**National Institute for Health and Care Excellence**

**Health Technology Evaluation**

# Mirvetuximab soravtansine for treating folate receptor alpha-positive platinum-resistant advanced epithelial ovarian, fallopian tube or primary peritoneal cancer [ID6442]

## Response to stakeholder organisation comments on the draft remit and draft scope

**Please note:** Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how recommendations are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its officers or advisory committees.

**Comment 1: the draft remit and proposed process**

| Section | Stakeholder | Comments [sic] | Action |
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| Appropriateness of an evaluation and proposed evaluation route | AbbVie | AbbVie agrees with the approach to evaluate mirvetuximab via the single technology appraisal (STA) process. | Comment noted. No action required. |
| Wording | AbbVie | AbbVie has no comments on the suggested remit as the remit covers the anticipated licensed indication.<br><br>The license wording is anticipated to be: [redacted] | Comment noted. No action required. |

| Section | Stakeholder | Comments [sic] | Action |
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| | | [redacted] | |
| Timing | AbbVie | There is a high unmet need for patients with platinum-resistant ovarian cancer who have a poor prognosis and the worst survival outcomes among patients with ovarian cancer, with a median overall survival of ≤12 months (1). Currently, there are limited treatment options with no targeted treatment available in this population. Mirvetuximab soravtansine offers a highly effective and innovative treatment option for patients with platinum-resistant ovarian cancer, and is the first targeted therapy to demonstrate a significant overall survival benefit in a Phase III trial in platinum-resistant ovarian cancer vs standard of care (2). As such, the NHS and patients would benefit from mirvetuximab soravtansine being prioritised for evaluation and are pleased that this is reflected in the current NICE scheduling. | Comment noted. No action required. |
| | Ovacome | There is an urgent need for patients who have platinum resistant epithelial ovarian cancer to be able to access effective treatment options to improve progression free survival. Therefore we feel that is imperative that Mirvetuximab soravtansine is evaluated. | Comment noted. No action required. |
| | Ovarian Cancer Action | One woman dies of ovarian cancer in the UK every two hours. Ovarian Cancer Action believes this appraisal should go ahead in a timely manner so as to give women facing a diagnosis the best chance at survival. | Comment noted. No action required. |

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| | Target Ovarian Cancer | There are few treatment options for platinum resistant ovarian cancer. With around 70 per cent of those with ovarian cancer experiencing a recurrence which may then become resistant to platinum it is vital that more treatment options are available to this underserved population as soon as possible. | Comment noted. No action required. |

**Comment 2: the draft scope**

| Section | Consultee/ Commentator | Comments [sic] | Action |
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| Background information | **AbbVie** | AbbVie propose the change in bold to clarify the proportion of patients expressing FRα.<br><br>"Approximately 80% of epithelial **recurrent** ovarian cancers express FR-alpha **and approximately 32% show high FR-alpha expression (2)**." | Comment noted. This has been added to the text. |
| | Ovarian Cancer Action | It would be useful to include the proportion of patients who are/ who become platinum resistant.<br><br>Details about the effectiveness of the options currently available for platinum resistant recurrent disease would help set the scene for patients in this position.<br><br>Please include information about the testing process and testing availability for folate receptor alpha expression.<br><br>Please include dosage information and how the drug is administered (inc. | Comment noted. The background section is intended to provide a brief summary of the condition. The issues raised in these comments will be explored during the appraisal. No further action is needed. |

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| | | frequency), as this should factor into health-related quality of life assessment as a frequently mentioned concern by our supporters. | |
| Population | AbbVie | As highlighted above, the license wording is anticipated to be: [redacted]. Therefore, the population in the draft scope covers the anticipated licensed indication.<br><br>†To be considered positive for FRα expression, ≥75% of viable tumour cells must exhibit 2 and/or 3 membrane staining intensity (2). | Comment noted. The text has been updated to include the threshold for positive FRα expression used in the pivotal trial. |
| Subgroups | AbbVie | AbbVie have clinical evidence available for the subgroups mentioned in the draft scope and can provide this evidence should they be required.<br>Number of previous lines of therapy was a stratification factor used in randomisation while the rest of the subgroups mentioned in the draft scope were not stratification factors. | Comment noted. No action required. |
| | Target Ovarian Cancer | HRD status should also be considered along with BRCA status | NICE is not aware of any evidence to suggest that the clinical or cost effectiveness of mirvetuximab soravtansine differs by HRD status. HRD |

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| | | | status has not been added as a subgroup. |
| Comparators | AbbVie | AbbVie agree that pegylated liposomal doxorubicin hydrochloride (PLDH) monotherapy and paclitaxel monotherapy are relevant comparators to mirvetuximab soravtansine. | Comment noted. No action required. |
| Outcomes | AbbVie | AbbVie considers the listed outcomes to be appropriate. | Comment noted. No action required. |
| | Ovacome | Yes, as long as the health-related quality of life outcome also captures the psychological benefits of being able to access an effective treatment choice for people with platinum resistant epithelial ovarian cancer. There is an awareness among our community that there are a lack of effective treatment options for platinum resistant ovarian cancer. Being told that their cancer is platinum resistant is a source of deep distress to many of our members. They have shared their concerns that treatment options are limited and lines of treatment to control the disease will be exhausted leaving symptom control only. Being able to access effective treatment options offers a significant psychological benefit as well as physical health benefits. | Comment noted. The company and other stakeholders are welcome to submit evidence regarding any health-related benefits that may not be captured in standard economic analysis. |
| | Target Ovarian Cancer | Quality of life should be broader than health related, Ovarian cancer can impact family and other personal relationships as well work volunteering and hobbies all of which can affect quality of life | As noted in the NICE manual for health technology evaluations, NICE's assesses the impact of treatments on the NHS and personal |

