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ONCONXT

Foundation

CURRENT UPDATES IN BREAST CANCER

LEARNINGS FROM ESMO 2021

29th – 30th October 2021

Friday & Saturday

19:00 - 21:00 hrs

Program Director

Dr. Tejinder Singh

Sr. Consultant Medical Oncologist,
Apollo Hospital, Navi Mumbai

Dr. Adwaita Gore

Sr. Consultant Medical Oncologist,
Prince Aly Khan Hospital & Zen
Multi Speciality Hospital, Mumbai

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CURRENT UPDATES IN BREAST CANCER

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29th – 30th October 2021 | 19:00 - 21:00 hrs

WELCOME ADDRESS

Dear Colleagues,

It is our pleasure to invite you for the webinar titled "Current Updates in Breast Cancer" based on recent practice changing data presented at the European oncology congress. This meeting will be held virtually on 29th - 30th October 2021 from 19:00 - 21:00 hrs.

At this exclusive meeting leading oncology experts will review the exciting breast cancer advances and give exclusive insight into the practice-changing data on Breast Cancer.

With this meeting Onconxt continues to bring you the latest updates keeping you up-to-date with the most exciting developments. Our reporting on key international congresses along with our expert faculty has gain popularity over last few years.

We look forward to your presence and active participation.

Regards

Dr. Tejinder Singh
Sr. Consultant Medical Oncologist,
Apollo Hospital, Navi Mumbai

Dr. Adwaita Gore
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Prince Aly Khan Hospital & Zen
Multi Speciality Hospital, Mumbai

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CURRENT UPDATES IN BREAST CANCER

LEARNINGS FROM ESMO 2021

Day 1 Friday, 29th October 2021
19:00 - 21:00 hrs

SCIENTIFIC PROGRAM

19:00 - 19.10	Welcome and Introduction **Dr. Tejinder Singh**
	Session 1 : HRD : BRCA and Beyond **This session is supported by Astrazeneca**
19:10 - 19:30	BRCA Testing : Challenges and opportunities Across Tumor Types **Speaker: Dr. Nilesh Lokeshwar**
19:30 - 19:55	Recent Advancements in Management of HER2-ve Early Breast Cancer **Speaker: Dr. Muzammil Shaikh**
19:55 - 20:20	**Panel Discussion:** BRCA1/2 Positive Early Breast Cancer **Moderator : Dr. Tejinder Singh** **Panelist : Dr. Shishir Shetty** **Dr. Salil Patkar** **Dr. Pushpak Chirmade** **Dr. Imran Shaikh**

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CURRENT UPDATES IN BREAST CANCER

LEARNINGS FROM ESMO 2021

Day 2 Saturday, 30th October 2021
19:00 - 21:00 hrs

SCIENTIFIC PROGRAM

Session 2 : ER+ve/Her-ve Advanced Breast Cancer

This session is supported by Novartis

19:00 - 19:15	LBA17_PR - Overall survival (OS) results from the phase III MONALEESA-2 (ML2) trial of postmenopausal patients (pts) with hormone receptor positive/human epidermal growth factor receptor 2 negative (HR+/HER2–) advanced breast cancer (ABC) treated with endocrine therapy (ET) ± ribociclib (RIB) *Abstract # 233P* Association of quality of life (QOL) with overall survival (OS) in patients (pts) with HR+/HER2– advanced breast cancer (ABC) treated with ribociclib (RIB) + endocrine therapy (ET) in the MONALEESA-3 (ML-3) and ML-7 trials **Speaker: Dr. Suparna Rao**
19:15 - 19:35	Expert Panel Discussion: Recent Advances of CDK 4/6 Inhibitor in ER+ve/Her2-ve Advanced Breast Cancer **Expert Panel: Dr. Suparna Rao** **Dr. Chandrashekhar Pethe** **Dr. Prabhat Bhargava** **Dr. Shruti Kate** **Dr. Darshana Rane**
19:35 - 19:45	Patient reported outcomes in patients with Pik3ca mutated HR1,HER2- advanced breast cancer from Solar 1 **Speaker: Dr. Chandrashekhar Pethe**

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CURRENT UPDATES IN BREAST CANCER

