FDA clears a promising new therapy for advanced prostate cancer patients. After a phase III trial at UCH, described in MD Thomas Flaig’s *New England Journal of Medicine* article last week, patients across the U.S. can now use a promising new hormone therapy.

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Patients nationwide with advanced prostate cancer now have access to a promising new hormone therapy, abiraterone acetate, that extends lives with minimal side effects. It’s a drug patients at UCH have been taking quite some time.

That’s thanks to Thomas W. Flaig, MD, and colleagues, who have for years been enrolling patients and caring for them in clinical trials that led to the U.S. Food and Drug Administration’s late-April approval of abiraterone.

Flaig, medical oncologist at the University of Colorado Hospital’s Tony Grampsas Urologic Oncology Clinic and assistant professor at the School of Medicine, was a co-author of the May 26 *New England Journal of Medicine* article that reported the results of the phase III clinical trial that led to the FDA approval.

The multi-center trial of 1,195 participants looked at the effectiveness of a combination of abiraterone and prednisone in treating patients with late-stage prostate cancer that had spread to bones and/or lymph nodes. The patients had received prior chemotherapy. At UCH, more than 15 patients participated.

When the trial started, there were no treatments that clearly prolonged survival in this late phase of prostate cancer. The patients were randomized at a 2:1 ratio, with 797 receiving abiraterone plus prednisone and 398 receiving a placebo plus prednisone each day. Their treatment continued until or unless the cancer progressed, they had unfavorable reactions, a new treatment was initiated or the patient withdrew from the trial.

**Striking results.** During the trial, when researchers assessed interim results, they found a striking result. The patients on abiraterone lived an average of four months longer – 14.8 months versus 10.9 months – than the control group. In addition, abiraterone reduced the prostate-specific antigen (PSA) blood levels by at least half in 29 percent of patients, versus just six percent in the control group. The study’s leaders then unblinded the study, and allowed all participants access to the drug.

“These patients with a very advanced phase of prostate cancer showed a substantial improvement in survival from the use of this drug – more benefit than from taking chemotherapy every three weeks and losing their hair,” Flaig said.

Abiraterone’s light touch is one of its most appealing traits, Flaig said. It extends lives without most of the side effects observed with traditional chemotherapy. It’s also a pill, so there are no injections.

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“What I love about it is it’s extraordinarily well tolerated,” he said. “Many patients can’t tell they’re on it.”

**Testosterone scrubber.** The drug works by erasing the last vestiges of a patient’s testosterone, which researchers have long known to be a key fuel for prostate cancer growth, explained E. David Crawford, MD, head of the School of Medicine’s section of Urologic Oncology.

While the testes are the primary producers of testosterone, the adrenal gland also chips in, making eradication difficult, but no longer impossible.

“With abiraterone, it’s testosterone annihilation. It blocks testosterone production from every source, including the cancer itself,” Crawford explained. “When you do that, even with men that fail in normal therapies, you can improve the outcome. It’s a game-changer,” he concluded.

The game’s not over. Flaig and colleagues at the School of Medicine and elsewhere are investigating abiraterone’s effectiveness in patients with less advanced forms of the disease. Patients at UCH are also enrolled in a similar study examining the effects of abiraterone with prednisone before the use of chemotherapy.

Abiraterone is the latest of several emerging weapons against the prostate cancer, many of which CU School of Medicine researchers at UCH have been instrumental in advancing.

Among the others are three-dimensional prostate mapping and tumor ablation; a new chemotherapy; and the drug Provenge, which trains the immune system to go after prostate cancer cells. Each represents another step down the long road to taming prostate cancer from a killer of 32,000 American men each year into a chronic disease like diabetes, as Crawford put it.

“The good news for prostate cancer care is that we’re entering an optimistic time with more effective and better tolerated medical therapy,” Flaig said.