



International Clinical Program Update

***National Niemann-Pick Disease Foundation Conference
Chicago, Illinois --- August 2015***

Sharon H. Hrynkow, PhD

www.ctd-holdings.com

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Scientific Advisory Board



Sharon Hrynkow, Ph.D./Global Health



Caroline Hastings, M.D./Pediatric Oncology/Hempel-Hastings IND/Shares Protocol Globally

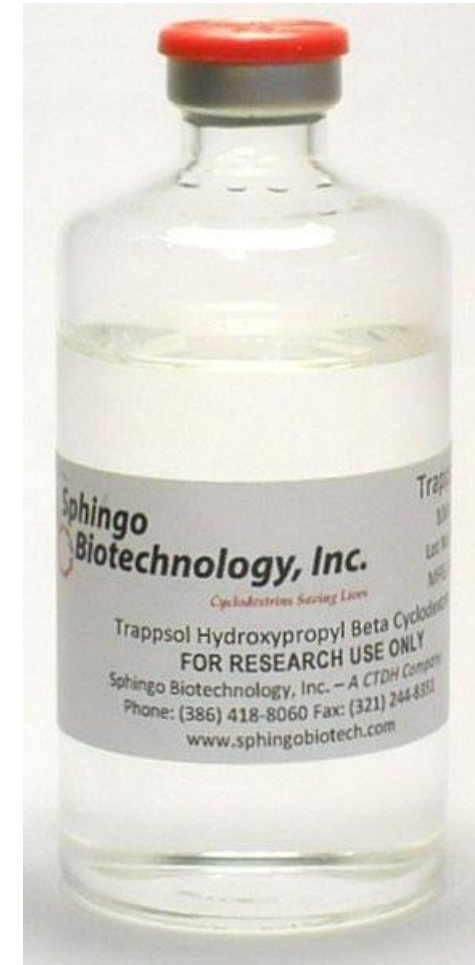


James E.K. Hildreth, M.D., Ph.D./President,
Meharry Medical College

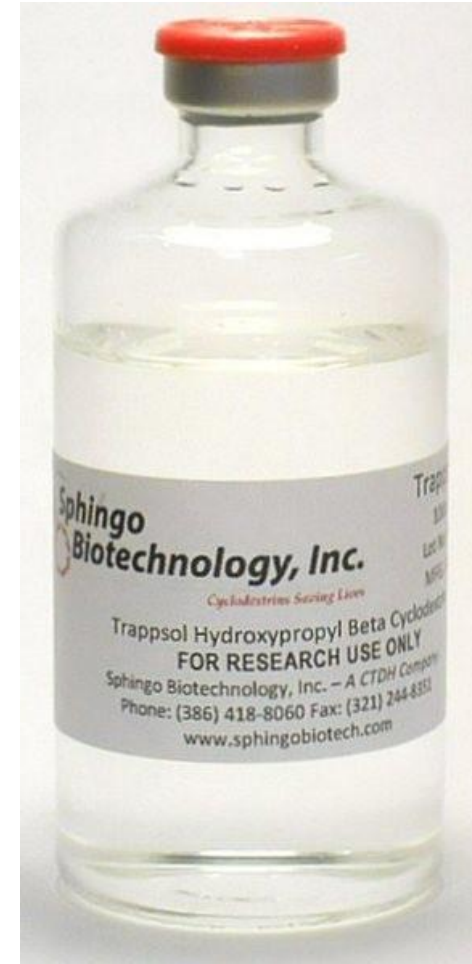


Benny Liu, M.D./Gastroenterologist/Seminal studies
on NPC in animals

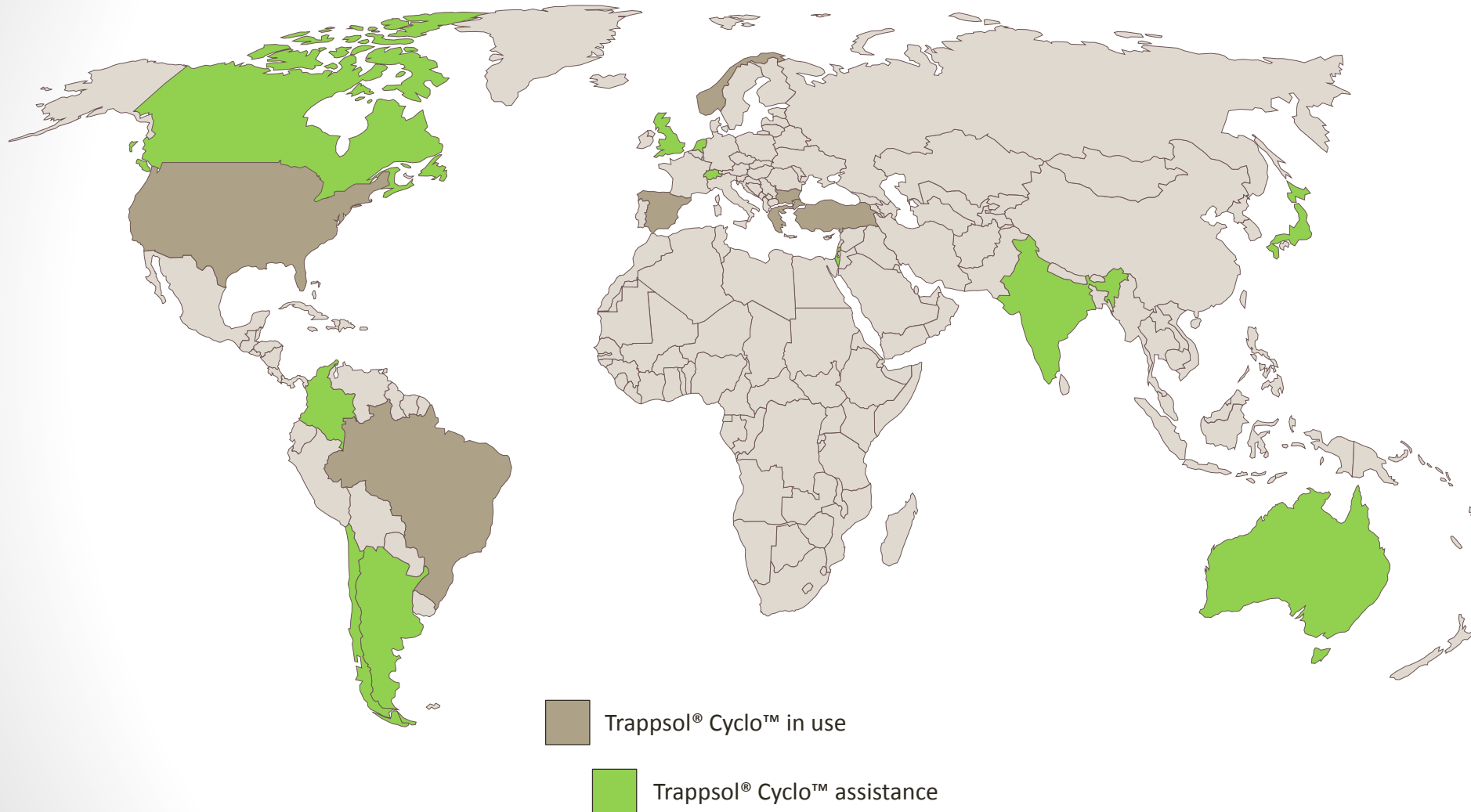
- 2008 – Hempel family contacts CTD for assistance in obtaining cyclodextrin
- 2009 – CTD's Trappsol[®] Cyclo[™] provided to Caroline Hastings for treatment of Hempel twins
- 2010 – CTD's Trappsol[®] Cyclo[™] provided to Pessoa family in Brazil
- 2011 – 2015 Compassionate use grows
- 2012 – Distribution agreement for South America established with Uno Healthcare
- 2012 – Second generation Trappsol[®] Cyclo[™] begins distribution
- 2013 – Distribution agreement for Europe established with Medical Need Europe
- 2014 – CTD launches program to develop International Clinical Program
 - Manufacturing validation of Trappsol[®] Cyclo[™] completed
- 2015 – Orphan Drug Designations transferred to CTD from Sue French (UK & Europe) and Caroline Hastings (US)
 - Type II Drug Master File accepted by U.S. FDA



- **Drug Master File; On file with FDA**
- A Drug Master File (DMF) is a submission to the FDA of information, including the Chemistry, Manufacturing and Controls (CMC) of a component of a drug product, to permit the FDA to review this information in support of a third party's submission.



Compassionate Use - Trappsol[®] Cyclo[™]



Trappsol® Cyclo™ Compassionate Use

- Hastings' IND and all others cite Trappsol® Cyclo™
- Trappsol® Cyclo™ is only cyclodextrin available in Brazil
