69TiP

MADELINE Asia: A Mobile App-Based Prospective Observational Study of Patient-Reported Outcomes in Advanced Breast Cancer in Asia

Anna Yin Ping Tai,[1] Manmohan Singh,[2] Justin Binko,[3] Kaylene Lilly,[4] Sean Chang,[5] Scott Bowles,[6] Mahmood Alam[7]

[1]Clinical Oncology, Queen Elizabeth Hospital, Hong Kong, China; [2]Pfizer Medical Affairs, Pfizer Inc, Quarry Bay, Hong Kong, PRC; [3]Pfizer Medical Affairs, Pfizer Inc, Melbourne, ACT, Australia; [4]Project Management, Parexel International Pty Ltd, North Ryde, NSW, Australia; [5]Biostatistics, Parexel International Pty Ltd, Taipei, Taiwan; [6]Account Services, Intouch Solutions, New York, NY, United States of America; [7]Pfizer Medical Affairs, Pfizer Inc, Sydney, ACT, Australia

Abstract Plain Language Summary
Please scan this quick response (QR) code with your smartphone app to view a plain language summary of the accepted scientific abstract.
https://epg-digital.com/u/esmoasia20-1

Electronic Poster
An electronic version of this poster may be obtained by scanning this QR code with your smartphone app. Copies of this e-poster obtained through the QR Code are for personal use only and may not be reproduced without written permission of the authors. To request permission or to ask questions about the poster, please contact typ065@ha.org.hk.

Background

- The incidence of breast cancer in Asia is rising.
- Recent advances in hormone receptor (HR)–positive and human epidermal growth factor receptor 2–negative (HR+/HER2–) advanced breast cancer (ABC) includes introduction of the CDK 4/6 inhibitors.
- Palbociclib was the first drug in this class to be introduced in Asia and is approved for use in ABC in combination with aromatase inhibitors (P+AI) as initial endocrine-based therapy in postmenopausal women or with fulvestrant (P+F) in women with disease progression following endocrine therapy.
- Globally, there have been few evaluations on the daily effects and patient-reported outcomes of palbociclib through real-world data studies.
- This information has been scarce in Asian patients.

Study Objectives

- Primary objective
  - To assess clinical outcomes and patient-reported outcomes (PROs) in women with locally advanced/unresectable or metastatic (ABC/mBC) HR+/HER2– breast cancer receiving palbociclib in combination with an aromatase inhibitor or fulvestrant as per local country label
- Secondary objectives
  - Characterize patients with HR+/HER2– ABC initiating treatment (e.g., baseline patient demographics and clinical characteristics [e.g., comorbidities, tumor stage, histology])
  - Describe changes in patients' general health status as measured by monthly (cycle-based) administration of the 12-Item Short Form Health Survey (SF-12)
  - Describe changes in patients' psychological distress as measured by monthly (cycle-based) administration of the Center for Epidemiological Studies Depression Scale (CES-D)
  - Describe the extent to which locally advanced or metastatic breast cancer and its treatment are associated with changes in patients' lives in terms of symptoms, functioning and QOL as measured by daily and weekly administration of targeted patient-reported questions
  - For patients who are employed at baseline, quantify time lost from work in relation to locally advanced or metastatic breast cancer and its treatment
  - Describe the incidence, severity, and duration of neutropenia; time to first neutropenia event changes in palbociclib dose and/or schedule
  - Explore the association between patient-reported functioning and neutropenia
  - Describe dosing patterns (e.g., reduction, interruptions, duration)
  - Describe neutropenia monitoring patterns

Methods

STUDY DESIGN (FIGURE 1)

- EU PAS Registration Number: EUPAS23593

PATIENT ELIGIBILITY

Inclusion Criteria

- Access to Apple iPhone (Version 8.0 or higher; with latest software iOS 11.0 or higher) or Android phone (Nexus or Galaxy with latest software version 6.x and 7.x or higher)
- Women (≥18 years of age) with proven diagnosis of adenocarcinoma of the breast with evidence of metastatic disease or locoregionally advanced disease not amenable to resection or radiation therapy with curative intent
- HR+/HER2–
- Initiating treatment with:
  - Palbociclib and aromatase inhibitor as per label
  - Palbociclib with fulvestrant as per label
- Personally signed and dated informed consent
- Able to read and understand English or Mandarin Chinese
- Willing and able to complete collection of data via mobile app

