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- Orphan drug development for Niemann-Pick Disease type C
- **Launch CTD's clinical trials of Trappsol® Cyclo™ in Europe and the United States!**

Today's Presenters

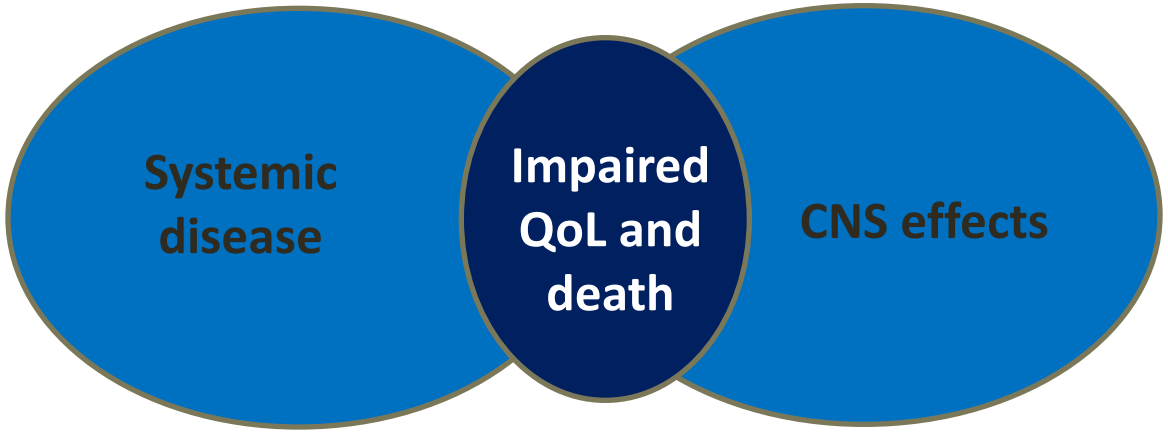
- N. Scott Fine, CEO, CTD
- Sharon H. Hrynkow, Ph.D., CTD
- Alan Boyd, MD
- Caroline Hastings, MD, UCSF - CHORI

- Overview of NPC
- Summarize compassionate use data from intravenous (IV) use of Trappsol® Cyclo™
- Presentation of IV Trappsol® Cyclo™ clinical trials
  - Describe phase I/II Clinical Trial – Europe
  - Describe phase I Clinical Trial – United States
- Next Steps
- Q/A Session

