Brand Name: Faslodex **Generic:** fulvestrant **Type:** small molecule

Year Accepted/Phase: 2002

Mechanism:

Fulvestrant binds to the estrogen receptor and causes its degradation, leading to inhibition of estrogen-mediated signaling in breast cancer cells.

Chemical Structure:

Indication:

Faslodex is indicated for the treatment of hormone receptor-positive metastatic breast cancer in postmenopausal women who have experienced disease progression after anti-estrogen therapy.

Clinical trials:

CONFIRM Trial (Phase III)

Purpose: Compare the efficacy and safety of fulvestrant 500 mg versus fulvestrant 250 mg in postmenopausal women with hormone receptor-positive advanced breast cancer.

Dates: Conducted from 2004 to 2006.

Results: The CONFIRM trial showed that fulvestrant 500 mg was superior to fulvestrant 250 mg in terms of median progression-free survival (PFS) and overall survival (OS). It also demonstrated a favorable safety profile.

Impact: These results supported the approval of Faslodex at a dose of 500 mg as the standard regimen for hormone receptor-positive advanced breast cancer.

FALCON Trial (Phase III)

Purpose: Compare the efficacy and safety of fulvestrant 500 mg versus anastrozole in postmenopausal women with hormone receptor-positive, locally advanced or metastatic breast cancer who had not received prior endocrine therapy.

Dates: Conducted from 2012 to 2014.

Results: The FALCON trial showed that fulvestrant 500 mg was superior to anastrozole in terms of median PFS. It also demonstrated a similar safety profile to anastrozole.

Impact: These results supported the expanded use of Faslodex as a first-line treatment option for postmenopausal women with hormone receptor-positive, locally advanced or metastatic breast cancer.

COMPARE Trial (Phase III)

Purpose: Compare the efficacy and safety of fulvestrant plus anastrozole versus anastrozole alone in postmenopausal women with hormone receptor-positive, locally advanced or metastatic breast cancer.

Dates: Conducted from 2004 to 2007.

Results: The COMPARE trial showed that the combination of fulvestrant and anastrozole did not significantly improve PFS compared to anastrozole alone. However, there was a trend towards improved OS with the combination.

Impact: These results did not lead to a change in the standard of care, and Faslodex continues to be primarily used as a monotherapy in this setting.