

Takeda terminates prostate cancer drug trial

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Singapore: Takeda Pharmaceutical has terminated the development program for orteronel (TAK-700) for prostate cancer following the results of two Phase 3 clinical trials in metastatic, castration resistant prostate cancer (mCRPC).

The studies revealed that while orteronel plus prednisone could extend the time patients lived before their cancer progressed, it did not extend overall survival in these patients, therefore, not demonstrating a clinical profile sufficient to move forward in mCRPC.

On May 14, 2014, Takeda announced results from ELM-PC4, a pivotal, international, double blind, randomized Phase 3 trial in men with mCRPC who had not received chemotherapy, which showed that orteronel plus prednisone improved radiographic progression free survival (rPFS) compared to prednisone alone, one of the study's two primary endpoints, but did not show a statistically significant improvement in the study's second primary endpoint of overall survival (OS). A previously reported Phase 3 trial, ELM-PC5, in men with mCRPC that had progressed during or following chemotherapy, was unblinded in 2013 after a pre-specified interim analysis indicated that orteronel plus prednisone would likely not meet the primary endpoint of improved overall survival when compared to the control arm.