BUDGET IMPACT OF LEUPROLIDE ACETATE 3-MONTHLY DEPOT FORMULATIONS FOR THE MANAGEMENT OF PATIENTS WITH ADVANCED AND METASTATIC PROSTATE CANCER IN GREECE

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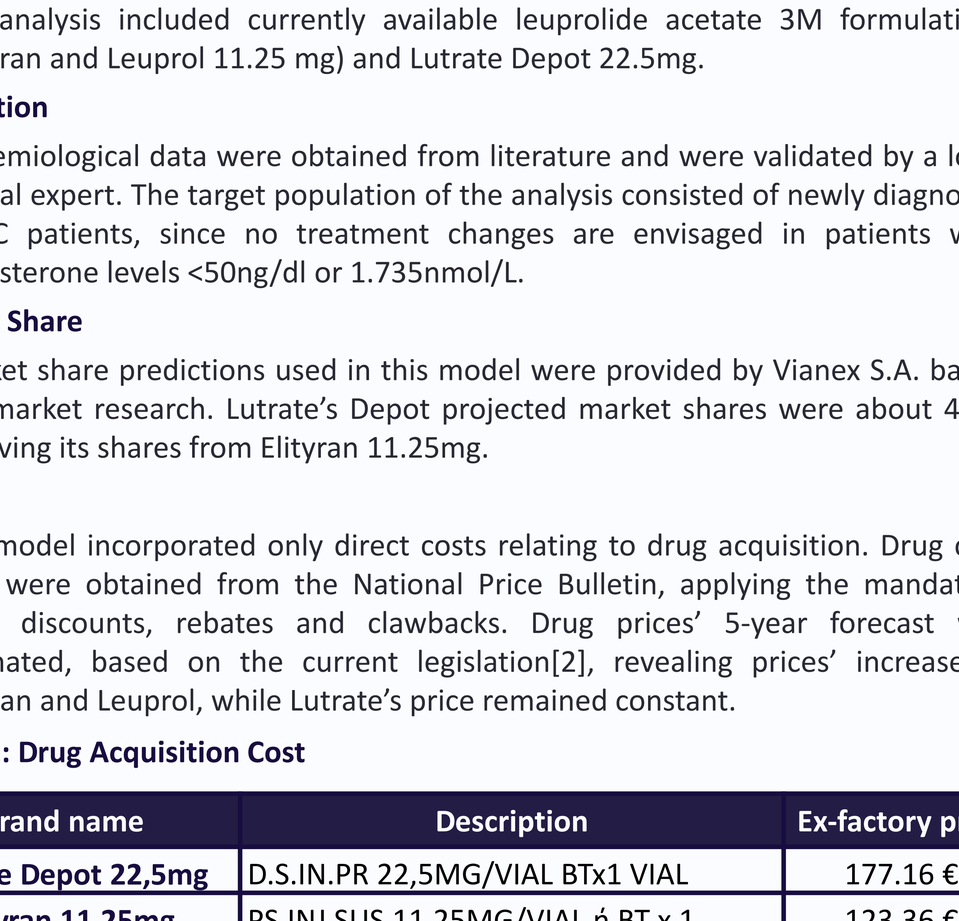
BACKGROUND

- Luteinizing hormone-releasing hormone (LHRH) agonists represent the main treatment for the management of patients with advanced and metastatic prostate cancer (amPC). Leuprolide, LHRH agonist, is used as first-line treatment in amPC.
- Lutrate Depot 22.5 mg comprising leuprolide acetate is an innovative pharmaceutical formulation product which has its own patent [1]. Lutrate Depot offers a unique novel system of leuprolide acetate extended and sustained release based in a double chamber control.
- The aim of this study was to evaluate the economic implications of leuprolide acetate 3-monthly (3M) depot formulations, from payer perspective in Greece (EOPYY).

METHODS

- A traditional budget-impact model with a 5-year time-horizon (2019-2023) was developed using Microsoft Excel.
- A scenario where the all currently available leuprorelide acetate 3M formulations are reimbursed for the indicated populations (Current Market) is compared with a scenario where Lutrate Depot 22,5 mg is also marketed and reimbursed (Revised Market). (Figure 1).

Figure 1: Model schematic



Comparators

- The analysis included currently available leuprolide acetate 3M formulations (Elityran and Leuprol 11.25 mg) and Lutrate Depot 22.5mg.

Population

- Epidemiological data were obtained from literature and were validated by a local clinical expert. The target population of the analysis consisted of newly diagnosed amPC patients, since no treatment changes are envisaged in patients with testosterone levels <50ng/dl or 1.735nmol/L.

Market Share

- Market share predictions used in this model were provided by Vianex S.A. based on market research. Lutrate's Depot projected market shares were about 45%, receiving its shares from Elityran 11.25mg.

