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

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BACKGROUND

- Bravecto® (pembrolizumab) is a novel, polyvalent-dependent monoclonal IgG4 antibody approved in the United States for human use. Pembrolizumab blocks the PD-1 ligand, which is expressed on tumor-associated antigen-presenting cells such as dendritic cells and lymphocytes.

STUDY OBJECTIVES

- To assess PROs in women with locally advanced or metastatic breast cancer who are receiving ABC therapies, including the first class in clinical studies' pembrolizumab in real-world settings and to document the management of these therapies to determine the needs of this patient population.
- To determine the experience of patients initiating ABC therapies, including the first class in clinical studies' pembrolizumab in real-world settings and to document the management of these therapies to determine the needs of this patient population.
- To understand the experiences of patients initiating ABC therapies, including the first class in clinical studies' pembrolizumab in real-world settings and to document the management of these therapies to determine the needs of this patient population.
- To determine the utility of the virtual community at the conclusion of the observation event management, and monitoring.

STUDY DESIGN

- A prospective, observational, noninterventional multicenter study
- Participation in this study is not intended to change the routine treatment that patients receive as determined by their prescribing clinicians; all treatment decisions and type and timing of disease monitoring are at the discretion of the treating physician. No additional visits to the clinic will be required for the purposes of the study.

STUDY POPULATION

- Inclusion Criteria
  - Able to read and understand English
  - Documented evidence of an HER2– tumor based on the patient’s most recent tumor biopsy
  - Documented evidence of HR+ tumor based on the patient’s most recent tumor biopsy
  - Has been informed of all pertinent aspects of the study
  - In the judgment of the investigator, the patient’s life expectancy is at least 5 months
  - The patient is participating in any interventional clinical trial that includes investigational or marketed products. Patients participating in other investigator-initiated research or noninterventional studies can be included as long as their standard of care is not altered or marketed products. Patients participating in other investigator-initiated research or noninterventional studies can be included as long as their standard of care is not altered

- Exclusion Criteria
  - Patients meeting any of the following criteria will not be included in the study:
    - Patient is receiving investigational systemic therapy
      - In the judgment of the investigator, the patient’s life expectancy is <5 months at the time of diagnosis of ABC or MBC.
  - Patients participating in any interventional clinical trial that includes investigational or marketed products. Patients participating in other investigator-initiated research or noninterventional studies can be included as long as their standard of care is not altered
  - Patient is not in active treatment for other malignancies other than ABC or MBC
  - Patient will be reviewed, documented, and confirmed by an appropriately qualified member of the investigator’s study team before patients are enrolled in the study

STUDY DURATION

- It is anticipated that data collection for this study (Figure 2) will occur over a 12-month period from the first patient’s first visit to the last patient’s final visit (follow-up assessment) during the study period.
- The number of patients was chosen on a practical basis in conjunction with the ability to have reasonable precision around key estimates.
- No formal power calculation has been performed.
- This is an observational study designed to provide descriptive summary information and is not designed for hypothesis testing; as such, no formal power calculation has been performed.
- The number of patients was chosen on a practical basis in conjunction with the ability to have reasonable precision around key estimates.

SITE AND PATIENT ENROLLMENT

- Approximately 450 patients hep up to 10 US centers will be enrolled.
- Approximately 150 patients hep up to 5 US centers will be enrolled.
- As of November 15, 2016, 4 centers had been enrolled and were awaiting site initiation.
- No patients have been enrolled yet. Patient enrollment is expected to begin in December 2016.

SPONSOR

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