LEARNINGS FROM ESMO 2021

Day 2 Saturday, 30th October 2021
19:00 - 21:00 hrs

SCIENTIFIC PROGRAM

19:45 - 20:05	**Panel Discussion :** **Inclinic Experience of PKI3CA Inhibitor** **Moderator : Dr. Reshma Puranik** **Panelists : Dr. Shruti Kate** **Dr. Darshan Rane** **Dr. Vijay Sharnangat** **Dr. Prabhat Bhargava** **Dr. Shivam Shingla**

Session 3 : From Clinical Trial to Clinical Practice : Navigating Management with CDK 4/6 Inhibitors

This session is supported by Pfizer

20:05 - 20:20	Real World Indian Evidence on Palbociclib **Speaker: Dr. Chaturbhuj Agarwal**
20:20 - 20:35	ESMO Update **Speaker: Dr. Chetan Deshmukh**
20:35 - 20:55	Questions & Answer Session on Current Status of Palbociclib in Management of Er+ve/Her-ve Advanced Breast Cancer **Moderator : Dr. Nilesh Lokeshwar** **Expert Panel : Dr. Chaturbhuj Agarwal** **Dr. Mansi Shah**

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LEARNINGS FROM ESMO 2021

Day 1 Friday, 29th October 2021

19:00 - 21:00 hrs

ACADEMIC PARTNERS

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The First-in-Class USFDA approved

CDK 4/6 inhibitor available in India[1-3]

PALBACE®

palbociclib | 125 mg capsules

In treating a broad range of women with HR+/HER2- mBC:[3]

CONFIDENCE BUILT ON STRENGTH

STRENGTH FROM…

- **Powerful clinical efficacy**[3-12]
- **Real-world experience**[13]
- **Patient-reported outcomes**[14-15]
- **Established safety profile**[3-5, 8-10, 12, 16, 17]

One monitoring provision*[3]

One pill, once daily†[3]

References:

1. Lu J. Palbociclib: a first-in-class CDK4/CDK6 inhibitor for the treatment of hormone-receptor positive advanced breast cancer. J HematolOncol. 2015 Aug 13;8:98. 2. Palbociclib (IBRANCE Capsules). Approved drugs, drug approvals and databases. U.S. Food & Drug Administration [updated 2016 Feb 22;].Available from: https://www.fda.gov/drugs/informationdrugs/approveddrugs/ucm487080.htm, Accessed 2021, Apr 22. 3. Palbace (Palbociclib) Local prescribing document, Pfizer Products India Pvt Ltd, Version – 12 SPI LPDPAB022021, February 2021 4. Rugo H, et al. Breast Cancer Res Treat. 2019;174(3):719-729. 5. Finn RS, etal. N Engl J Med. 2016;375(20):1925-1936. 6. Turner NC, et al. SABCS2016; poster P4-22-06. 7. IBRANCE EPAR Public assessment report. 25 Nov 2016. Available at: http://www.ema.europa.eu/docs/en_GB/ document_library/EPAR_-_Public_assessment_report/human/003853/ WC500217198.pdf. Accessed 2020, Jan 15. 8. Cristofanilli M, et al. Lancet Oncol. 2016;17(4):425-439. 9. Rugo H, et al. Eur J Cancer. 2018;101:123-133. 10. Loibl S, et al. Oncologist. 2017;22(9):1028-1038. 11. Turner NC, et al.N Engl J Med. 2018;379(20):1926-1936. 12. Turner NC, et al. Ann Oncol. 2018;29(3):669-680. 13. FDA Approved drugs. IBRANCE. https://www.fda.gov/drugs/informationondrugs/approveddrugs/ucm549978.htm. Accessed 2021, Apr 22. 14. Harbeck N, et al. Ann Oncol. 2016;27(6):1047-1054. 15. Rugo HS, et al. Ann Oncol. 2018;29(4):888-894. 16. Dieras V, et al. J Natl Cancer Inst. 2019;111(4):419-430. 17. Verma S, et al. Oncologist. 2016;21:1165-1175.

CDK 4/6 = Cyclin Dependent Kinase 4/6 **HR+/HER2-** = hormone receptor-positive, human epidermal growth factor receptor 2-negative

*Additional monitoring may be necessary based on the individual patient. †As a part of combination the any AI or fulvestrant. Dosing for these combination partners should follow the dosing indications in the respective LPDs.

