

## Faslodex® (fulvestrant) - Expanded indication

- On November 15, 2017, <u>AstraZeneca announced</u> the FDA approval of <u>Faslodex (fulvestrant)</u> for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with <u>Ibrance<sup>®</sup> (palbociclib)</u> or <u>Verzenio<sup>®</sup> (abemaciclib)</u> in women with disease progression after endocrine therapy.
  - Previously, this indication was only approved for use in combination with Ibrance.
  - Faslodex is also indicated for the treatment of HR-positive, HER2-negative advanced breast cancer in postmenopausal women not previously treated with endocrine therapy or HRpositive advanced breast cancer in postmenopausal women with disease progression following endocrine therapy.
- The expanded indication for Faslodex was based on data from a clinical study (MONARCH 2) of 669 women with HR-positive, HER2-negative advanced breast cancer randomized to Faslodex plus Verzenio vs. Faslodex plus placebo. Primary efficacy measures were progression free survival (PFS) and objective response rate (ORR).
  - The results showed a statistically significant increase in median PFS of 7.1 months (16.4 months vs. 9.3 months) in patients who received Faslodex plus Verzenio vs. Faslodex plus placebo (HR: 0.553; 95% CI: 0.449, 0.681; p < 0.0001).</li>
  - The ORR with Faslodex plus Verzenio was greater (48.1%, 95% CI: 42.6, 53.6) vs.
    Faslodex plus placebo (21.3%, 95% CI: 15.1, 27.6).
- When Faslodex is used in combination with Ibrance or Verzenio, the recommended dose of Faslodex is 500 mg administered intramuscularly into the buttocks (gluteal area) slowly (1 – 2 minutes per injection) as two 5 mL injections, one in each buttock, on days 1, 15, 29 and once monthly thereafter.
  - When Faslodex is used in combination with Verzenio, the recommended dose of Verzenio is 150 mg orally, twice daily.
  - Refer to the Faslodex drug label for dosing recommendations for all other indications.



## optumrx.com

OptumRx® specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at **optum.com**.

All Optum<sup>®</sup> trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners.

This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxNews® is published by the OptumRx Clinical Services Department.

©2017 Optum, Inc. All rights reserved.