



Budget impact analysis on new 3-year imatinib adjuvant treatment for patients with operable GIST at high risk of recurrence

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BACKGROUND

The results of Phase III -(SSG)XVIII/AIO- clinical study on Imatinib (IM) in adjuvant therapy of GIST show that, after five years of follow up, 3 years of therapy lead to 66% of patients free of recurrence compared to 48% who received IM for only one year, with a 18% relative risk reduction. This result will determine the new standard of 3 years of adjuvant IM therapy in GIST patients at high risk of recurrence.

PURPOSE

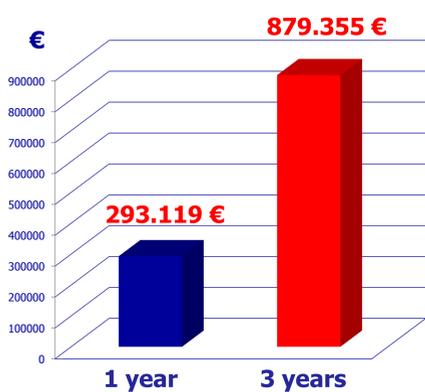
The aim of our study was to analyze the budget impact on Piedmont Region, on 3 years analysis, after the approval by the Italian National Regulatory Agency of 3 years adjuvant therapy in high risk GIST.

MATERIALS AND METHODS

The analysis was performed considering the estimated incidence of 60 new cases of GIST in Piedmont: 28 patients are at very low/low risk of relapse and don't need IM; 8 patients are at intermediate risk of recurrence and should receive IM only for 1 year; 12 patients are at very high/high risk and are treated with adjuvant IM for 3 years; 12 patients are metastatic at diagnosis and require therapy all lifelong (5-13 years). The price of IM considered in this study was fixed (6-2011) in the regional competition in Piedmont (16,7305 €/capsule 100 mg).

RESULTS

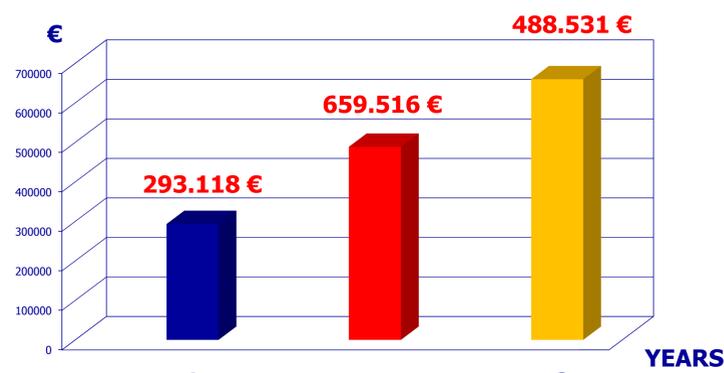
The annual expenditure for 12 very high/high risk patients is 293.118,6 € that adds up to a total of 879355,08 € in 3 years.



Given GIST stability in incidence (5 cases/1.000.000 people) and 30% drop off from therapy for intolerance as reported in SSG/AIO study.

The result of our study is:

- ✓ the first year 12 patients are treated with a whole cost of 293.118,36 €;
- ✓ the second year for 20 patients (8 of the first year + 12 new) the expenditure is 488.530,6 € (+66,66%);
- ✓ the third year there are 27 patients (7 of the first year, 8 of the second year, 12 new) and a total amount of 659.516,31 € (+35% compared to second year).



The very high/high risk patients total expenditure at the end of 3 years of observational study is 1.441.165,27 € and the overall incremental cost is +125%.

CONCLUSIONS

The cost of sanitary interventions in rare tumors should be carefully planned with a specific cancer and pharmacological registry. The availability of comprehensive databases or regional registries of these treatments would allow a more accurate analysis that takes into account both cost of medicines and ambulatory therapy and follow up cost. Even though data on current costs are alarming it is important to consider that IM in 2014 will lose the Novartis patent and costs will drop about 30-40%.