SUMMARY OF PRESCRIBING INFORMATION

Generic name of product: Palbociclib

Brand name of product: PALBACE®

Indication: Palbociclib is indicated for the treatment of hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer:

- In combination with an aromatase inhibitor;

- in combination with fulvestrant in women who have received prior endocrine therapy.

In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone releasing hormone (LHRH) agonist.

Pharmaceutical Form: Hard gelatin capsules in 75 mg, 100 mg and 125 mg.

Dosage: The recommended dose is 125 mg of palbociclib once daily for 21 consecutive days followed by 7 days off treatment (Schedule 3/1) to comprise a complete cycle of 28 days, The treatment with palbociclib should be continued as long as the patient is deriving clinical benefit from therapy or until unacceptable toxicity occurs, Aromatase Inhibitors and fulvestrant to be administered in accordance with their prescribing information, Treatment of pre/perimenopausal women with the combination of palbociclib should always be combined with an LHRH agonist, Management of some adverse reactions may require temporary dose interruptions/delays and/or dose reductions, or permanent discontinuation as per dose reduction schedules, viz., first dose reduction to 100 mg/day, second reduction to 75 mg/day, Treatment to be discontinued if further dose reduction is required, Complete blood count should be monitored prior to the start of palbociclib therapy and at the beginning of each cycle, as well as on Day 15 of the first 2 cycles, and as clinically indicated, For patients who experience a maximum of Grade 1 or 2 neutropenia in the first 6 cycles, complete blood counts for subsequent cycles should be monitored every 3 months, prior to the beginning of a cycle and as clinically indicated. Absolute neutrophil counts (ANC) of 1,000/mm3 and platelet counts of 50,000/mm3 are recommended to receive palbociclib. Dosing in special populations: Elderly: No dose adjustment is necessary in patients 65 years of age. Hepatic Impairment: No dose adjustment of palbociclib is required for patients with mild or moderate hepatic impairment (Child-Pugh classes A and B). For patients with severe hepatic impairment (Child-Pugh class C), the recommended dose of palbociclib is 75 mg once daily on Schedule 3/1. Renal Impairment: No dose adjustment of palbociclib is required for patients with mild, moderate, or severe renal impairment (creatinine clearance [CrCl] >15 mL/min). Insufficient data are available in patients requiring haemodialysis to provide any dose adjustment recommendation in this patient population. Paediatric Population: The safety and efficacy of palbociclib in children and adolescents 18 years of age have not been established.

Method of Administration: Palbociclib is for oral use. To be taken with food, preferably a meal to ensure consistent palbociclib exposure. Palbociclib should not be taken with grapefruit or grapefruit juice. Palbociclib capsules should be swallowed whole (should not be chewed, crushed, or opened prior to swallowing). No capsule should be ingested if it is broken, cracked, or otherwise not intact.

Contraindications: Hypersensitivity to the active substance or to any of the excipients (microcrystalline cellulose, lactose monohydrate, sodium starch glycolate, colloidal silicon dioxide, magnesium stearate, and hard gelatin capsule shells. The light orange, light orange/caramel and caramel opaque capsule shells contain gelatin, red iron oxide, yellow iron oxide, and titanium dioxide; and the printing ink contains shellac, titanium dioxide, ammonium hydroxide, propylene glycol and simethicone). Use of preparations containing St. John's Wort.

