Camcevi® (leuprolide) – New drug approval

- On May 26, 2021, Foresee Pharmaceuticals announced the FDA approval of Camcevi (leuprolide), for the treatment of adult patients with advanced prostate cancer.

- Camcevi is a ready-to-use 6-month subcutaneous (SC) depot formulation of leuprolide mesylate.

- Several other injectable formulations of leuprolide are currently approved for palliative treatment of prostate cancer, including: generic leuprolide acetate, Lupron Depot®, and Eligard®.

- The efficacy of Camcevi was established in an open label, single arm study in patients with advanced prostate carcinoma. Camcevi was administered SC at a dose of 42 mg initially on day 0 and on week 24. The major efficacy outcome measure was medical castration rate, defined as achieving and maintaining serum testosterone suppression to ≤ 50 ng/dL by week 4 through week 48 of treatment.

    — Following the first injection of Camcevi, serum testosterone levels were suppressed to ≤ 50 ng/dL by week 4 (+/-7 days) in 98.5% of the patients; and from week 4 through week 48 in 97.0% of patients (95% CI: 92.2, 98.9) estimated using the Kaplan-Meier method.
    — The percentage of patients with testosterone suppression to ≤ 20 ng/dL was 69.3% on day 28.

- Warnings and precautions for Camcevi include tumor flare; hyperglycemia and diabetes; cardiovascular diseases; QT/QTc prolongation; convulsions; laboratory tests; and embryo-fetal toxicity.

- The most common adverse reactions (≥ 10%) with Camcevi use were hot flush, hypertension, injection site reactions, upper respiratory tract infections, musculoskeletal pain, fatigue, and pain in extremity.

- The recommended dose of Camcevi is 42 mg administered SC once every 6 months.

    — Camcevi must be administered by a healthcare provider.

- Camcevi is exclusively licensed to Accord BioPharma and the launch plans are pending. Camcevi will be available as a 42 mg injectable emulsion.