

CONFIDENTIAL

**External Assessment Group Report commissioned by the
NIHR Evidence Synthesis Programme on behalf of NICE**

**Relugolix for treating hormone-sensitive prostate cancer
[ID6187]**

**Addendum 4 to the EAG report:
Additional analysis to the relative risk of MACE for
comparators post-factual accuracy check**

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| Date completed | 29/04/2024 |

Confidential information from the company submission is highlighted in blue.

1 Introduction

In this addendum, we performed additional analyses to investigate the sensitivity of the ICER to the relative risk of MACE. We used the EAG preferred assumptions and PAS discount for relugolix to identify threshold values for the relative risk of MACE at which the cost-effectiveness conclusions change, based on £20,000 and £30,000 per QALY decision thresholds. In section 2 we report the threshold analysis for the base case population and in section 3 we show the same threshold analysis focusing on the metastatic HSPC subgroup.

2 Base case population

Table 1 **Error! Reference source not found.** details the ICER by relative risk of MACE from 0.95 to 1 (no treatment effect). Figure 1 below shows illustrates this relationship, with relative risk of MACE estimates from references in the company submission and EAG base case and scenarios indicated.

Table 1 Relative risk of MACE with the PAS discount for relugolix

| Relative Risk of MACE | ICER (£ per QALY gained) |
|-----------------------|--------------------------|
| 0.9500 | ■ |
| 0.9600 | ■ |
| 0.9761 | ■ |
| 0.9800 | ■ |
| 0.9879 | ■ |
| 0.9900 | ■ |
| 0.9950 | ■ |
| 1.0000 | ■ |

Abbreviations: ICER, incremental cost-effectiveness ratio; MACE, major cardiovascular events

We note:

- There is a slow increment in the ICER up to a relative risk of MACE value of 0.9 (see Figure 1). Varying the relative risk from 0.38 (HERO trial estimate and EAG Base case) to 0.9 increases the ICER by £2,287.
- There is asymptotic behaviour above a relative risk MACE value of 0.9 (Figure 1).

- The EAG base case ICER remained below £20,000 per QALY with the relative risk of MACE [REDACTED] and below £30,000 per QALY gained (remained cost-effective) with the relative risk of MACE [REDACTED].

3 Subgroup with spinal metastases

We repeated this analysis for the metastatic HSPC subgroup and estimated the net monetary benefits of relugolix versus GnRH agonists and degarelix versus GnRH agonists as a function of the MACE relative risk. We considered willingness-to-pay (WTP) thresholds of £20,000 and £30,000 per QALY, see Figure 2.

- For a WTP of £20,000, the net monetary benefit for Relugolix versus GnRH agonists [REDACTED] up to the relative risk of MACE [REDACTED]. Considering a WTP equal to £30,000, the net monetary benefit [REDACTED].
- For WTP equal to £20,000, the net monetary benefit for Degarelix versus GnRH agonists [REDACTED] up to the relative risk of MACE [REDACTED]. Considering a WTP equal to £30,000, the net monetary benefit [REDACTED].

