Different by design – Abemaciclib

Continuous dosing schedule

Provides uninterrupted inhibition to prevent rebound and head, to cell, death* (preclinical).

Can be taken every day, so patients can feel they are doing everything they can to delay the progression of their cancer.

Blood-brain barrier crossing

Early data from phase II study demonstrated CNS response.

CSF samples from phase. I study were, collected from a subset of patients and demonstrated, that concentrations of Abemaciclib in CSF were generally consistent with theunbound plasma concentrations.

Distinct safety profile

With a minority of patients experiencing grade 3 or above neutropenia (less than 1/3).

With 9 to 20% of patients experiencing grade 3 or above diarrhea.

CDK 4 & CDK 6

Only CDK4 & 6 inhibitor that has demonstrated single agent activity and provides the flexibility to meet the needs of patients at more points in their journey.

Only CDK4/6 approved as monotherapy.

Consistent Benefit in harder to treat population

The only CDK4/6 inhibitor, reaching in phase 3 trials:

- Higher magnitude of benefit in hard to treat population.
- Statistically well designed subgroup analysis.

Abridged Pack Insert- Abemaciclib (Verzenio™)

Product description: •Abemaciclib (Verzenio™) •Film coated tablets [available in 50mg, 100mg, 150mg and 200mg]. **Indication and Usage:** (I) Verzenio™ is indicated for the treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy. • In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist. (ii) As monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting. **Dose and method of administration:** The recommended dose of Abemaciclib is 150 mg twice daily when used in combination with endocrine therapy. Recommended starting dose in combination with fulvestrant or an aromatase inhibitor: 150 mg twice daily. Recommended starting dose as monotherapy: 200 mg twice daily orally. **Method of Administration:** For Oral use, the dose can be taken with/ or without food. **Contra-indications:** Hypersensitivity to the active substance or to any of the excipients. **Undesirable effects:** The most commonly occurring adverse reactions are diarrhoea, infections, neutropenia, anaemia, fatigue, nausea, vomiting and decreased appetite. **Overdose:** In the event of an abemaciclib overdose, fatigue and diarrhea may occur. General supportive care should be provided. **Special warning and precaution: Neutropenia**: Neutropenia was reported in patients receiving abemaciclib. Dose modification is recommended for patients who develop Grade 3 or 4 neutropenia. Fatal events occurred in <1% of patients. **Infections/infestations:** Infections were reported in patients receiving abemaciclib plus endocrine therapy at a higher rate than in patients treated with placebo plus endocrine therapy. Lung infection was reported in patients receiving abemaciclib without concurrent neutropenia. Fatal events occurred in < 1% of patients. Patients should be monitored for signs and symptoms of infection and treated as medically appropriate. **Venous thromboembolism:** Venous thromboembolic events were reported in 5.3 of patients treated with abemaciclib plus fulvestrant or aromatase inhibitors, compared to 0.8% of patients treated with placebo plus fulvestrant or aromatase inhibitors. Patients should be monitored for signs and symptoms of deep vein thrombosis and pulmonary embolism and treated as medically appropriate. **Increased aminotransferases:** Increases in ALT and AST were reported in patients receiving abemaciclib. Based on the level of ALT or AST elevation, abemaciclib may require dose modification. **Diarrhoea:** Diarrhoea is the most common adverse reaction. Across clinical studies, median time to onset of the first diarrhoea event was approximately 6 to 8 days, and median duration of diarrhoea was 9 to 12 days (Grade 2) and 6 to 8 days (Grade 3). Diarrhoea can be associated with dehydration. Patients should start treatment with antidiarrhoeal agents such as loperamide at the first sign of loose stools, increase oral fluids and notify their healthcare provider. Dose modification is recommended for patients who develop Grade 2 diarrhoea. **Concomitant use of inducers of CYP3A4:** Concomitant use of CYP3A4 inducers should be avoided due to the risk of decreased efficacy of abemaciclib. **Visceral crisis:** There are no data on the efficacy and safety of abemaciclib in patients with visceral crisis. **Lactose:** Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

*Under license from the registered trademark owners Eli Lilly and Company, USA
Literature revised: 27 Jan 2020; Version Control No. 1.0

PP-AL-IN-0006

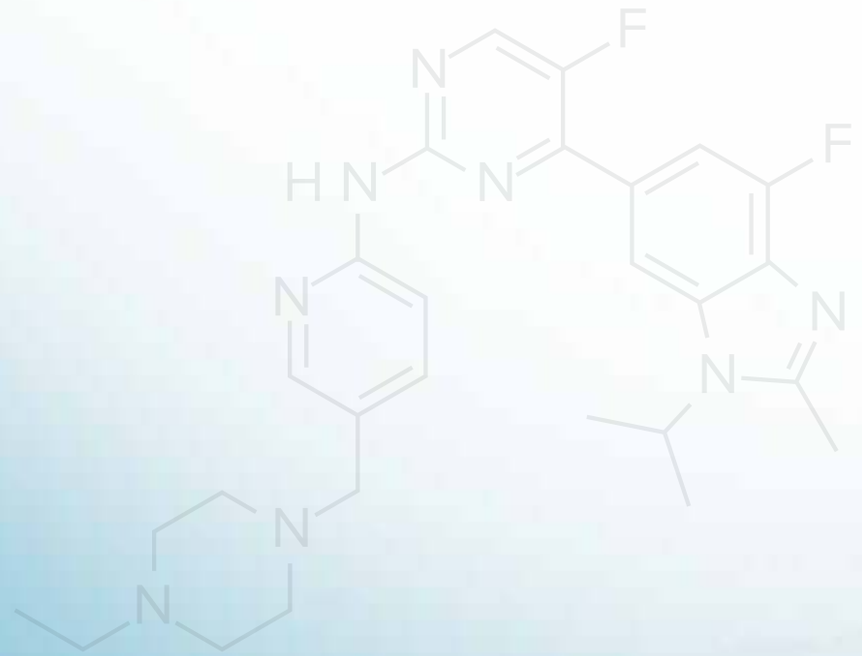
Eli Lilly and Company (India) Pvt. Ltd.
Plot # 92, Sector 32, Institutional Area, Gurgaon-122001, HARYANA, INDIA.
Phone : 91-124-4753000/01 • Fax : 91-124-4753012/13 • For Patient Concerns : 18001230021 • Email: lillyindia@lilly.com

Lilly

1. Are all HR+ & HR- patients same?

2. Do you see patients who are likely to do worse?

3. How Abemaciclib is 'different by design'?



Lilly symposium different by design

"poor prognosis"

"endocrine resistant"

"aggressive disease"

"patients who are likely to do worse"

"recurred on adjuvant"

"failed an AI"

Agenda

Chairperson: Dr. S. H. Advani	
6:00 PM to 6:20 PM	Abemaciclib- Benchside to Bedside **Dr. P. S. Dattatreya**
6:20 PM to 6:35 PM	Prognostic characteristics in HR+ ABC and Abemaciclib: **Dr. Vineet Gupta**
6:35 PM to 6:55 PM	Differentiated discussion and wrap up moderated by: **Dr. Chanchal Goswami**
	Panelist: **Dr. P. S. Dattatreya, Dr. Vineet Gupta, Dr. Ashish Singh, Dr. Ashish Kaushal, Dr. Pritesh Lohar, Dr. Ghanshyam Biswas and Dr. M. Vamshi Krishna**
6:55 PM to 7:00 PM	Key Takeways by: **Dr. S. H. Advani**