung metastases
- When these mice are crossed with PTP1B knockout animals tumor development is delayed and lung metastasis decreased

***An inhibitor of PTP1B could offer a new approach to treatment of HER2-positive breast cancer***

# Breast Cancer Market

- 300,000 new cases per year
- 60,000 to 75,000 patients will have HER2+ disease
  - HER2+ breast cancer is more aggressive and has a poorer prognosis

## Market Leaders

- Herceptin<sup>®</sup> (Genentech) \$6.5b+ in annual sales
- Tykerb<sup>®</sup> (GlaxoSmithKline) \$325mm in annual sales

# Phase I Trial in Breast Cancer

- Pre-IND meeting conducted
- IND to be submitted in Q4 2014
- Phase I single agent, open label, dose escalation trial
- Up to 21 patients
- Metastatic breast cancer
- Clinical trial at North Shore-LIJ
- Initiation expected in early 2015

# Clinical Strategy

- Conduct Phase I trial with Trodusquemine in metastatic breast cancer
  - Validate therapeutic value of inhibiting PTP1B in breast cancer
  - Determine safety of multiple ascending doses
  - Optimal dose, regimen, and patient population for future studies to be determined from clinical results



# Research and Development

Concurrent with Breast Cancer Clinical trial

- Develop oral formulations of Trodusquemine
- Further research on novel analogs with in vivo efficacy
  - More potent inhibitors of PTP1B than trodusquemine
  - Potential oral availability
- Research to initially be done at CSHL by Dr. Tonks
- Open a lab facility with 1-2 research employees
- Prof Tonks to chair SAB to advise regarding the research program

# Intellectual Property

## Trodesquamine

- Method of use
  - 2021
- Manufacture and Synthesis
  - 2021

## Novel Analogs- greater potency and orally available

- Composition of Matter
  - Latest application filed in 2013- Includes MSI-2511

Patent portfolio managed by Morgan, Lewis, and Bockius

# Capital Requirements

- Seeking \$2 million in seed equity financing (\$300k of which is already committed as a bridge into this series A round)
- Use of funds (\$1 million):
  - Phase I clinical trial \$450K
  - Key employee \$300k
  - Operating capital \$100k
  - Continued R&D CSHL \$150k
- Additional \$1mm- expansion of R&D program, dedicated lab space, 1-2 additional employees

# For more information

Teri F Willey

Director, DepYmed, Inc.

Vice President

Business Development & Technology Transfer

Cold Spring Harbor Laboratory

Direct: 516-367-5267; [twilley@cshl.edu](mailto:twilley@cshl.edu)