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Letter to editor

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Quick Response Code:

Dear Editor,

We read with interest the article by Bapna *et al.* on the real-world experience with palbociclib (first cyclin-dependent kinase 4/6 inhibitor receiving regulatory approval in India in October 2016) in their patients of breast cancer.[1]

It is heartening to note that targeted therapy has become the standard of care in several high-volume centers in India, matching what is recommended in many international guidelines. Bapna has treated 67 females over a period of <4 years. When such a large number can be treated at a single center in a tier two city of India in the real world, we have to wake up. It is evidence that blanket labeling of such medications as "expensive" or responsible for "financial toxicity" can no longer be used as a general excuse for failure to follow the standard of care in India, the SAARC region, and other low- and middle-income countries (LMICs).

Their data confirm previously published and well-established facts that outcome was better in patients with bony only metastasis (OS 22.7 months) as well as the use of palbociclib in the first line (OS of 23.2 months).

That radiological CR was documented in 11 cases is quite significant. Could it be additional evidence that a small but significant number of such patients can hope to be potentially cured?

The only significant adverse effect seen by them was neutropenia. Fortunately, this self-limiting side effect was reversed in all patients and palbociclib could not be restarted only in one patient, and that too because she had progressive disease. This is good documentation of this drug's safety in Indian patients.

Since India is an extremely price-sensitive market, let us delve deeper into some aspects of the economics of palbociclib treatment.[2,3] By the year 2018, Pfizer's annual sales for palbociclib touched USD 4.12 billion globally.[4,5] This was an impressive 32% increase over the previous year. On the other hand, several West European countries concluded that there were insufficient data regarding the benefit of palbociclib in saving lives or improving overall survival.[6-8] The incremental cost-effective ratio was found to be 88,854 USD/quality-adjusted life years (QALY) in the United States; 182,779 USD/QALY in China; and CHF301,227/QALY in Switzerland. Even when the parameter was reduced to months (instead of years; quality-adjusted life months – QALM), as compared to letrozole, the addition of palbociclib provided 14.7 QALM at an incremental cost of $161,508.[8,9]

To reduce the financial burden for patients with breast cancer, Pfizer launched a patient assistance program in Australia.[10] Eligible patients had to initially purchase palbociclib ($4,850 per pack × eight cycles = $38,800). Thereafter, Pfizer agreed to provide it free, as long as the patient continued to have clinical benefit. In China, Pfizer took a different approach. In this global No. 2 pharmaceutical market (projected to be $170 billion in 2023),[4] they launched a money-back

Table 1: Benefit of patient assistance programs in India – comparison when extrapolated to Pfizer's models in China and Australia * (all figures in INR) (*cost taken of full treatment without taking into consideration any dose interruptions or dose modification).

	If all patients had to pay the full cost	Indian model	China model	Australia model
		Pay for the first 10 months and then free till the duration of clinical benefit	If PD within 4 months, 33% refunded	Pay for the first 8 months and then free till the duration of clinical benefit
Bapna *et al*.'s 67 patients	54,270,000			
Saving under scheme	NA	30,240,000	445,500	36,450,000
Benefit to		Responders	Non-responders	Responders
Net revenue for Pfizer	54,270,000	24,030,000	5,824,500	17,820,000
Revenue reduction under Model	NA	55.72%	0.82%	67.16%

arrangement scheme (called Bo'ai Xin'an).[5] Here, if PD was seen in the first 4 months of starting palbociclib treatment, they will be refunded 33% of the cost incurred. This scheme was limited to the first 500 patients put on palbociclib. If this Chinese scheme was available to Bapna's patients, a total of 15 patients would have received a combined sum of INR 445,500/-. On the other hand, if their patients had access to the Australian model of patient assistance, Bapna *et al*.'s 67 patients would have spent only for the first 8 months of treatment – namely, Rs. 17,820,000/-, equivalent of Rs. 29,552 per month of treatment. However, the fact is that Pfizer's Indian patient assistance program requires patients to pay for the first 10 months of treatment.

To understand clearly, Table 1 compares the impact on cost with and without the Indian patient assistance program. We also compare what would be the impact if Australian or Chinese models were extrapolated to India.

In conclusion, palbociclib is used and results in benefits among Indian patients in the real world. It is well tolerated. The patient assistance program is a significant factor in reducing the financial burden. Such an approach is of value in bringing a standard of care to a wider group of breast cancer patients, especially in India, SAARC region, and other LMIC.[11]

Declaration of patient consent

Patient's consent not required as there are no patients in this study.

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Nil.

Conflicts of interest

Dr. Purvish Parikh is the Emeritus Editor of IJMIO.

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