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Clinuvel gets positive results in Scenesse trial

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Clinuvel gets positive results in phase IIa Scenesse trial

Singapore: Australian company Clinuvel Pharmaceuticals reported successful, statistically significant results from its US phase IIa pilot study (CUV102) of the novel drug Scenesse (afamelanotide 16mg implant) in the common pigmentation disorder vitiligo. These results show that Scenesse in combination with narrowband UVB therapy significantly improves repigmentation of depigmented lesions in vitiligo patients compared to NB-UVB as a monotherapy.

Vitiligo is a common skin disorder, affecting approximately 45 million people, in which particular pigment producing cells of the skin (melanocytes) appear to become dysfunctional. As a result, lighter depigmented patches of skin (lesions) appear in different parts of the body due the loss of melanin (pigment). Vitiligo therapy is primarily intended to arrest depigmentation and to stimulate repigmentation of affected skin as a secondary action. There is no known cure for vitiligo. The current standard of care is treatment with NB-UVB, a controlled light therapy given in two to three sessions per week over the course of 12 to 18 months. The response rate to NB-UVB is low and repigmentation is incomplete, with combination therapies often employed in an attempt to enhance repigmentation.

Scenesse is a first-in-class drug that activates melanin in skin by mimicking the body's natural melanin production process. Developments in Clinuvel's clinical program, and broader progress in the field of human pigmentation over the past three years, have led to widespread support from the medical and patient communities to trial Scenesse as a repigmentary agent in vitiligo.

"I think this is an exciting, major advancement for vitiligo, a disease for which we do not have adequate effective treatments," said Dr Mark Lebwohl, professor and chair of Dermatology at Mount Sinai Hospital in New York and an investigator on the CUV102 study, said. "We were thrilled with the speed at which the pigment returned."

"The clinical significance of these observations from CUV102 is most promising. The proposed combination therapy with SCENESSEÃ?Â® enables a faster and more complete repigmentation for people with vitiligo," said Dr Dennis Wright, acting

chief scientific officer, Clinuvel. "This has the potential to substantially reduce the current regimen of 18 months of NB-UVB treatment thrice per week, while the new treatment achieves a better outcome for patients, enabling them a life without being stigmatised."

Pending regulatory filings and approvals, Clinuvel considers advancing its clinical program for vitiligo to a phase IIb study, likely to be conducted first in Europe and Asia, with the goal of making Scenesse available to vitiligo patients as a repigmentation therapy.