6714 NW 16th Street, Suite B
Gainesville, FL 32653-3975
Phone: (386) 418-8060
Fax: (321) 244-8351
info@cyclotherapeutics.com

13 April 2021

Dear NPC Family and Friends,

Following on from the positive results from our Phase I and Phase I/II trials, we are excited to share news that our Phase III pivotal trial using Trappsol® Cyclo™ will soon be enrolling, first in the United States then in other countries. This will be a placebo-controlled trial conducted in 9 countries and in 23 sites. Our drug is an investigational hydroxypropyl beta cyclodextrin (HPBCD) administered intravenously. Infusions will be 6.5 hours every two weeks. We will share additional information about the trial protocol with this community as soon as the posting to ClinicalTrials.gov becomes available.

Although the full inclusion/exclusion criteria have not been posted yet on ClinicalTrials.gov, we thought it would be important to notify this community now that, for scientific reasons, one of the exclusion criteria for the pivotal study is having been treated previously with any HPBCD via any route of administration (including intrathecal).

Cyclo Therapeutics, Inc. will make its investigational Trappsol® Cyclo™ product available for intravenous use under individual investigator INDs (iIND) for those patients who are not eligible to participate in our pivotal trial because of their prior or current use of investigational HPBCD products, including those distributed by other providers, including J&J and Mallinckrodt. Cyclo Therapeutics plans to provide Trappsol® Cyclo™ to eligible participants at no cost while iINDs are in effect. Cyclo Therapeutics does not plan to provide any other costs of treatment outside of supplying the drug product. All individual iINDs would be handled in a manner consistent with the company's new policy for use of the drug for expanded access.

We plan to begin support of iINDs in the manner discussed above starting in August 2021. We can assure the community that in no manner will this deter the Company from fully enrolling the Pivotal study nor will it delay those timelines for seeking market approval of Trappsol® Cyclo™ as quickly as possible so it can become accessible to all patients. With that, initially there will be limitations on the number of iINDs the company can support. The company will assess this on a continuing basis. NPC patients or their physicians should direct inquiries to Jannine Green at Jannine.Green@aptusclinical.com.

Our commitment to the NPC community has been steady and sure, and it will continue during the upcoming Phase III trial and the iINDs that will be put in place to support those who previously have received HPBCD and are not eligible for the trial.

We thank all of the NPC patients and their families and caregivers who have participated in our prior trials and extension study, and we look forward to next steps as we work to bring our investigational product, Trappsol® Cylco ™, to market approval for the benefit of all.

Sincerely,

Gerald F. Cox, MD, PhD
Chief Medical Officer

Sharon H. Hrynkow, PhD
Chief Scientific Officer &
Senior VP for Medical Affairs