Costs

- The model incorporated only direct costs relating to drug acquisition. Drug cost data were obtained from the National Price Bulletin, applying the mandatory price discounts, rebates and clawbacks. Drug prices' 5-year forecast was estimated, based on the current legislation[2], revealing prices' increase in Elityran and Leuprol, while Lutrate's price remained constant.

Table 1: Drug Acquisition Cost

Brand name	Description	Ex-factory price
Lutrate Depot 22,5mg	D.S.IN.PR 22,5MG/VIAL BTx1 VIAL	177.16 €
Elityran 11,25mg	PS.INJ.SUS 11,25MG/VIAL ή BT x 1	123.36 €
Leuprol 11,25mg	PS.INJ.SUS 11,25MG/VIAL: BTx1 VIAL	85.64 €

Source: Price Bulletin February 2019

RESULTS

- The estimated number of patients eligible to receive leuprolide was 914 in the first model year and 4,883 patients over a 5-year horizon; 414 and 2,197 on Lutrate Depot, respectively (Figure 2). Among the total of 4,883 patients estimated to be on treatment, ~20.6% (1,007 patients) were incident patients and ~79.4% were receiving leuprolide throughout the model horizon (Figure 3).
- Introduction of Lutrate Depot in the market would lead to budget savings of €5,171 to €117,747 in the first and fifth model-years, respectively (Figure 4).
- The cumulative budget-impact over 5-years resulted in cost-savings of €129,071 for the payer (€6,194,671 vs €6,323,742).
- The model yielded average annual cost-savings of 5.9% compared to the current treatment scenario.