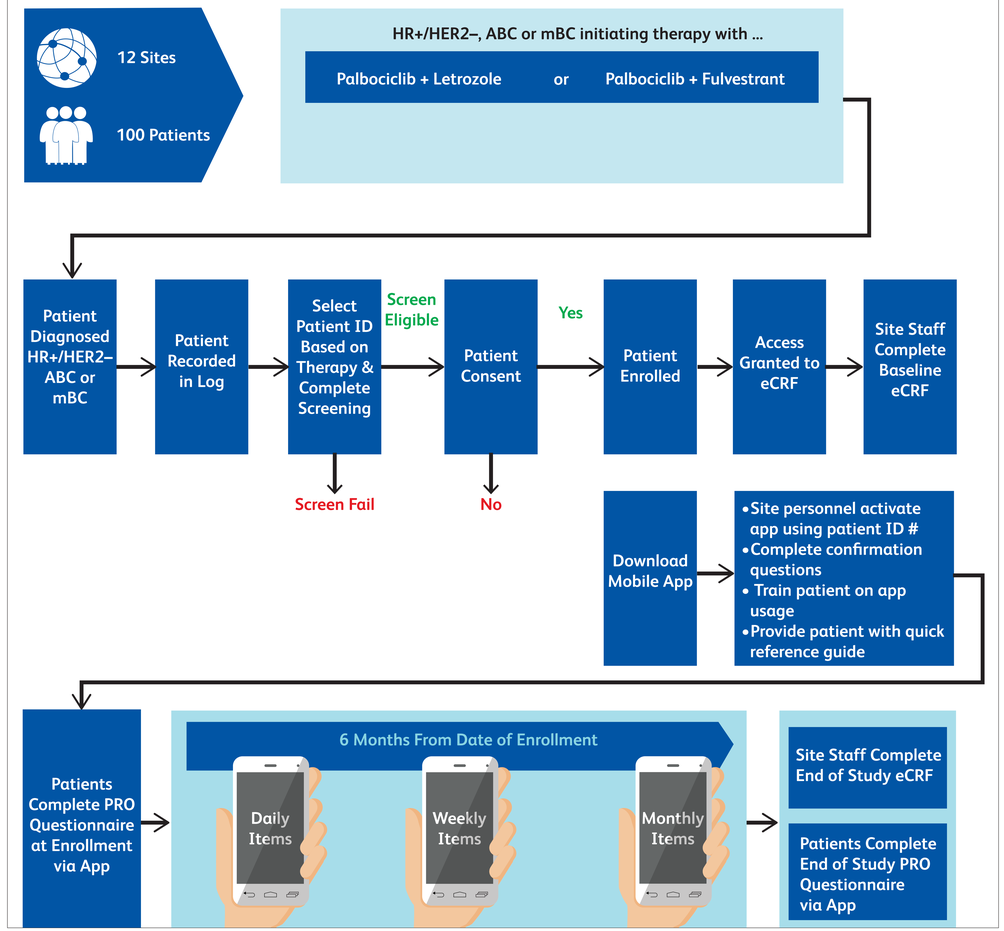
Exclusion Criteria

- Life expectancy is fewer than 3 months
- Patient is participating in any interventional clinical trial that includes investigational or marketed products
- Patients participating in other investigator-initiated research or non-interventional studies can be included as long as their standard of care is not altered by the study
- The patient is on active treatment for malignancies other than ABC or mBC

Patient-Reported Outcomes

- All patients will be asked to complete a baseline questionnaire, as well as a series of questions at daily, weekly, and monthly/cycle-based intervals via a mobile application downloaded onto their smartphones
- Two validated PRO instruments will be administered at baseline and monthly
  - 10-item short form of the Center for Epidemiologic Studies Depression Scale (CES-D-10)
  - 12-Item Short Form Health Survey (SF-12)

Figure 1. Study Design



Protocol Review – eCRF

- Sites will record clinical and treatment data from patients' medical records into an eCRF at baseline and at the end of the study period. Types of data to be obtained from patient charts will include:

Study Timelines & Duration

- Approximately 100 women with HR+/HER2– ABC/mBC who are initiating therapy will be enrolled into the study as per the following two indications:
  - Palbociclib + letrozole per local country label
  - Palbociclib + fulvestrant per local country label
- Study enrollment timelines are as follows:
  - First Patient In: November 2019
  - Last Patient In: May 2021
  - Last Patient Out: November 2021

Study Sites (Ongoing)

- Hong Kong
  - Hong Kong Integrated Oncology Centre
  - Hong Kong United Oncology Centre
  - Queen Elizabeth Hospital
- India
  - Manipal Hospital, Bengaluru
- Malaysia
  - Penang Adventist Hospital
  - Pantai Hospital Kuala Lumpur
  - Sunway Medical Centre
- Taiwan
  - National Cheng Kung University Hospital

Results

STUDY STATUS (TABLE 1)

Table 1. Study Status

Countries	Number of Sites Initiated	Number of Sites Activated	Number of Ongoing Subjects	Number of Withdrawn Subjects
Hong Kong	3	3	9	0
India	1	1	2	0
Malaysia	3	3	3	1
Taiwan	1	1	4	1
Total	**8**	**8**	**18**	**2**

Acknowledgements : Study sponsored by Pfizer Inc. The study team would like to thank Pfizer Global Medical Communications for their support. The support provided by Anny Wu, PharmD, of ICON plc (North Wales, PA, USA) and funded by Pfizer Inc, consisted solely of poster formatting and no contribution was made to editorial content.

Disclosures: Dr. Tai declares no conflicts of interest.

Presented at the European Society for Medical Oncology (ESMO) Asia Virtual Congress 2020 • November 20–22, 2020