

Joint Exhibit 13

Plan for completion of DCPA developmental thyroid studies:

1) DCPA (Chlorthal Dimethyl): Dose Range Finding Pre and Post Natal Developmental Thyroid Study in Sprague Dawley Rats by Oral Administration (Envigo Study: BDG0204).

We need to rerun Phase I of this study because the rat Luminex immunofluorescence assay which was used at the time the study was performed was not able to detect quantifiable levels of T4 and T3 in plasma from rat fetuses: and these are critical endpoints on the study. The assays were validated to the lowest possible limits of detection taking into account the limited available scientific literature on this subject.

As Phases II and III of the study were scheduled to start after Phase I, we acted quickly and those phases were not performed and will be performed once the rerun of Phase I has been completed. Detection of T4 and T3 and TSH in the dams and TSH in the fetuses was successful using the Luminex assay.

In order to overcome this challenge Envigo has now developed an LC-MS MS assay with much lower detection limits (pg/ml) which has been proven to detect T4 and T3 in Control fetuses. The assay, which detects T4 and T3 simultaneously, has been satisfactorily validated for accuracy and precision and we also have 1 month frozen stability data and are currently investigating stability for longer periods of storage. The Luminex assay is also currently being validated for detection of TSH in serum so that all 3 hormones are assayed in the same medium, serum.

The rerun of Phase I was authorised by UK Home Office and the in life phase and thyroid hormone assays have been successfully completed as follows:

Animal arrival 22 February 2017.

Start of dosing on Day 6 after mating: 6 March 2017

Completion of in life phase: 26 March 2017

Thyroid hormone assay results issued: 19 May 2017

The results from Phase I which are currently being reviewed by US EPA will aid in the selection of doses for Phases II and III and also identify the optimal time point for assessment of effects on thyroid hormone levels (2 or 24 hours after administration of the final dose).

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Current status of validation of TSH assay in serum

On Phase I of the study, T4/T3 assays were in serum; TSH assay was performed in plasma not serum, as serum validation not yet completed due to technical problems possibly related to Millipore kit faults (kit faults not accepted by Millipore); current status of validation of TSH assay in serum is as follows:

The following assessments have been completed as part of the validation of the measurement of TSH in serum;

- Matrix screen,
 - QC preparation and establishment,
 - 8 and 24 hour bench top stability,
 - Freeze thaw stability (5 freeze thaw cycles),
 - Parallelism,
 - Comparison of measured TSH levels in plasma and serum collected from the same individuals.
- The long term stability assessment is ongoing.

An interim report (with all data 100% QC checked) will be available on 10 November 2017 and is expected to be submitted to EPA on 13 November 2017.

Phases II and III – schedule

Testing is currently on hold while US EPA Scientists review the results from Phase I of the study, the PTU positive control study (XJ05HV) and T4, T3 and TSH assays validation data.

Testing will proceed as soon as possible following authorisation to proceed is received from US EPA.

The results will determine the doses for the definitive main pre and post natal developmental thyroid study (BDG0202) and the precise design and size of the study (i.e. if direct dosing of pups required) and if it is how many groups of pups will need to be dosed.

**2) DCPA (Chlorthal Dimethyl): Definitive Main Pre and Post Natal
Developmental Thyroid Study in CD Rats by Oral Administration (Envigo
Study:BDG0202)**

Testing will proceed as soon as possible once Phases II and III of the Dose range finding study (BDG0204) have been completed and all of the results from that study have been reviewed by US EPA and authorisation to proceed is received.

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