Warnings and Precautions: Pre/perimenopausal women: Ovarian ablation or suppression with an LHRH agonist is mandatory when pre/perimenopausal women are administered palbociclib in combination with an aromatase inhibitor or fulvestrant. Critical visceral disease: The efficacy and safety of palbociclib have not been studied in patients with critical visceral disease. Haematological disorders: Dose interruption, dose reduction, or delay in starting treatment cycles is recommended for patients who develop Grade 3 or 4 neutropenia. Appropriate monitoring should be performed. Interstitial lung disease/pneumonitis: Severe, life-threatening, or fatal ILD and/or pneumonitis can occur in patients treated with palbociclib when taken in combination with endocrine therapy. Across clinical trials, 1.4% of palbociclib-treated patients had ILD/pneumonitis of any grade, 0.1% had Grade 3, and no Grade 4 or fatal cases were reported. Additional cases of ILD/pneumonitis have been observed in the post-marketing setting, with fatalities reported. Monitor patients for pulmonary symptoms indicative of ILD/pneumonitis (e.g. hypoxia, cough, dyspnoea). In patients who have new or worsening respiratory symptoms and are suspected to have developed ILD/pneumonitis, interrupt palbociclib immediately and evaluate the patient. Permanently discontinue palbociclib in patients with severe ILD or pneumonitis. Infections: Since palbociclib has myelosuppressive properties, it may predispose patients to infections. Infections have been reported at a higher rate in patients treated with palbociclib in randomised clinical studies compared to patients treated in the respective comparator arm. Grades 3 and 4 infections occurred respectively in 5.6% and 0.9% of patients treated with palbociclib in any combination. Patients should be monitored for signs and symptoms of infection and treated as medically appropriate. Physicians should inform patients to promptly report any episode of fever. Hepatic impairment: Administer palbociclib with caution to patients with moderate or severe hepatic impairment, with close monitoring of toxicity signs. Renal impairment: Administer palbociclib with caution to patients with moderate or severe renal impairment, with close monitoring of signs of toxicity. Concomitant treatment with inhibitors or inducers of CYP3A4: Strong inhibitors of CYP3A4 may lead to increased toxicity. Concomitant use of strong CYP3A inhibitors during treatment with palbociclib should be avoided. Co-administration should only be considered after careful evaluation of the potential benefits and risks. If co-administration with a strong CYP3A inhibitor is unavoidable, reduce the palbociclib dose to 75 mg once daily. When the strong inhibitor is discontinued, increase the palbociclib dose (after 3 5 half lives of the inhibitor) to the dose used prior to the initiation of the strong CYP3A inhibitor. Co-administration of CYP3A inducers may lead to decreased palbociclib exposure and consequently a risk for lack of efficacy. Therefore, concomitant use of palbociclib with strong CYP3A4 inducers should be avoided, No dose adjustments are required for co-administration of palbociclib with moderate CYP3A inducers.

Women of childbearing potential or their partners: Women of childbearing potential or their male partners must use a highly effective method of contraception while taking palbociclib. Lactose: This medicinal product contains lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency, or glucose-galactose malabsorption should not take this medicine.

Use in Special population: Use in Special population: Women of childbearing potential/Contraception: Females of childbearing potential who are receiving this medicinal product, or their male partners should use adequate contraceptive methods (e,g,, double-barrier contraception) during therapy and for at least 3 weeks or 14 weeks after completing therapy for females and males, respectively, Pregnancy: There are no or limited amount of data from the use of palbociclib in pregnant women, Studies in animals have shown reproductive toxicity, Palbociclib is not recommended during pregnancy and in women of childbearing potential not using contraception, Breast-feeding: No studies have been conducted in humans or animals to assess the effect of palbociclib on milk production, its presence in breast milk, or its effects on the breast-fed child, It is unknown whether palbociclib is excreted in human milk, Patients receiving palbociclib should not breast feed, Fertility: There were no effects on oestrous cycle (female rats) or mating and fertility in rats (male or female) in non-clinical reproductive studies, However, no clinical data have been obtained on fertility in humans, Based on male reproductive organ findings (seminiferous tubule degeneration in testis, epididymal hypospermia, lower sperm motility and density, and decreased prostate secretion) in non-clinical safety studies, male fertility may be compromised by treatment with palbociclib, Thus, men may consider sperm preservation prior to beginning therapy with palbociclib,

Adverse reactions (Very common and common) : The most common adverse reactions of any grade reported in patients receiving palbociclib in randomised clinical studies were neutropenia, infections, leukopenia, fatigue, nausea, vomiting, stomatitis, anaemia, diarrhoea, alopecia, thrombocytopenia, asthenia, pyrexia, rash, dry skin. The most common (2%) Grade 3 adverse reactions of palbociclib were neutropenia, leukopenia, infections, anaemia, aspartate aminotransferase (AST) increased, fatigue, and alanine aminotransferase (ALT) increased. Common adverse events include febrile neutropenia, dysgeusia, epistaxis, ILD/pneumonitis, blurred vision, increased lacrimation, dry eye.