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| | | | social services. This includes the health effects for both patients and, when relevant, their carers (including family). Any wider societal and economic impacts are considered only in exceptional circumstances. No action required. |
| Equality | AbbVie | None identified. | Comment noted. No action required. |
| Other considerations | AbbVie | No comments | No action required. |
| Questions for consultation | AbbVie | **Is rechallenge with platinum-based chemotherapy used for people with platinum resistant disease (that is, cancer that has relapsed within 6 months of completion of platinum-based chemotherapy)?**<br>There is a paucity of data from randomised trials in understanding whether people with platinum-resistant disease can be rechallenged with platinum-based chemotherapy. | Comment noted. No action required. |

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| | | **Would paclitaxel with platinum chemotherapy or pegylated liposomal doxorubicin hydrochloride with platinum chemotherapy be relevant comparators for people with platinum resistant cancer?**<br>UK clinicians have indicated that paclitaxel with platinum chemotherapy or PLD with platinum chemotherapy are not relevant comparators for people with platinum-resistant cancer.<br>In the NICE appraisal TA389 (3), the committee considered paclitaxel, PLD, and topotecan, all given as monotherapy for platinum-refractory or platinum-resistant disease, and they were not considered in combination with platinum chemotherapy.<br>Furthermore, the 2024 BGCS guidelines state: “In the platinum refractory / resistant setting there does not appear to be any advantage in using combination therapies, which are associated with higher rates of adverse events” (4).<br><br>**Where do you consider mirvetuximab soravtansine will fit into the existing care pathway for folate receptor alpha-positive platinum-resistant advanced epithelial ovarian, fallopian tube or primary peritoneal cancer?**<br>In line with the anticipated licensed indication, mirvetuximab soravtansine is expected to be a treatment for [redacted] | Comment noted. No action required.<br><br>Comment noted. No action required. |

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| | | The population in the draft scope covers the anticipated licensed indication.<br><br>**Would the treatment pathway for this population be different depending on whether the person had maintenance treatment following chemotherapy?**<br>Feedback from UK clinicians did not suggest that there would be a difference in treatment strategy for this population, regardless of whether the person had maintenance treatment following chemotherapy.<br><br>**Please select from the following, will mirvetuximab soravtansine be:**<br>**A. Prescribed in primary care with routine follow-up in primary care**<br>**B. Prescribed in secondary care with routine follow-up in primary care**<br>**C. Prescribed in secondary care with routine follow-up in secondary care**<br>**D. Other (please give details):**<br>Option C – prescribed in secondary care with routine follow-up in secondary care. | Comment noted. No action required.<br><br>Comment noted. No action required. |

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| | | **For comparators and subsequent treatments, please detail if the setting for prescribing and routine follow-up differs from the intervention.**<br>The comparators and subsequent treatments are prescribed and monitored in the same way as the intervention. | Comment noted. No action required. |
| | | **Would mirvetuximab soravtansine be a candidate for managed access?**<br>The preferred funding of mirvetuximab for patients with platinum-resistant ovarian cancer is through routine NHS funding via baseline commissioning. AbbVie does not consider managed access appropriate given the maturity of the survival data supporting the submission, which comes from a Phase 3 randomised controlled trial. | Comment noted. No action required. |
| | | **Do you consider that the use of mirvetuximab soravtansine can result in any potential substantial health-related benefits that are unlikely to be included in the QALY calculation?**<br>**Please identify the nature of the data which you understand to be available to enable the committee to take account of these benefits.**<br>No comments. | Comment noted. No action required. |
| Additional comments on the draft scope | **AbbVie** | In the economic analysis row, the first sentence seems to be misplaced as an instruction text and could be removed. Additionally, AbbVie propose adding clarification to the FRa expression: "~~**If there is a companion diagnostic that is not already in routine use in the**~~ | Comment noted. The text has been updated to include the threshold for positive |

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| | | ~~**NHS, include the following sentences: ‘**~~The use of mirvetuximab soravtansine is conditional on the high expression of folate receptor alpha (≥75% Ps2+). The economic modelling should include the costs associated with testing for folate receptor alpha expression in people with ovarian cancer who would not otherwise have been tested. A sensitivity analysis should be provided without the cost of the diagnostic test. See section 4.8 of the guidance development manual (available here: **https://www.nice.org.uk/process/pmg36/chapter/introduction-to-health-technology-evaluation).”** | FRα expression used in the pivotal trial. |

**The following stakeholders indicated that they had no comments on the draft remit and/or the draft scope**

N/A