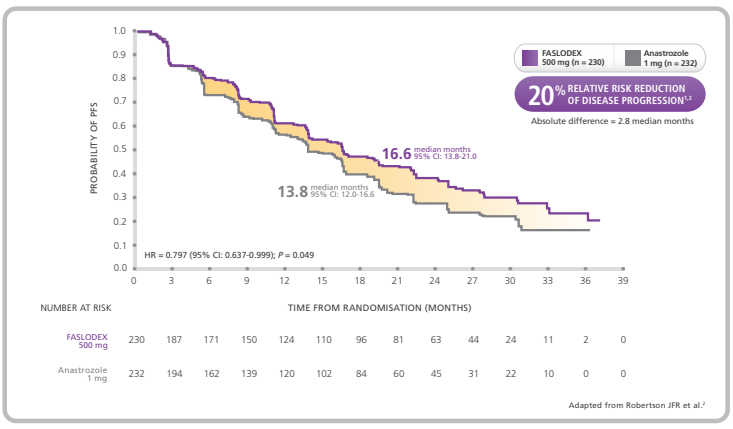
FASLODEX® fulvestrant

PERFORMANCE ALONE
PERFORMANCE TOGETHER

IN HR-POSITIVE, HER2- NEGATIVE LOCALLY ADVANCED OR METASTATIC BREAST CANCER[1]

As initial monotherapy for advanced breast cancer, endocrine therapy-naive postmenopausal women

FASLODEX had proven superior PFS vs the aromatase inhibitor anastrozole in a head-to-head trial[1,2]



Adapted from Robertson JFR et al.[2]

In the FALCON Trial

FASLODEX achieved median PFS of 16.6 months (95% CI 13.83-20.99) vs 13.8 months (95% CI 11.99-16.59) for anastrozole[1]

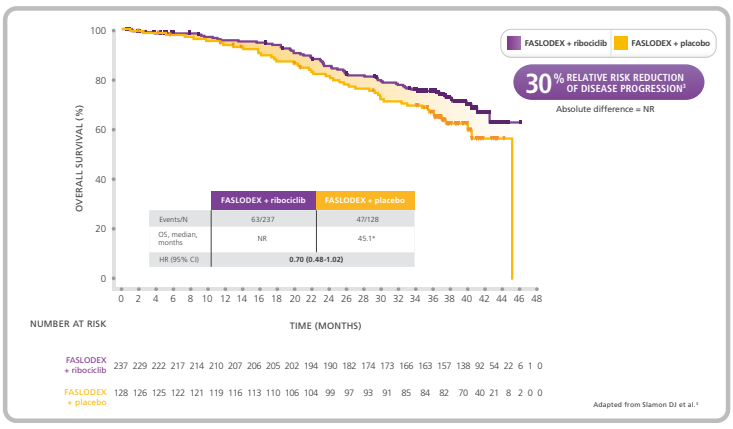
Trial design: FASLODEX 500 mg was studied vs anastrozole 1 mg in FALCON, a phase III, randomised, double-blind, double-dummy, multicentre study in postmenopausal women (N = 462) who had not previously been treated with endocrine therapy.[1,2] All patients had locally advanced breast cancer or mBC.[1] All patients tested ER+ and/or PgR+, and most (except 1 patient) tested HER2-negative.[1,2] Patients were randomised 1:1 to FASLODEX or anastrozole, and stratified by disease setting (locally advanced or metastatic), use of prior chemotherapy for advanced disease, and presence or absence of measurable disease. The major efficacy outcome measure of the FALCON trial was investigator-assessed PFS, evaluated according to RECIST v.1.1.[1,2]

PERFORMANCE ALONE[1]

Overall survival by line of therapy in MONALEESA-3[3]

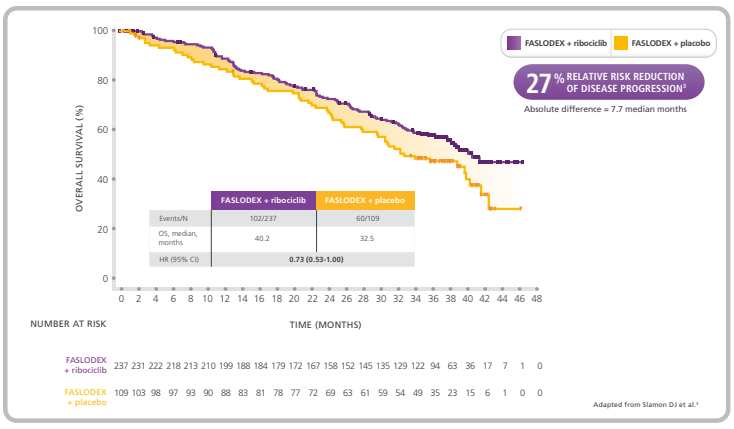
OS by line of therapy was consistent with overall population

FIRST LINE



Adapted from Slamon DJ et al.[3]

EARLY RELAPSE + SECOND LINE



Adapted from Slamon DJ et al.[3]