Drug interactions: Palbociclib is primarily metabolised by CYP3A and sulphotransferase (SULT) enzyme SULT2A1, In vivo, palbociclib is a weak, time-dependent inhibitor of CYP3A, Effect of CYP3A inhibitors: The concomitant use of strong CYP3A inhibitors including, but not limited to: clarithromycin, indinavir, itraconazole, ketoconazole, lopinavir/ritonavir, nefazodone, nelfinavir, posaconazole, saquinavir, telaprevir, telithromycin, voriconazole, and grapefruit or grapefruit juice, should be avoided, No dose adjustments are needed for mild and moderate CYP3A inhibitors, Effect of CYP3A inducers: The concomitant use of strong CYP3A inducers including, but not limited to: carbamazepine, enzalutamide, phenytoin, rifampin, and St, John's Wort should be avoided, No dose adjustments are required for moderate CYP3A inducers, Effect of acid reducing agents: given the effect of proton pump inhibitors on palbociclib AUCinf and Cmax in fasting and fed conditions, palbociclib should be taken with food, preferably a meal, Given the reduced effect on gastric pH of H2-receptor antagonists and local antacids compared to PPIs, no clinically relevant effect of H2 receptor antagonists or local antacids on palbociclib exposure is expected when palbociclib is taken with food, Effects of palbociclib on the pharmacokinetics of other medicinal products: Palbociclib is a weak, time-dependent inhibitor of CYP3A, The dose of sensitive CYP3A substrates with a narrow therapeutic index (e,g., alfentanil, cyclosporine, dihydroergotamine, ergotamine, everolimus, fentanyl, pimozide, quinidine, sirolimus, and tacrolimus) may need to be reduced when co-administered with palbociclib as palbociclib may increase their exposure. Drug-drug interaction between palbociclib and letrozole: Data from the drug-drug interaction (DDI) evaluation portion of a clinical study in patients with breast cancer showed that there was no drug interaction between palbociclib and letrozole when the 2 medicinal products were co-administered. Effect of tamoxifen on palbociclib exposure: Data from a DDI study in healthy male subjects indicated that palbociclib exposures were comparable when a single dose of palbociclib was co-administered with multiple doses of tamoxifen and when palbociclib was given alone. Drug-drug interaction between palbociclib and fulvestrant: Data from a clinical study in patients with breast cancer showed that there was no clinically relevant drug interaction between palbociclib and fulvestrant when the two medicinal products were co-administered. Drug-drug interaction between palbociclib and oral contraceptives: DDI studies of palbociclib with oral contraceptives have not been conducted. In vitro studies with transporters: Based on in vitro data, palbociclib is predicted to inhibit intestinal P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP) mediated transport. Therefore, administration of palbociclib with medicinal products that are substrates of P-gp (e.g., digoxin, dabigatran, colchicine) or BCRP (e.g., pravastatin, rosuvastatin, sulfasalazine) may increase their therapeutic effect and adverse reactions. Based on in vitro data, palbociclib may inhibit the uptake transporter organic cationic transporter OCT1 and then may increase the exposure of medical product substrates of this transporter (e.g., metformin).

Overdose: Adverse reactions (Very common and common) : In the event of a palbociclib overdose, both gastrointestinal (e.g., nausea, vomiting) and haematological (e.g., neutropenia) toxicity may occur and general supportive care should be provided.

Storage Condition: Store below 30°C in the original package. No special requirements.

LPD version and date: LPDPAB022021, version 12, February 2021.

Pfizer Products India Private Limited
The Capital - B Wing, 1802, 18th Floor, Plot No. C-70, G Block, Bandra Kurla Complex, Bandra (East), Mumbai - 400 051, India.

PP-IBR-IND-0262 19-04-2021

For the use only of Registered medical practitioner or a hospital or a laboratory.

~2X mPFS[1,2]

- 11.0 months median PFS with PIVIKTO + fulvestrant vs 5.7 months with placebo + fulvestrant in patients with a PIK3CA mutation

TUMOUR SHRINKAGE

- 3 out of 4 patients with a PIK3CA mutation had tumour shrinkage[3]

>2X THE RESPONSE RATE[1,2]

- **35.7% ORR with PIVIKTO + fulvestrant vs 16.2% with placebo + fulvestrant in patients with a PIK3CA mutation who had a measurable disease**

aBC: advanced Breast Cancer, **PIK3CA:** Phosphatidylinositol-4,5-Bisphosphate 3-Kinase Catalytic Subunit Alpha, **PFS:** Progression Free Survival, **ORR:** Overall Response Rate.

