NON-INTERVENTIONAL STUDY REPORT ABSTRACT

Title: Understanding Early and Ongoing Treatment Utilization of Palbociclib in a US Community Oncology Setting

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Rationale and background: Palbociclib was approved in the United States in February 2015. Palbociclib is approved for treatment of hormone receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced or metastatic breast cancer in combination with: letrozole as initial endocrine based therapy in postmenopausal women, or fulvestrant in women with disease progression under accelerated approval based on progression-free survival (PFS). This study aimed to evaluate real world usage patterns of early palbociclib clinical prescribing.

Research question and objectives: To describe the demographic and clinical characteristics of patients who were prescribed palbociclib combination therapy for the treatment of HR+/HER2- metastatic breast cancer and to describe early treatment utilization including time to discontinuation.

Study design: A descriptive, retrospective longitudinal study of breast cancer patients newly initiating treatment with palbociclib.

Setting: Community oncology practices that are part of the US Oncology Network and utilize the full capabilities of the iKnowMed (iKM) electronic health record (EHR).

Subjects and study size, including dropouts: Adult breast cancer patients with a new prescription for palbociclib were identified in rolling two-month intervals during the 12 month period following palbociclib US approval.

Variables and data sources: Structured data were extracted from the iKM EHR database, which captures outpatient medical oncology practice encounter histories for patients under community-based care across over 19 states and 400 practice sites. No chart review was planned for this study. Data was handled in compliance with HIPAA.

Results: Overall, 1741 patients were identified as having newly started palbociclib during the first year post-approval. Median age at initiation of palbociclib treatment was 64 years, 94% were ER+/HER2-. The median Karnofsky performance status at time of treatment was 90%. The majority of patients had prior exposure to chemotherapy (57%) or endocrine treatment (84%) prior to palbociclib. Documented visceral metastases were present in 32% of patients and bone only metastases in 18%. Ninety-one percent of patients started palbociclib 125mg. Palbociclib was most frequently used in combination with letrozole (80%). Among patients with ≥1 CBC (n=1502), 39% and 8% of patients had neutrophil counts <1000 and <500 (grade 3/4 and grade 4), respectively. Among patients with at least 6 months of follow-up (n=886), 29% had a dose reduction at any time, 20% had discontinued treatment, and median time to discontinuation was 3.6 months.

Discussion: This research describes patient characteristics, dosing, and treatment patterns one year post-approval for patients receiving palbociclib. Given that novel metastatic therapies are often introduced and utilized by patients with few options, these patients are clinically more heterogeneous from the RCT cohort, and understanding use in clinical practice is critical to informing evidence-based practice. In this study, a higher proportion of patients had prior exposure to chemotherapy than patients in the RCT PALOMA-1 (57% vs. 40%). Likewise, prior endocrine treatment in this population was more than double that in the PALOMA-1 (84% vs. 32% respectively). This may reflect a limitation of the current analysis in that line of therapy was not able to be identified; thus, the patient populations may reflect use in later line patients. Despite a more heterogeneous population, the proportion of patients with reduction in neutrophil counts to <500 in this study was consistent with the reported frequency of grade 4 neutropenia in PALOMA-1 (8% vs. 6% grade 4 neutropenia, respectively). Additional analysis will be required after further duration of follow up is available to glean further insight from the real world treatment with palbociclib.