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 (PAI) as initial endocrine-based therapy in premenopausal women or with fulvestrant (PFV) 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.

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 metastatic or locoregionally advanced disease not amenable to resection or radiation therapy with curative intent
- HR+/HER2−
- Initiating treatment with:
  - Palbociclib + 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 involves investigational or marketed products
- Patients participating in other investigator-initiated research or non-interventional studies can be included as long as 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)
  - Functional assessment of Patient-Reported Outcomes in Advanced Breast Cancer in Asia (TIP-ABC/BOCA)

Results

STUDY STATUS (TABLE 1)

Table 1. Study Status

<table>
<thead>
<tr>
<th>Countries</th>
<th>Number of Sites Initiated</th>
<th>Number of Sites Activated</th>
<th>Number of Ongoing Subjects</th>
<th>Number of Withdrawn Subjects</th>
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</thead>
<tbody>
<tr>
<td>Hong Kong</td>
<td>3</td>
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<td>9</td>
<td>0</td>
</tr>
<tr>
<td>India</td>
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</tr>
<tr>
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<tr>
<td>Total</td>
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<td>8</td>
<td>18</td>
<td>2</td>
</tr>
</tbody>
</table>

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: November 2019
    - Last Patient: May 2021
    - Last Patient: 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 Kuolai Lumpur
- Taiwan
  - Surgery Medical Centre
- China
  - National Cheng Kung University Hospital

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