FDA Approves 3-Month Leuprolide Mesylate 21 mg Formulation for Advanced Prostate Cancer

Key Takeaways

- Leuprolide mesylate 21 mg, a long-acting injectable, is FDA-approved for advanced prostate cancer, administered every three months.
- Advanced prostate cancer often spreads to bones and lymph nodes, causing symptoms like fatigue and bone pain.
- Leuprolide mesylate reduces testosterone levels, inhibiting tumor growth, with 97.9% of patients achieving castrate-level testosterone suppression in a phase 3 study.
- Common mild to moderate adverse events include hot flushing and hypertension, confirming the treatment's safety and efficacy.

The FDA has approved a ready-to-use long-acting injectable formulation that is administered every 3 months as a treatment for advanced prostate cancer.

The FDA approved the new drug application (NDA) for leuprolide mesylate 21 mg (Camcevi ETM; Foresee Pharmaceuticals), a ready-to-use long-acting injectable (LAI) formulation that is administered every 3 months as a treatment for advanced prostate cancer. Leuprolide mesylate 21 mg now joins the 6-month, 42-mg formulation of leuprolide mesylate as an FDA-approved treatment for adults with advanced prostate cancer, which was previously granted approval in 2021.[1]

Signs and Symptoms of Advanced Prostate Cancer

Advanced prostate cancer is cancer that has spread from the prostate to other parts of the body that develops when the prostate cancer cells move through the bloodstream or lymphatic system. While prostate cancer can spread to any part of the body, it commonly presents itself in the bones and lymph nodes, which are found in the pelvic area near the prostate. Symptoms of prostate cancer include fatigue, bone pain, and problems urinating; however, they can vary depending on the area the cancer has spread to.[2]

Treatments for advanced prostate cancer include hormone therapy, chemotherapy with hormone therapy, and clinical trials. These treatments can only manage patient symptoms and are not curable methods.[2]

As an androgen deprivation therapy (ADT), leuprolide mesylate could provide treatment for patients with advanced prostate cancer by preventing the testicles from making testosterone, making it harder for the tumor to grow. About 4 weeks after treatment with the 42-mg formulation of leuprolide mesylate, the testosterone levels are expected to drop to very low levels and remain low for a duration of 6 months.[3]

Clinical Trial Data for 21 mg Leuprolide Mesylate

The approval of the 3-month 21-mg formulation of leuprolide mesylate was based on positive results from the global, open-label, single-arm phase 3 study (NCT03261999) that evaluated the safety, efficacy, and pharmacokinetic behavior of leuprolide mesylate in adults with prostate cancer that received 2 injections, 3 months apart.[1,4]

The study included 144 patients who received a minimum of 1 dose of a 25-mg leuprolide injection. Among these patients, 132 received a second dose of the drug 12 weeks following the first injection. Overall, the study met its primary end point with 97.9% of patients achieving a serum testosterone concentration suppression to castrate levels from day 28 to day 168.[1,4,5]

The most common adverse events, including hot flushing, hypertension, increased body weight, and injection site hemorrhage, were all of mild or moderate intensity. The study authors noted that despite the adverse events, 3-month treatment with leuprolide mesylate was safe and effective.[1,5]

"The approval of [leuprolide mesylate 21 mg] is a significant step toward our mission in improving the standard of care and the lives of patients," Ben Chien, founder, chairman, and CEO of Foresee, said in a news release. "It is also a key step in our efforts to build Foresee as a profitable and growing business. We want to thank the team and all stakeholders for their tireless work, which has made this approval possible.1

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