Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma

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Addendum:

22 Mar 2017

Confidential information that is commercial-in-confidence is [redacted].

Contents

1 Background to this STA

We submitted our final report for this STA to NICE on 9th March 2017.

Cost-effectiveness results were presented for two comparisons:

- OlaDox and Dox
- OlaDox and IfoDox

On 10 March, 2017, we received a request from NICE to critique Lilly's additional analysis incorporating a Commercial Access Agreement (CAA) scheme.

Lilly wrote in the CAA submission that [redacted]

Olaratumab is currently available as 50 mL vial (contains 500 mg of olaratumab). The list price is £1,000 excluding VAT.

[redacted]

[redacted]

In response to above, we agreed with the figure of [redacted]

[redacted] NHSE have a contract with Public Health England to fund SACT data analysis to support use of medicines within the CDF. We have no information on whether Lilly would be asked to bear any of the cost of the SACT data analysis, and so do not include it in the ICER calculations in this Addendum.

The only change Lilly has made to their base case in their recent analysis is incorporating the CAA.

In this addendum, we first present our critique of Lilly's most recent results. We then describe our base case modified in light of the CAA, and report the results of sensitivity analyses.

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2 Cost-effectiveness results

2.1 Critique of Lilly's base case results, with the CAA

Lilly's base-case ICERs with and without the CAA are as follows:

- For OlaDox vs. Dox comparison, the respective ICERs are [redacted] and [redacted] per QALY gained.
- For OlaDox vs. IfoDox comparison, the ICERs are [redacted] and [redacted] per QALY gained.

We have checked the updated base-case results and the results of the most important sensitivity analyses provided by Lilly, and found an error. It relates to [redacted]

[redacted]

2.1.1 [redacted]

The assumption of only 500mg vial of Ola available results in the acquisition cost per administration of [redacted] including VAT of 20%). Assuming availability of both vial sizes decreases the cost per administration to [redacted] with VAT). The difference in the cost per administration with VAT included is [redacted]. These estimates are based on the assumption of the mean patient weight of 82.5 kg as per PenTAG base case.

Assuming the mean patient weight of 77.3 kg as in Lilly's base case, the relevant acquisition costs per Ola administration are [redacted] VAT inclusive) and [redacted] with VAT), and the difference is [redacted] (including VAT)), i.e., almost identical to as when assuming the mean weight of 82.5 kg.

2.1.2 [redacted]

[redacted]

Correction of this error:

- decreases the ICERs for both comparisons by about £300 which is a minor change to the base-case ICERs
- increases [redacted]

2.2 PenTAG base case results incorporating the CAA

Our base case is derived by the same changes as to Lilly's model that we presented in our main report, with the exception that we now assume availability of both vial sizes (see Table 1). [redacted]

Table 1: Derivation of PenTAG base case ICERs (£ per QALY), with the CAA scheme applied

					OlaDox vs. Dox	**IfoDox**
		PenTAG's assumption in the base case	**Lilly's base case**	**Reference**	[redacted]	[redacted]
1	Parametric survival function for OS	Log-normal	Gamma	Section 5.3.5.1.2, p**Error! Bookmark not defined.**.	[redacted]	NA as the model uses a fractional polynomial function for the indirect comparison
2	Coefficients of fractional polynomials estimated in NMA	Mean values	Median values	Section 5.3.5.2 p**Error! Bookmark not defined.**.	[redacted]	[redacted]
3	Patients' mean weight	82.5 kg	77.3 kg	Section 5.3.7.1, p**Error! Bookmark not defined.**	[redacted]	[redacted]
4	Ifo prices	£66.08 and £130.04 for 1g and 2g vials, respectively	£91.32 and £179.88 for 1g and 2g vials, respectively	Section 5.3.7.1.2**.** p**Error! Bookmark not defined.**	[redacted]	[redacted]

5	Mesna prices	£9.77 and £3.95 for 1000mg and 400mg vial, respectively	£29.41, and £13.41 for 1000mg vial and 400mg vial, respectively	Section 5.3.7.1.2**.** p148	[redacted]	[redacted]
6	HRG codes and unit costs	Corrected		Section 5.3.7.2, p**Error! Bookmark not defined.**.	[redacted]	[redacted]
Overall: 1+2+3+4+5+6	PenTAG base case				[redacted]	[redacted]

2.3 Sensitivity analyses

The results of sensitivity analyses conducted by the ERG summarised in Table 2. These are the same sensitivity analyses as in our original report except a SA for availability of vial sizes.

Table 2: Sensitivity analyses, with the CAA scheme applied

	OlaDox vs. Dox	**OlaDox vs. IfoDox**
Utility values from the Amdahl and Delea studies	[redacted]	[redacted]
Weibull OS	[redacted]	[redacted]
Gompertz OS	[redacted]	[redacted]
Treatment costs post-progression (2)	[redacted]	[redacted]
Treatment costs post-progression (1.5)	[redacted]	[redacted]
PenTAG base case	[redacted]	[redacted]
Patients mean weight	[redacted]	[redacted]
Gamma OS	[redacted]	[redacted]

	OlaDox vs. Dox	OlaDox vs. IfoDox
Cost of the Ola monotherapy in the Dox arm	[redacted]	[redacted]

The sensitivity analyses are applied individually to the ERG's updated base case. They are as follows:

- The utility values taken from the Amdahl and Delea studies are 0.674 and 0.349 for PFS and PPS respectively from Table 60 (p **Error! Bookmark not defined.**)
- Weibull, Gompertz, and gamma OS curves change the ERG's base case from the log-normal OS curve to the respective choice.
- Two scenario analyses assuming that treatment costs in PD depend on survival, and:
    - if the mean time from progression to death is doubled, the treatment cost is multiplied by 1.5;
    - if the mean time from progression to death is doubled, the total cost is also doubled.
- Patients' mean weight adjusts the mean weight of patients back to the Lilly base case of 77.3kgs.
- Costing the Ola monotherapy in the Dox arm. This is done by multiplying the fraction of Dox patients in the JGDG study who switched to Ola monotherapy by their mean number of infusions (10.6) and costing the infusions and administrations as usual. Administrations are assumed to be Ola monotherapy infusions for costing purposes.

2.4 Uncertainty in cost-effectiveness

We conducted probabilistic sensitivity analyses for the updated PenTAG base case. The results for both comparisons, mean probabilistic ICERs and probabilities of cost-effectiveness of OlaDox at different thresholds are presented below.

2.4.1 OlaDox vs. Dox

The mean probabilistic ICER for OlaDox and Dox comparison is [redacted] per QALY gained. The probability of OlaDox being cost-effective at £20,000 and £30,000 per QALY gained is

[redacted] At the threshold of £50,000 per QALY, OlaDox is cost-effective with the probability of [redacted]

2.4.2 OlaDox vs. IfoDox

The mean probabilistic ICER for OlaDox vs. IfoDox is [redacted] per QALY gained. The probability of OlaDox being cost-effective at £20,000 and £30,000 per QALY gained is [redacted] and [redacted] respectively.