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Cyclopharm: Technegas US Trial Meets Endpoints Early

Cyclopharm says its 240-patient, phase III Technegas lung imaging trial has been halted after data from 200 patients met the primary efficacy endpoint.

Cyclopharm said that an independent data monitoring efficacy committee, requested by the US Food and Drug Administration as part of its assessment process, reviewed data sets of groups of 40 patients imaged with xenon-133 and then with its Technegas and unanimously recommended that the trial had successfully met its endpoints and should be stopped.

In 2016, Cyclopharm said the FDA had approved a special protocol assessment for a phase III trial comparing Technegas with xenon-133 (BD: Nov 23, 2016).

Today, Cyclopharm managing-director James McBrayer told Biotech Daily that in December 2017, the FDA approved diethylene-triamine-penta-acetate, or DTPA, against which the company had extensive comparative data.

Mr McBrayer said that decision allowed Cyclopharm to move to a comparative 505(b)(2) FDA pathway.

Mr McBrayer said he had expected that approval process to take until at least April 2021, but with the early closing of the trial the company had notified the FDA and expected to have a teleconference with the regulator “likely within the next couple of weeks”.

Mr McBrayer said he was “very pleased” to be able to announce successful trial results.

In a media release to the ASX, Cyclopharm said that due to the Covid-19 pandemic, patient recruitment had slowed significantly, but given that 85 percent of the target number of patients have been recruited, the FDA determined that it would be helpful, in its review of the Technegas new drug application, to understand the substance of the CYC-009 trial efficacy data.

The company said that to maintain the integrity of the prospective, non-inferiority trial by keeping the data blinded to the company, the FDA recommended an independent data monitoring committee conduct an interim analysis focused on efficacy.

Cyclopharm company said it was awaiting an FDA question and answer response and would inspect a manufacturing site by April 2021, with Technegas sales expected in the US in 2021.

Mr McBrayer said the company was “in a position to move to final approval for sales of Technegas in the US ... this will be a great milestone for the company”.

Cyclopharm was up 18.5 cents or 13.2 percent to \$1.585.