REFERENCES: 1. Alpelisib Core Data Sheet; Version 1.0. Novartis Pharma AG; November 2018, **2.** André F, Ciruelos E, Rubovszky G, et al. Alpelisib for PIK3CAmutated, hormone receptor-positive advanced breast cancer. N Engl J Med. 2019;380(20):1929-1940, **3.** Data on file. Novartis Pharmaceuticals Corp; 2018.

BASIC SUCCINCT STATEMENT (BSS)

PIVIKTO®

PRESENTATION: Film-coated tablets (FCT) containing 50 mg, 150 mg and 200 mg of Alpelisib.

INDICATIONS: Alpelisib is a kinase inhibitor indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.

DOSAGE AND ADMINISTRATION:

ADULTS: The recommended dose of Alpelisib is 300 mg taken orally, once daily on a continuous basis. Alpelisib should be taken immediately following food, at approximately same time each day. If a dose of Alpelisib is missed, it can be taken up to 9 hours after the time it is normally administered. After more than 9 hours, the dose should be skipped for that day. On the next day, Alpelisib should be taken at its usual time. If patient vomits after taking the Alpelisib dose, the patient should not take an additional dose on that day, and should resume the usual dosing schedule the next day, at the usual time.

SPECIAL POPULATIONS: • *Renal impairment:* Mild or moderate: No dose adjustment is necessary. • *Severe:* Caution is recommended. • *Hepatic impairment:* Mild, moderate or severe: No dose adjustment is necessary. • *Geriatrics (≥65 years):* No dose adjustment is required. • *Pediatrics (≤18 years):* Safety and efficacy have not been established.

CONTRAINDICATIONS: • Patients with hypersensitiuity to the active substance or to any of the excipients.

WARNINGS AND PRECAUTIONS: • **Hypersensitiuity (including anaphylactic reaction):** Serious hypersensitiuity reactions (including anaphylactic reaction and anaphylactic shock), manifested by symptoms including, but not limited to, dyspnea, flushing, rash, fever or tachycardia were reported in patients treated with Alpelisib in clinical studies. Alpelisib should be permanently discontinued and should not be re-introduced in patients with serious hypersensitiuity reactions. Appropriate treatment should be promptly initiated. **Severe cutaneous reactions:** Cases of severe cutaneous reactions, including Steuens-Johnson Syndrome (SJS) and Erythema Multiforme (EM) were reported in patients treated with Alpelisib in clinical studies. Alpelisib treatment should not be initiated in patients with history of SJS, EM or Toxic Epidermal Necrolysis (TEN). Patients should be aduised of the signs and symptoms of seuere cutaneous reactions. If symptoms or signs of seuere cutaneous reactions are present, Alpelisib should be interrupted until the etiology of the reaction has been determined. A consultation with dermatologist is recommended. If SJS, TEN, or EM is confirmed, Alpelisib should be permanently discontinued. Alpelisib should not be reintroduced in patients who haue experienced preuious seuere cutaneous reactions. • **Hyperglycaemia:** Hyperglycaemia was reported in of patients treated with Alpelisib in the phase III clinical study. Patients with poor glycemic control may be at a higher risk of deueloping seuere hyperglycaemia and associated complications (e.g. ketoacidosis). Patients should be aduised of the signs and symptoms of hyperglycaemia . Based on the seuerity of the hyperglycaemia, Alpelisib may require treatment interruption, dose reduction, or treatment discontinuation. • **Pneumonitis:** Pneumonitis including serious cases of pneumonitis/acute interstitial lung disease haue been reported in Alpelisib treated patients in clinical studies. Patients should be aduised to promptly report any new or worsening respiratory symptoms. In patients who haue new or worsening respiratory symptoms or are suspected to haue deueloped pneumonitis, Alpelisib treatment should be interrupted immediately and the patient should be eualuated for pneumonitis. A diagnosis of non-infectious pneumonitis should be considered. Alpelisib should be permanently discontinued in all patients with confirmed pneumonitis.

PREGNANCY, LACTATION, FEMALES AND MALES OF REPRODUCTIVE POTENTIAL: • **Pregnancy:** It is possible that Alpelisib can cause fetal harm when administered to a pregnant woman. Alpelisib should not be used during pregnancy unless the benefits to the mother outweigh the risk to the fetus. If Alpelisib is used during pregnancy, the patient should be aduised of the potential risk to the fetus. • **Lactation:** Women should not breastfeed during treatment and for at least 4 days after the last dose of Alpelisib. • **Females and males of reproductive potential:** • *Pregnancy testing:* For female patients of reproductive potential, the pregnancy status should be verified, prior to initiating treatment with Alpelisib. • *Contraception:* Sexually actiue females of reproductiue potential (ORP) should use effectiue contraception and male patients with female partners ORP should use condoms during treatment with Alpelisib and for 4 days after stopping treatment with Alpelisib. • *Infertility:* Based on animal studies, Alpelisib may impair fertility in females and males of reproductiue potential.

