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

Foresee Pharmaceuticals Co., Ltd. (6576.TWO) ("Foresee"), recently announced that it has submitted to the U.S. Food and Drug Administration a 505(b)(2) New Drug Application for LMIS 50 mg, 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.

"This is a proud day for Foresee, as our NDA submission represents the culmination of years of dedication and hard work from of our team and its close collaborators and great efforts from our investigators, service providers, and patients," said Dr. Ben Chien, Founder and Executive Chairman of Foresee. "As we make this important step towards a potential regulatory approval in the US, our main near-term objective is to establish a partnership with a strong commercial player that will successfully launch our FP-001/LMIS franchise in the US."

Foresee is a Taiwan and US-based biopharmaceutical company listed on the Taipei Exchange. Foresee's R&D efforts are focused in two key areas, namely its unique stabilized injectable formulation (SIF) depot delivery technology and derived drug products targeting specialty markets, and its transformative preclinical and clinical

first-in-class NCE programs targeting disease areas with high unmet needs.

Foresee's product portfolio includes late stage and early stage programs such as FP-001, 6-month and 3-month, stable, ready-to-use versions of leuprolide mesylate depot for injection, for which regulatory submissions are planned in 2019; FP-025, a highly selective oral MMP-12 inhibitor targeting inflammatory and fibrotic diseases, currently in a Phase 2 proof-of-concept study; FP-045, a highly selective oral small molecule allosteric activator of ALDH2, a mitochondrial enzyme, for which a Phase 1b/2 study is currently in planning (Fanconi Anemia; mitochondrial-mediated diseases); and FP-004, a novel, subcutaneously injectable depot product in development for the treatment of opioid use disorder and pain.

See: www.foreseepharma.com

Source: Foresee Pharmaceuticals Co., Ltd.
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