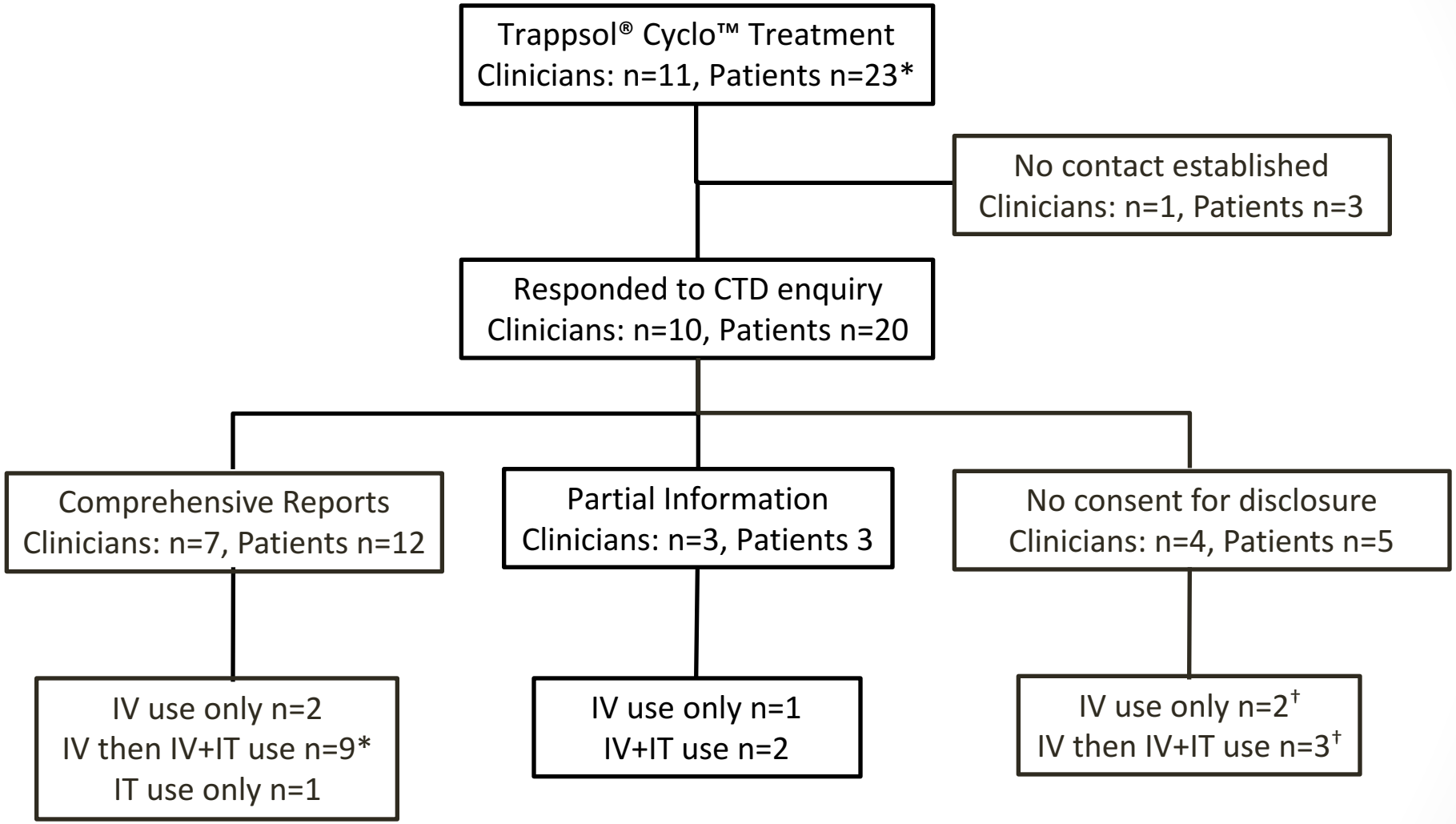
NPC has Multiple Manifestations

- Systemic
  - Liver disease and failure
  - Hepatomegaly
  - Splenomegaly
  - Respiratory dysfunction
- CNS
  - Impaired motor function
  - Behavioral disturbance
  - Loss of cognition
  - Vertical Supra-nuclear Gaze Palsy (VSGP)

No two sufferers are the same: No single outcome applies to all



Clinical Experience with Trappsol® Cyclo™



† Unvalidated/anecdotal reports
* Includes one patient who received only Kleptose® (Janssen R&D LLC)

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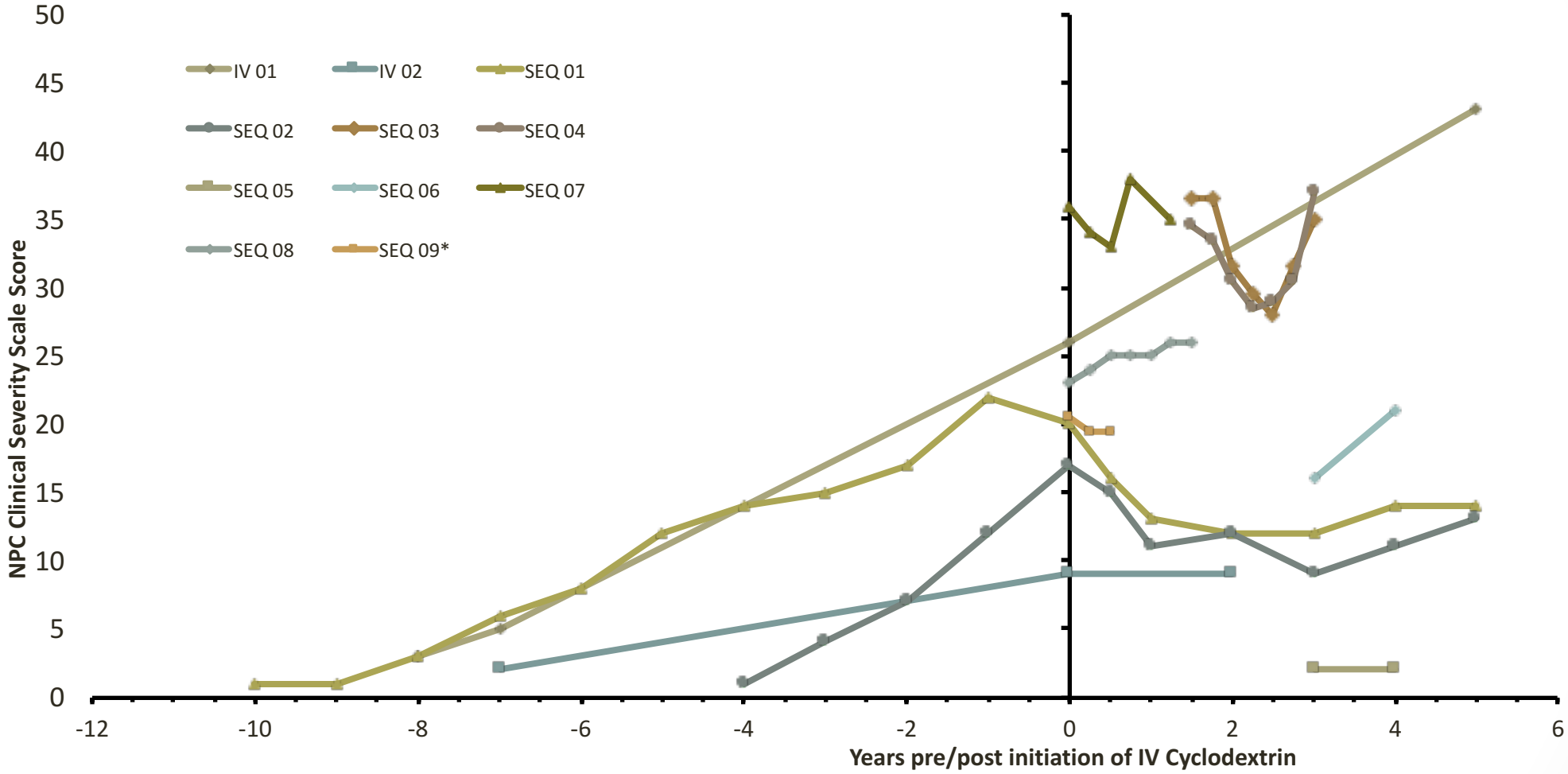
NPC Severity Scores: Pre and Post Treatment



