The role of capecitabine in first-line treatment for patients with metastatic breast cancer.

Capecitabine is an important drug in the therapeutic armamentarium for metastatic breast cancer. A comprehensive worldwide clinical trial program involving >10,000 patients with locally advanced and metastatic breast cancer has provided evidence for the current treatment strategies. On the basis of data demonstrating consistent activity across several trials in patients with heavily pretreated breast cancer, capecitabine was approved in the U.S. in 1998 for the treatment of patients with metastatic disease resistant to paclitaxel and anthracycline-containing therapy, with later European Union approval for single-agent capecitabine in the metastatic setting. Capecitabine plus docetaxel (XT) was approved by the U.S. Food and Drug Administration for the treatment of metastatic breast cancer in 2001 on the basis of the large phase III trial comparing XT with docetaxel alone, which showed a survival advantage for combination therapy compared with single-agent therapy. This was shortly followed by European approval for the combination in metastatic breast cancer. The clinical utility of capecitabine in the management of breast cancer is supported by its convenient oral dosing schedule and favorable safety profile, as well as its excellent clinical activity in primary and metastatic breast cancer. Recently, clinical trials have studied single-agent capecitabine as first-line treatment and evaluated other capecitabine-containing combinations with cytotoxic and novel targeted