

For postmenopausal women with hormone receptor-positive (HR+) metastatic breast cancer with disease progression following anti-estrogen therapy . . .

# FASLODEX 500 mg and the Mechanisms of Action of Other Hormonal Therapy Options\*



[1/DOF 1137113/p 1/Sec 4/para 1-2]  
The CONFIRM<sup>†</sup> trial compared FASLODEX 500 mg vs FASLODEX 250 mg in 736 postmenopausal women with advanced breast cancer who had disease recurrence on or after adjuvant endocrine therapy or progression following endocrine therapy for advanced disease.<sup>1</sup>

- In CONFIRM, 88.3% of the patient population recurred or progressed during or after **3 prior endocrine therapies**<sup>1</sup>
- The CONFIRM trial proved **increased progression-free survival (PFS)<sup>§</sup>** as well as a **comparable safety profile** for FASLODEX 500 mg vs FASLODEX 250 mg<sup>3</sup>
  - Median PFS: 65 months with 500 mg vs 5.4 months with 250 mg<sup>2</sup>

## Original approval of FASLODEX 250 mg based on noninferiority to ARIMIDEX<sup>2</sup>

- Efficacy was established, showing noninferiority in terms of objective response rates, and median time to progression of 5.5 months vs 4.1 months when compared with ARIMIDEX<sup>2,4</sup>
- No statistically significant difference in median overall survival: 27.4 months for FASLODEX 250 mg vs 27.7 months for ARIMIDEX<sup>2,5</sup>
- The most commonly reported adverse reactions in the FASLODEX 250 mg and ARIMIDEX treatment groups, regardless of the investigators' assessment of causality, were gastrointestinal symptoms (including nausea, vomiting, constipation, diarrhea, and abdominal pain), headache, back pain, hot flashes, and pharyngitis<sup>2</sup>

**FASLODEX®**  
fulvestrant injection

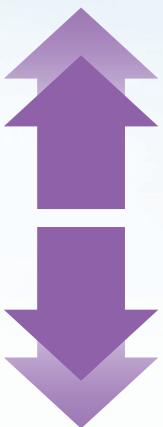
\*Not all hormonal therapy options for metastatic breast cancer are included.

<sup>†</sup>COmparisoN of FASLODEX In Recurrent or Metastatic Breast Cancer.

<sup>§</sup>Progression-free survival (PFS) is defined as the time between randomization and the earliest evidence of disease progression or death from any cause.

### Evidence from increased dose response led to CONFIRM trial<sup>3</sup>

Increasing the  
FASLODEX  
Dose  
results in  
Greater  
Downregulation  
of ER<sup>3</sup>



- FASLODEX causes downregulation of estrogen receptor (ER)<sup>2</sup>
- Greater downregulation of ER was shown with increasing dose<sup>3</sup>
  - In a clinical study of postmenopausal women with primary breast cancer treated with single doses of FASLODEX 15 to 22 days prior to surgery
- These findings led to CONFIRM trial studying a higher dose<sup>3</sup>
- The clinical significance of pharmacologic data is unknown. Pharmacologic data do not necessarily correlate with clinical outcomes

### Approved use for FASLODEX

FASLODEX is indicated for the treatment of hormone receptor–positive metastatic breast cancer in postmenopausal women with disease progression following antiestrogen therapy.

Please see accompanying full prescribing information for FASLODEX.

References: 1. Data on File, 1137103. AstraZeneca Pharmaceuticals LP, Wilmington, DE. 2. FASLODEX Full Prescribing Information. AstraZeneca Pharmaceuticals LP, Wilmington, DE. 3. Di Leo A, Jerusalem G, Petruzelka L, et al. Results of the CONFIRM phase III trial comparing fulvestrant 250 mg with fulvestrant 500 mg in postmenopausal women with estrogen receptor–positive advanced breast cancer. *J Clin Oncol.* 2010;28(30):4594-4600. 4. Robertson JF, Osborne CK, Howell A, et al. Fulvestrant versus anastrozole for the treatment of advanced breast carcinoma in postmenopausal women: a prospective combined analysis of two multicenter trials. *Cancer.* 2003;98(2):229-238. 5. Howell A, Pippen J, Elledge RM, et al. Fulvestrant versus anastrozole for the treatment of advanced breast carcinoma: a prospectively planned combined survival analysis of two multicenter trials. *Cancer.* 2005;104(2):236-239.



[www.faslodex.com/hcp](http://www.faslodex.com/hcp)

FASLODEX and ARIMIDEX are registered trademarks of the AstraZeneca group of companies.  
© AstraZeneca 2010. All rights reserved. 1647101 2/12

AstraZeneca