Figure 2: Estimated number of patients per treatment

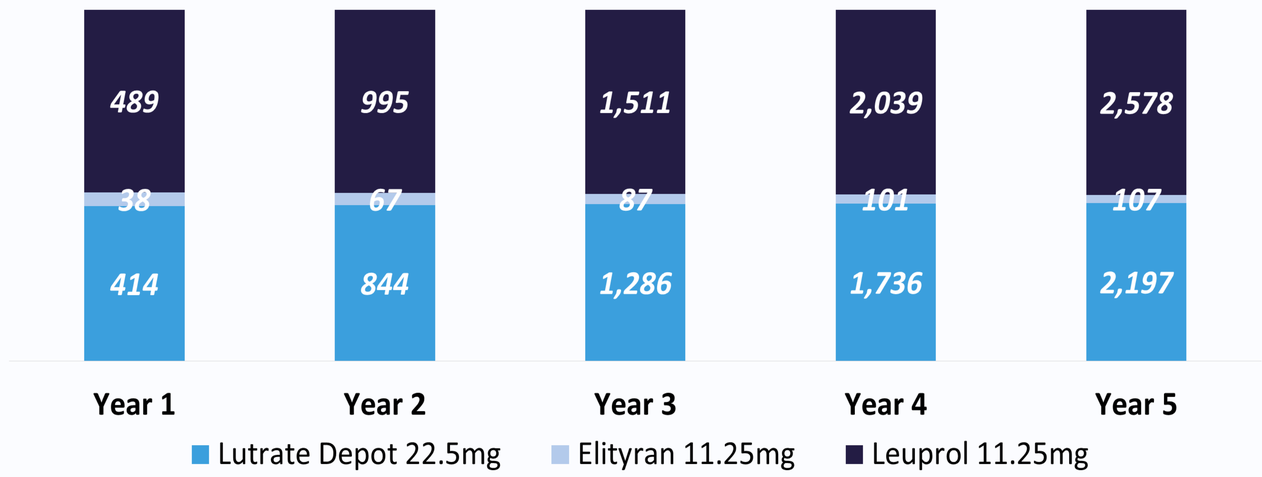


Figure 3: Absolute budget impact

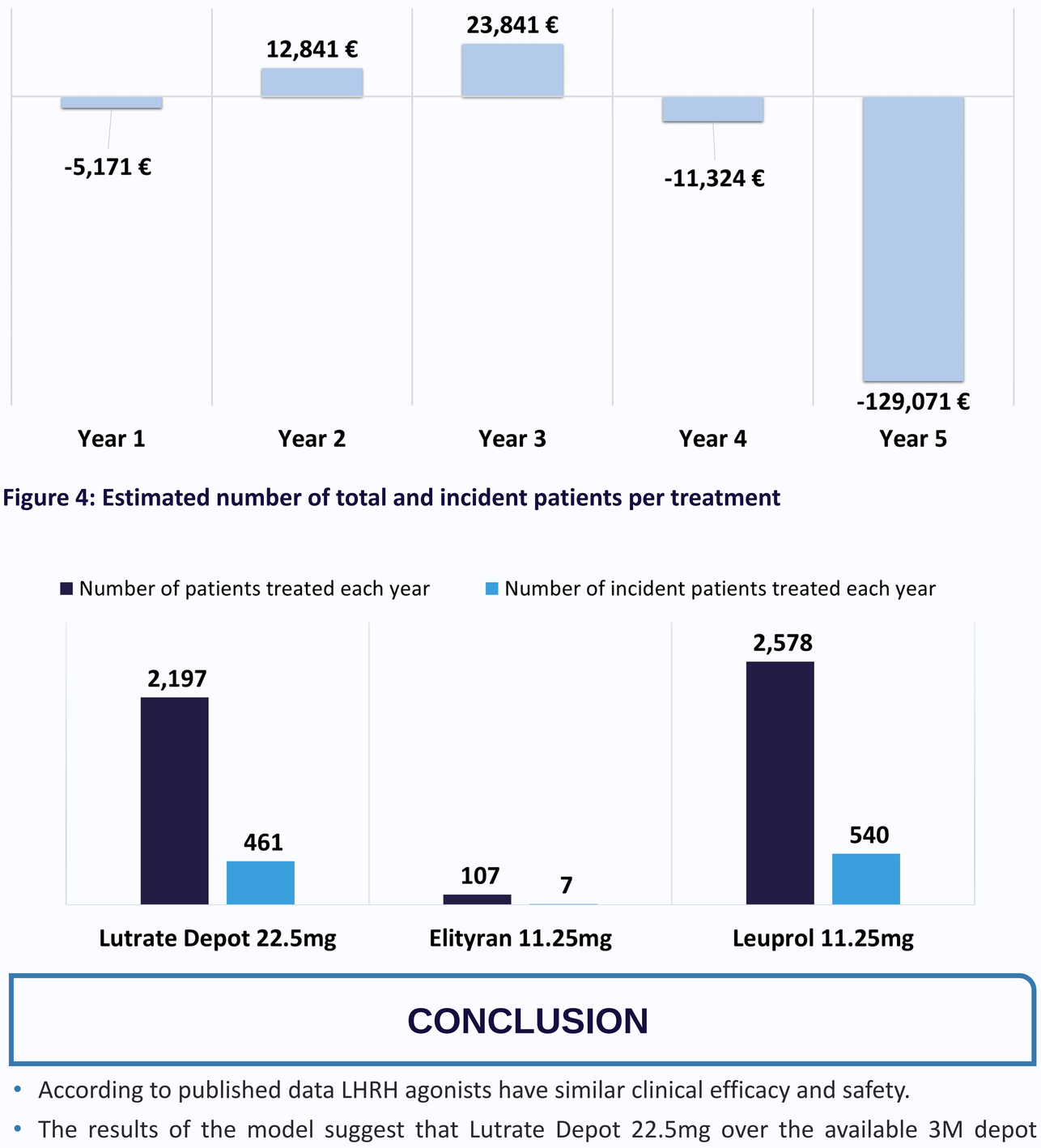
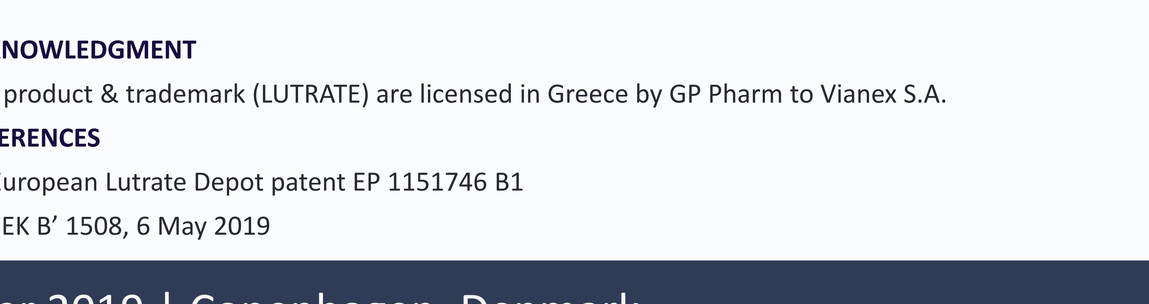


Figure 4: Estimated number of total and incident patients per treatment



CONCLUSION

- According to published data LHRH agonists have similar clinical efficacy and safety.
- The results of the model suggest that Lutrate Depot 22.5mg over the available 3M depot formulations could lead to considerable savings for EOPYY; consisting Lutrate Depot 22.5mg an alternative cost-saving treatment option for eligible amPC patients in Greece.

ACKNOWLEDGMENT

The product & trademark (LUTRATE) are licensed in Greece by GP Pharm to Vianex S.A.

REFERENCES

1. European Lutrate Depot patent EP 1151746 B1
2. FEK B' 1508, 6 May 2019