International Patent Reviews Releases Study on Clinuvel Pharmaceuticals' SCENESSE® patents

September 20 , 2022 – Dallas, TX. Today, International Patent Reviews, LLC (IPR) released a study on Clinuvel Pharmaceuticals' U.S. Patent Nos. 8,334,265 and 10,076,555 directed to technology around their Scenesse® (afamelanotide) implant for the treatment of erythropoietic protoporphyria (EPP). A copy of the study can be found at IPR's website.

IPR is focused on identifying patents filed by companies that do not represent novel inventions suitable for protection and has developed a comprehensive and multifaceted process for identifying those filings that take advantage of the system. IPR generates some of the most comprehensive studies available in the industry, but that work only improves with further public scrutiny and crowdsourcing of the technical information.

The '265 patent for Scenesse® was issued in 2012 but has a priority date stretching back to August 2006. According to Dr. R. L. Smith of IPR, the primary problem with these patents is that hardly any of the prior art available to use during prosecution was considered when the patents were initially examined. Dr. Smith says: "This is one of the worst cases we have seen where ample prior art was available for review, but little to none of it was used to question the novelty or obviousness of these patents." Dr Smith goes on to say that when IPR performed a search of the relevant art "we found almost 800 documents relating to the technology before August 2006, some going back as to the early 1980s. But only one United States patent document, two foreign patent documents and two scientific journal articles were cited on the face of the '265 patent. That floored us."

It is estimated that EPP affects about 30,000 – 60,000 individuals within the United States alone. The price of a single Scenesse® implant is currently around $50,000 per implant with recommended dosing suggested at one implant administered subcutaneously every two months with a maximum number of three implants within 12 months. IPR is releasing this study in hopes that interested parties, competitive pharmaceutical companies, and other stake holders will use this freely available information to improve upon and help bring down the cost of this drug for patients, hospitals, and caregivers.