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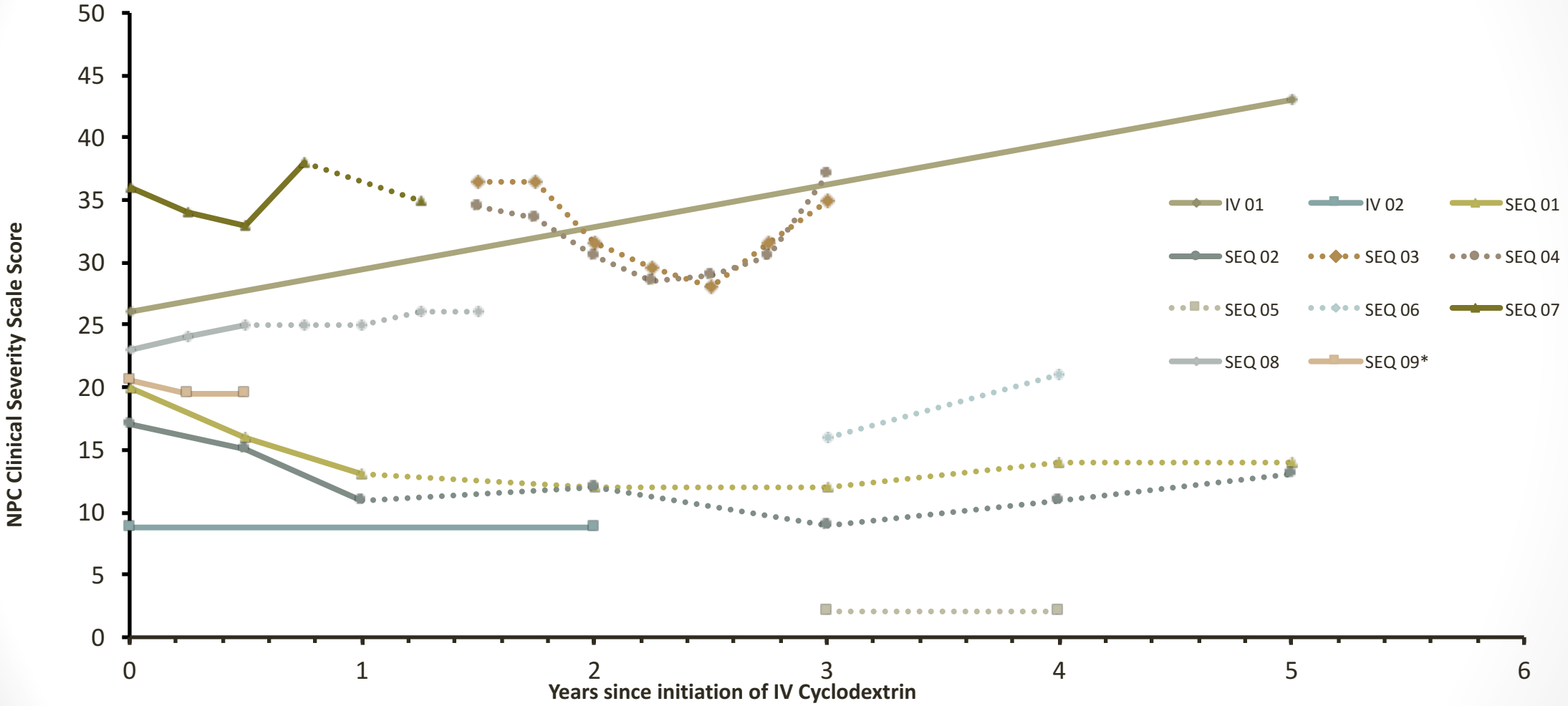
Post Treatment NPC Severity Scale