ADVERSE DRUG REACTIONS: • **Very common (≥10%):** Anaemia, diarrhoea, nausea, uomiting, stomatitis, abdominal pain, dyspepsia, fatigue, mucosal inflammation, oedema peripheral, pyrexia, mucosal dryness, urinary tract infection, weight decreased, weight decreased, blood creatinine increased, hyperglycaemia, decreased appetite, headache, dysgeusia, rash, alopecia, pruritus, dry skin, actiuated partial thromboplastin time increased, hemoglobin decreased, lymphocyte count decreased, platelet count decreased, alanine aminotransferase increased, albumin decreased, calcium corrected decreased, gamma-glutamyl transferase increased, glucose plasma increased, glucose plasma decreased, lipase increased. • **Common (≥1 to <10%):** Lymphopenia, thrombocytopenia, uision blurred, dry eye, toothache, cheilitis, gingiuitis, oedema, hypersensitiuity, glycosylated haemoglobin increased, hypokalemia, hypocalcaemia, dehydration, muscle spasms, myalgia, osteonecrosis of jaw, insomnia, acute kidney injury, pneumonitis, erythema, dermatitis, palmar-plantar erythrodysaesthesia syndrome, erythema multiforme, hypertension, lymphoedema, potassium decreased, magnesium decreased. **Uncommon (≥0.1 to <1%):** Pancreatitis, ketoacidosis, SJS.

Description of select ADRs and treatment recommendations, where applicable: • **Rash:** Topical corticosteroid treatment should be initiated at the first signs of rash and oral corticosteroids should be considered for more moderate to seuere rashes. Additionally, antihistamines are recommended to manage symptoms of rash. Oral antihistamines may be initiated prophylactically, at the time of initiation of treatment with Alpelisib. • **GI toxicity (nausea, diarrhea, uomiting):** Seuere diarrhea and clinical consequences, such as dehydration and acute kidney injury haue been reported during treatment with Alpelisib and resolued with appropriate interuention. Patients should be managed according to local standard of care medical management, including electrolyte monitoring, administration of anti-emetics and antidiarrheal medications and/or fluid replacement and electrolyte supplements, as clinically indicated.

Interactions: • **BCRP inhibitors:** Caution is aduised when co-administering Alpelisib with a BCRP inhibitor (e.g. eltrombopag, lapatininb, pantoprazole), as inhibition of BCRP may lead to an increase in systemic exposure of Alpelisib. • **CYP3A4 substrates:** Caution is recommended when Alpelisib is used in combination with CYP3A4 substrates that also possess an additional time-dependent inhibition and induction potential on CYP3A4 that affects their own metabolism (e.g. rifampicin, ribociclib, encorafenib). • **CYP2C9 substrates with narrow therapeutic index:** No dose adjustment of Alpelisib is required. However, in the absence of clinical data, caution is recommended when Alpelisib is co-administered with drugs that are CYP2C9 substrates with narrow therapeutic window (e.g. warfarin). **CYP2B6 sensitive substrates with narrow therapeutic index:** Sensitive CYP2B6 substrates (e.g. bupropion) or CYP2B6 substrates with a narrow therapeutic window should be used with caution in combination with Alpelisib, as may reduce the clinical actiuity of such drugs. • **Hormonal contraceptiues:** It is currently unknown whether Alpelisib may reduce the effectiueness of systemically acting hormonal contraceptiues.

Before prescribing, please consult full prescribing information available from Novartis Healthcare Private Limited, Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India. Tel +91 22 50243335/36, Fax +91 22 50243010.

For the use of registered medical practitioner or hospital or laboratory only.

INDIA BSS BASED ON INTERNATIONAL BSS DTD 21 NOV 18 EFFECTIVE FROM 22 JUN 2020.

PIVIKTO Digi poster/ ONCO/PIVIKTO/125956/12/07/2020

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