- Median OS by first line of therapy, in the FASLODEX + ribociclib arm was NR vs 45.1 months in the FASLODEX + placebo arm; HR 0.70 (95% CI: 0.48-1.02)[3]
- Median OS by early relapse + second line of therapy, in the FASLODEX + ribociclib arm was 40.2 months vs 32.5 months in the FASLODEX + placebo arm; HR 0.73 (95% CI: 0.53-1.00)[3]

*This median value may not be estimated reliably due to the last patient on follow-up, who had an event at 45.1 months.[3]

PERFORMANCE TOGETHER with ribociclib[3]

CI = confidence interval; ER = oestrogen receptor; HER2 = human epidermal growth factor receptor 2; HR = hazard ratio; mBC = metastatic breast cancer; NR = not reached; OS = overall survival; PFS = progression-free survival; PgR = progesterone receptor; RECIST = Response Evaluation Criteria in Solid Tumours.

References:

1. Faslodex Singapore Prescribing Information. SG Doc ID-000142462 V16.0 (30 Apr 2021).

2. Robertson JFR, Bondarenko IM, Trishkina E, et al. Fulvestrant 500 mg versus anastrozole 1 mg for hormone receptor-positive advanced breast cancer (FALCON): an international, randomised, double-blind, phase 3 trial. Lancet. 2016;388(10063):2997-3005.

3. Slamon DJ, Neven P, Chia S, et al. Overall survival with ribociclib plus fulvestrant in advanced breast cancer. N Engl J Med. 2019:1-11.

ABBREVIATED PRESCRIBING INFORMATION

Faslodex (Fulvestrant) Abbreviated Prescribing Information
For Healthcare Professionals only.
Please consult local full prescribing information before prescribing.

Faslodex (Fulvestrant) 250mg/5ml solution for injection. INDICATIONS: FASLODEX is indicated for the treatment of estrogen receptor positive, locally advanced or metastatic breast cancer in postmenopausal women not previously treated with endocrine therapy, or with disease relapse on or after adjuvant antiestrogen therapy, or disease progression on antiestrogen therapy. Combination therapy with palbociclib- FASLODEX is indicated in combination with palbociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women with disease progression following endocrine therapy. Combination therapy with abemaciclib- FASLODEX is indicated in combination with abemaciclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in women with disease progression after endocrine therapy. Combination therapy with ribociclib- FASLODEX is indicated in combination with ribociclib for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in postmenopausal women as initial endocrine based therapy or following disease progression on endocrine therapy. **DOSAGE:** Adult females (including the elderly): 500mg at intervals of one month, with an additional 500mg dose given 2 weeks after initial dose. When Faslodex is used in combination with palbociclib, refer to Faslodex monotherapy recommended dose instruction. Refer to the prescribing information for palbociclib for Posology and method of administration. When Faslodex is used in combination with abemaciclib, refer to monotherapy recommended dose instruction for Faslodex. Refer to the prescribing information for abemaciclib for Posology and method of administration. When Faslodex is used in combination with ribociclib, refer to monotherapy recommended dose instruction for Faslodex. Refer to the prescribing information for ribociclib for Posology and method of administration. Faslodex is not recommended for use in children or adolescents. No dose adjustments are recommended for patients with mild to moderate renal impairment (CrCl ≥30 ml/min). **CONTRAINDICATIONS:** Hypersensitivity to the active substance or to any of the excipients. **PREGNANCY & LACTATION:** Patients of child-bearing potential should be advised to use effective contraception while on treatment. Faslodex is contraindicated in pregnancy. Breast-feeding must be discontinued during treatment with Faslodex. **WARNINGS & PRECAUTIONS:** Use with caution in patients with mild to moderate hepatic impairment. Due to the intramuscular route of administration, Faslodex should be used with caution if treating patients with bleeding diatheses, thrombocytopenia or those taking anticoagulant treatment. Injection site related events including sciatica, neuralgia, neuropathic pain, and peripheral neuropathy have been reported. Caution should be taken when administering at the dorsogluteal injection site due to the proximity of the underlying sciatic nerve. Thromboembolic events are commonly observed in women with advanced breast cancer and have been observed in clinical studies with Faslodex. This should be taken into consideration when prescribing Faslodex to patients at risk. There are no long-term data on the effect of fulvestrant on bone. Due to the mechanism of action of fulvestrant, there is a potential risk of osteoporosis. Faslodex can interfere with oestradiol measurement by immunoassay, resulting in falsely elevated oestradiol levels. **UNDESIRABLE EFFECTS:** Asthenia, injection site reactions, nausea, and increased hepatic enzymes (ALT, AST, ALP), headache, vomiting, diarrhoea, urinary tract infections, rash, back pain, anorexia, venous thromboembolism, hot flushes, hypersensitivity reactions, elevated bilirubin. Combination therapy with palbociclib- See palbociclib local Prescribing Information for Contraindications, Pregnancy & Lactation, Warnings & Precautions and Undesirable effects. Combination therapy with abemaciclib- See abemaciclib local Prescribing Information for Contraindications, Pregnancy & Lactation, Warnings & Precautions and Undesirable effects. Combination therapy with ribociclib- See ribociclib local Prescribing Information for Contraindications, Pregnancy & Lactation, Warnings & Precautions and Undesirable effects.

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