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* This patient received only Kleptose® (Janssen R&D LLC)

Adverse Events Associated with Treatment

AEs associated with administration	AEs recognized as features of NPC	Other AEs of interest
Rash Generalized rash (trunk, elbow) Tremor/chills/vomiting/fever Headache Nausea Stomach pain	Seizures Pneumonia Thrombocytopenia Viral Illnesses Viral Syndrome	Port-a-Cath Infection Removal of Ommaya Reservoir Post-operative delayed Parenchymal hemorrhage Meningitis

Compassionate Use Program with IV Trappsol® Cyclo™

- IV HP-β-CD has been administered to > 20 patients worldwide
  - Favorable tolerability profile amongst patient treated to date
  - Safety profile enabling physicians to continue treatment > 6 years
- Individual patients exhibit objective Systemic/CNS responses
  - Reduction in hepatic size and improvement in transaminases
  - Restoration of language skills
  - Resolution of interstitial lung disease
  - Improvement in fine and gross motor skills
  - Improvement in quality of life
- Clinical data has allowed treating physicians to continue to use HP-β-CD compassionately for over 6 years in some cases

Phase I/II Study - Europe

- Application to MHRA made August 2016 for UK sites
- Salford Royal Hospital NHS Foundation Trust:
  - Dr. Reena Sharma, Coordinating Principal Investigator
- University College London:
  - Dr. Robin Lachmann
- Study looks to further evaluate in a Clinical setting the safety and pharmacokinetics of IV Trappsol® Cyclo™.
  - Additionally evaluating the pharmacodynamic effects of treatment upon markers of cholesterol metabolism and NPC disease
- 4 – 5 European Sites

Phase I/II Study - Europe

- Double-blinded, randomized parallel group studies
- 12 patients – ages 2 through adulthood
- 3 Doses: 1,500mg/kg; 2,000 mg/kg; 2,500 mg/kg
- Infusions over 8 hours every two weeks
- Treatment period 48 weeks

Phase I/II Study- Europe

Outcome Measures

- Plasma and CSF concentrations of Trappsol® Cyclo™ following IV Administration
- Serum cholesterol markers
- Global impression of disease, quality of life scores
- Change in NIH Severity Scores
- Changes in hepatic and splenic morphology

Phase I Study – United States

- Application to FDA made August 2016 for US site
- UCSF-CHORI:
  - Dr. Caroline Hastings, Principal Investigator
  - Dr. Benny Liu, Co-Investigator

Study will further evaluate

- Safety and tolerability of single and multiple-doses of IV Trappsol® Cyclo™
- Pharmacokinetics of cyclodextrin distribution
- Pharmacologic effects of dosing on biomarkers of NPC Disease

Phase I Study – United States

- Double-blinded, randomized, parallel group study
- 6 patients, 18 years old and older
- 3 doses: 1,500 mg/kg; 2,000 mg/kg; 2,500 mg/kg
- Infusions over 8 hours every two weeks
- Treatment period 14 weeks

Phase I Study – United States

Outcome measures

- Plasma and CSF concentrations of Trappsol® Cyclo™ following IV administration
- Serum cholesterol markers, CSF markers
- Changes in NIH Severity Score
- Changes in hepatic and splenic morphology
- Changes in hepatic cholesterol

Next Steps

- Preparing applications for other countries in Europe

Further Information Available

- ClinicalTrials.gov (to be uploaded soon)
- CTD Holdings will provide regular updates

Special Thanks

To all the patients, families and treating physicians who have worked with CTD Holdings, allowing us to move one step closer to helping find an effective treatment for this devastating disease.