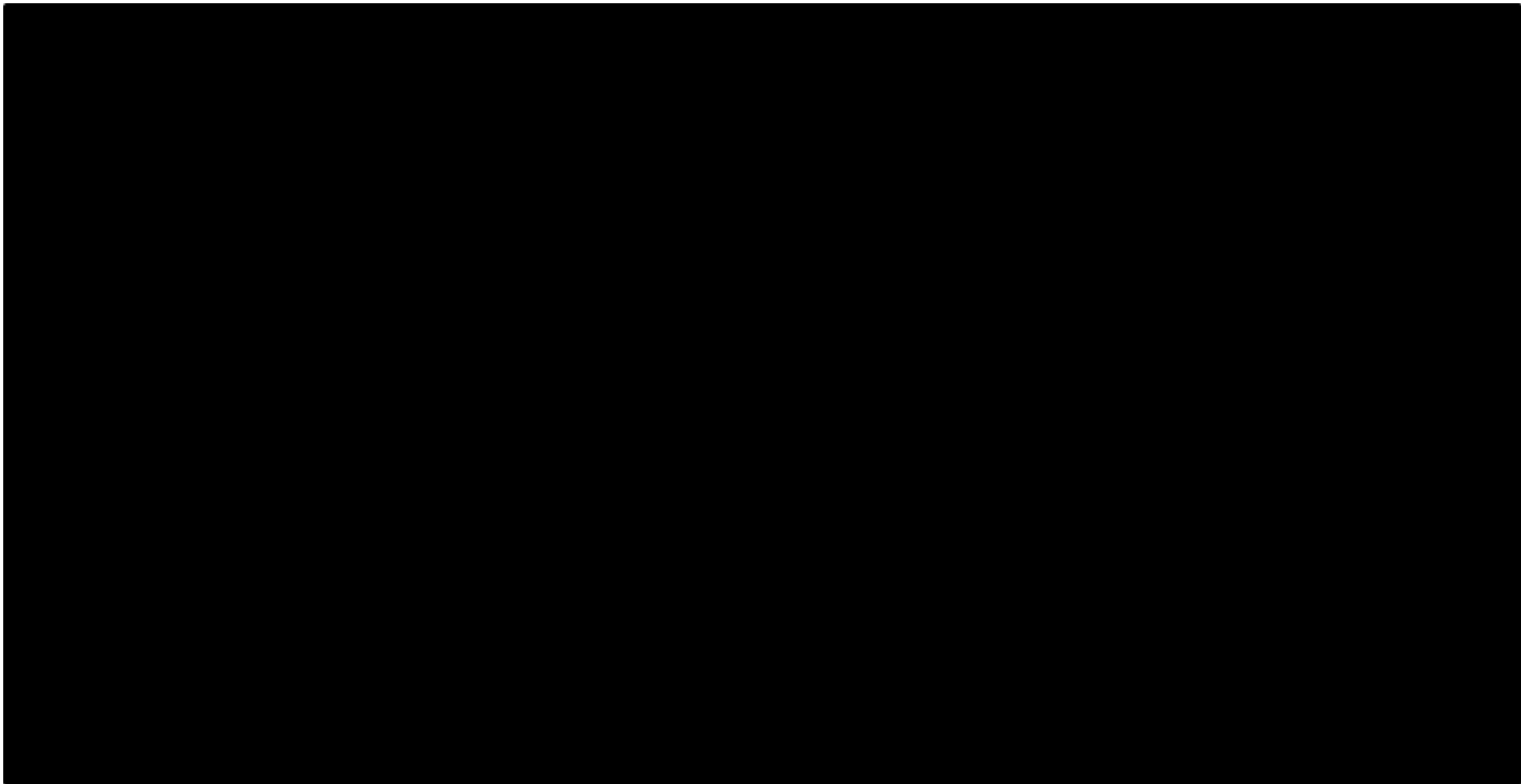


Figure 1 Threshold analysis for MACE relative risk: EAG preferred analysis with PAS discount for relugolix
ICER (Relugolix vs. GnRH agonists) by relative risk of MACE

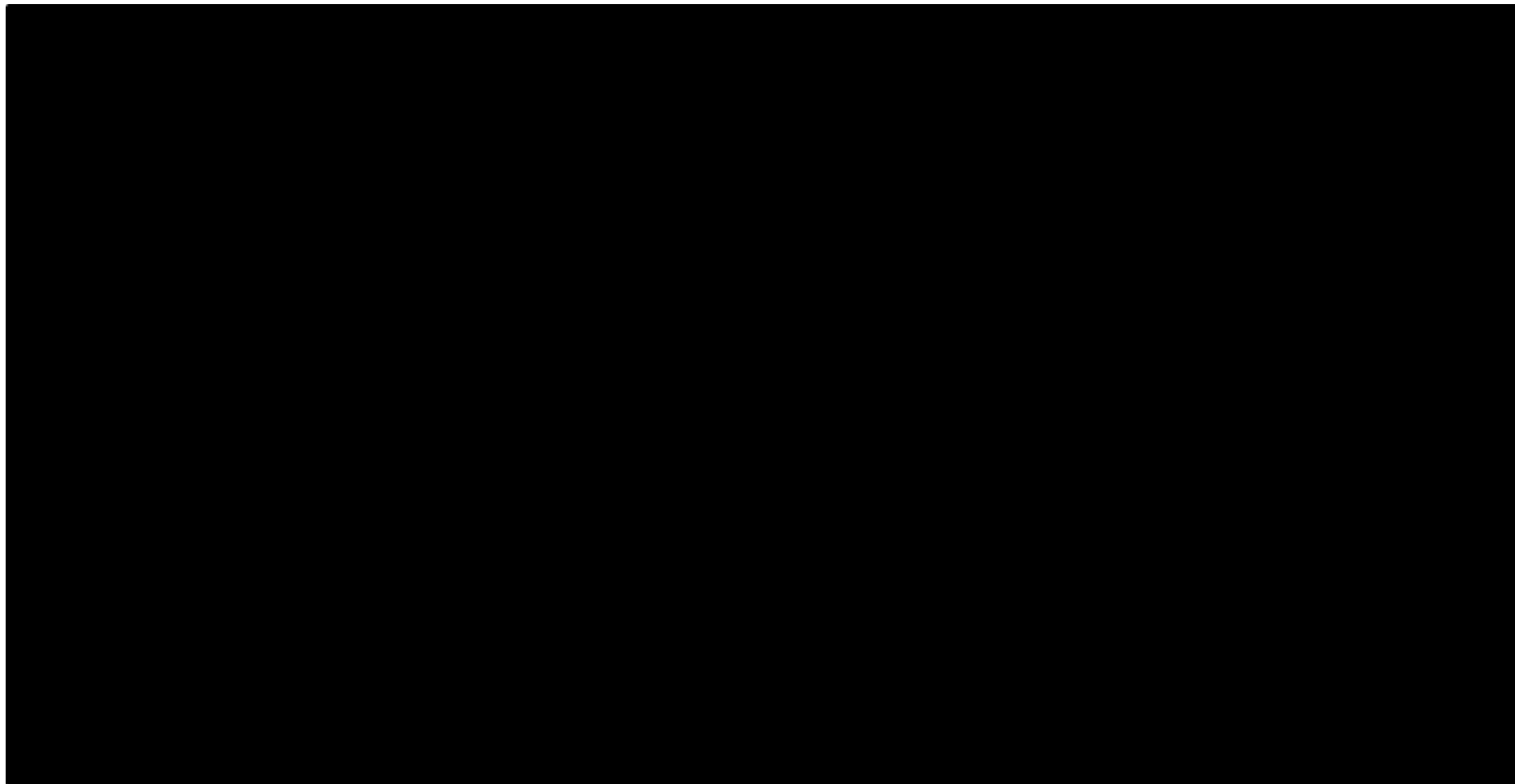


Figure 2 Threshold analysis for MACE relative risk: EAG preferred assumptions with PAS discount
Net monetary benefit (Relugolix vs. GnRH agonists and Degarelix vs. GnRH agonists)