- Frequent requests for information on Trappsol® Cyclo™
- Exclusive Distributors of Trappsol® Cyclo™
 - Medical Need Europe, Europe
 - Uno Healthcare, Brazil and Colombia

- Gaining market approval for use of Trappsol[®] Cyclo[®] in the treatment of NPC
- Initial steps: 2013 – 2015
- Established a team of experts to conduct the clinical program
 - Dr. Hrynkow, Sr. Medical Advisor, leads program for CTD
 - Accenture
 - Boyd Consultants
 - Aptus Clinical
 - KJC Statistics
 - Prism Ideas

Family and Physician Listening Circle

- Information sharing for Scientists, Parents, and Physicians
- Brings the voices of families and physicians into the clinical program development process
- Operational throughout, and continuing after, CTD's International Clinical Program
- Learning, sharing – CTD listens to those most affected

Family and Physician Listening Circle



Sue French
Co-Chair – UK/Parent



Caroline Hastings, M.D.
Co-Chair – US/Physician



David French, – UK/Parent



Robin Lachmann, M.D.
UK/Physician



Begoña Arias, M.D.
Spain/Physician



Camilo Vieira, M.D. – Brazil/Physician
www.ctd-holdings.com



Roberto and Renata Pessoa
Brazil/Parents

- We cordially invite you to participate in our Family and Physicians Listening Circle

- CONTACT INFORMATION

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- WEBSITE:

- www.ctdlistens.com

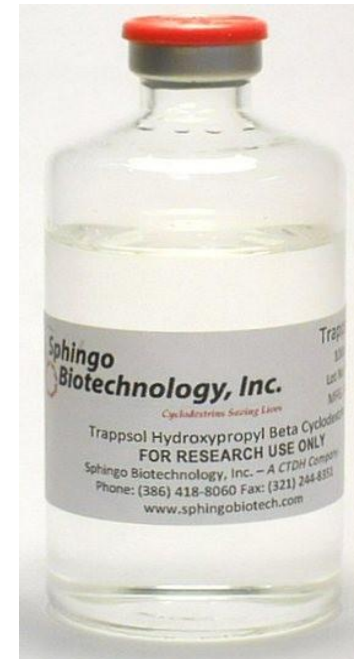


Scott Fine, Executive Chairman

- Purpose: Collect and assemble a library of adaptations of the original Hastings/Hempel IND protocol to identify improvements of delivering Trappsol[®] Cyclo[™] and other cyclodextrins

CTD Holding's Expanded Access Program

- Program will give \$1 Million of **Trappsol[®] Cyclo[™]** to families who struggle to cover treatment costs.
- Now available to patients and physicians who have received regulatory authorization.



Thank you



For more information,
please contact us at:

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