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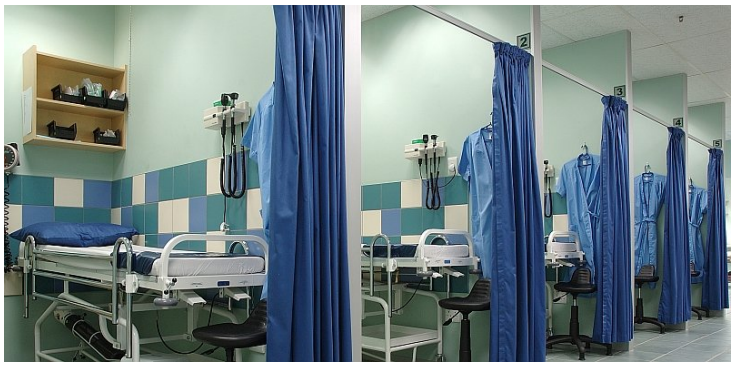

Singapore: Clinuvel Pharmaceuticals commenced its confirmatory phase III clinical trial of its novel drug SCENESSE (afamelanotide) in the US, among patients who have been diagnosed with the rare, light intolerance disorder, erythropoietic protoporphyria (EPP).

The six-month, randomised, multicenter, double-blind, placebo-controlled study (CUV039) will recruit up to 100 adult EPP patients in seven specialist centers, including Alabama, California, Michigan, New York, North Carolina, Texas and Utah. Presently there is no known effective treatment for EPP, which affects approximately 10,000 people globally.

Results were recently announced from pivotal phase II US and phase III EU trials (CUV029 and CUV030). These showed that SCENESSE could reduce the severity of EPP symptoms and enable patients to lead more normal lives. A marked improvement in quality of life was also reported. Clinuvel submitted a marketing authorisation application for SCENESSE for EPP with the European Medicines Agency. The US FDA allowed the trial to proceed during the earlier part of May. SCENESSE has been granted orphan drug status in the US and Europe.

Dr Hank Agersborg, CSO, Clinuvel, said that, "This phase III trial protocol has been designed in close consultation with the FDA. We anticipate that the results will confirm the safety and efficacy profiles seen in previous trials and enable us to file a new drug application (NDA) for the drug in the US."

"Clinuvel is working with all study sites in order to facilitate recruitment of patients during early summer. This period of the year is a particular burden to EPP patients, who are prone to suffer severe skin reactions when exposed to sunlight," Dr Agersborg said.