

Foresee announces submission of NDA for FDA approval of LMIS 50 mg

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Taiwan and US-based biopharmaceutical company, Foresee Pharmaceuticals Co., Ltd. (Foresee), recently announced that it has submitted to the U.S. Food and Drug Administration a 505(b)(2) new drug application for Camcevi™ 42mg (FP-001 LMIS 50mg), a ready-to-use 6-month depot formulation of leuprolide mesylate. The application seeks approval for the use of this product for the palliative treatment of advanced prostate cancer.

This NDA submission is supported by a previously communicated successful Phase 3 study in 137 Advanced Prostate Carcinoma patients, where treatment with LMIS 50 mg injection every 6 months was demonstrated to be effective, safe and well-tolerated.

According to Dr. Ben Chien, Founder, and Chairman of Foresee, "In the NDA submission in 2019, FDA suggested that additional device design verification data on the combination product be provided. Since then, with tireless efforts and commitment from the Foresee team and collaborators, as well as the continued support of our investors, we have undertaken diligent preparation for the requested information. We are confident in the resubmission of the NDA."