Sir,

Nearly, 80% of the breast cancers express estrogen receptors (ERs), progesterone receptors, or both. Endocrine therapies remain the backbone of the systemic treatment for hormone receptor positive cancers by substantially reducing the risk of relapse.[1] Many women still relapse during or after completing adjuvant therapy. Further systemic therapy remains considerably challenging for these patients. Fulvestrant, a selective ER modulator has modest activity in these patients[2,3] and the development of effective therapies that can reverse resistance to endocrine therapy, is of clinical importance.

Palbociclib (IBRANCE, developed by Pfizer) is an oral, reversible, selective, small-molecule inhibitor of cyclin-dependent kinases (CDK) 4, and CDK 6. CDKs are important modulators of cell cycle entry and progression in response to growth signals, and inhibition of these kinases with palbociclib could enhance the activity of other anticancer drugs in tolerable regimens.[4] On February 03, 2015, the USA Food and Drug Administration granted accelerated approval to palbociclib (IBRANCE, Pfizer, Inc.) for use in combination with letrozole for the treatment of postmenopausal women with ER-positive, human epidermal growth factor receptor 2 (HER-2)-negative advanced breast cancer as initial endocrine-based therapy for their metastatic disease.[5] This approval was based on encouraging results found in Phase III study PALOMA3. This Phase III randomized controlled study involved 521 patients with advanced hormone-receptor-positive, HER-2 neu negative breast cancer that had relapsed or progressed during prior endocrine therapy. Patients in a 2:1 ratio received palbociclib and fulvestrant or placebo and fulvestrant. The primary endpoint was progression-free survival and secondary endpoints were overall survival, objective response; patient reported outcomes and safety. A preplanned interim analysis demonstrated that median progression-free survival was in favor of palbociclib arm (9.2 months vs. 3.8 months hazard ratio for disease progression or death, 0.42; 95% confidence interval: 0.32–0.56; P < 0.001). The most common Grade 3 or 4 adverse events in the palbociclib-fulvestrant group were neutropenia (62.0%, vs. 0.6% in the placebo-fulvestrant group), leukopenia (25.2% vs. 0.6%), and anemia (2.6% vs. 1.7%), thrombocytopenia (2.3% vs. 0%), and fatigue (2.0% vs. 1.2%). Febrile neutropenia was reported in 0.6% of the palbociclib-treated patients and 0.6% of the placebo-treated patients. The rate of discontinuation due to adverse events was 2.6% with palbociclib and 1.7% with placebo.[6]

The recommended dose of palbociclib is a 125 mg capsule taken orally once daily for 21 consecutive days, followed by 7 days off treatment to comprise a complete cycle of 28 days. The common side effects are neutropenia, fatigue, anemia, nausea, stomatitis, alopecia, diarrhea, thrombocytopenia, decreased appetite, vomiting, asthenia, peripheral neuropathy, and epistaxis.

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Conflicts of interest

There are no conflicts of interest.

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