## NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## **Appraisal consultation document**

## Abemaciclib with fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy

The Department of Health and Social Care has asked the National Institute for Health and Care Excellence (NICE) to produce guidance on using abemaciclib with fulvestrant in the NHS in England. The appraisal committee has considered the evidence submitted by the company and the views of non-company consultees and commentators, clinical experts and patient experts.

This document has been prepared for consultation with the consultees. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from the consultees and commentators for this appraisal and the public. This document should be read along with the evidence (see the <u>committee</u> <u>papers</u>).

The appraisal committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound and a suitable basis for guidance to the NHS?
- Are there any aspects of the recommendations that need particular consideration to ensure we avoid unlawful discrimination against any group of people on the grounds of race, gender, disability, religion or belief, sexual orientation, age, gender reassignment, pregnancy and maternity?

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#### Note that this document is not NICE's final guidance on this technology. The recommendations in section 1 may change after consultation.

After consultation:

- The appraisal committee will meet again to consider the evidence, this appraisal consultation document and comments from the consultees.
- At that meeting, the committee will also consider comments made by people who are not consultees.
- After considering these comments, the committee will prepare the final appraisal document.
- Subject to any appeal by consultees, the final appraisal document may be used as the basis for NICE's guidance on using abemaciclib with fulvestrant in the NHS in England.

For further details, see NICE's guide to the processes of technology appraisal.

The key dates for this appraisal are:

Closing date for comments: 5 March 2021

Second appraisal committee meeting: TBC

Details of membership of the appraisal committee are given in section 5

## 1 Recommendations

- 1.1 Abemaciclib plus fulvestrant is not recommended, within its marketing authorisation, for treating hormone receptor-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced breast cancer in adults who have had endocrine therapy.
- 1.2 This recommendation is not intended to affect treatment with abemaciclib plus fulvestrant that was started in the Cancer Drugs Fund before final guidance was published. For those people, abemaciclib with fulvestrant will be funded by the company until they and their NHS clinician consider it appropriate to stop.

#### Why the committee made these recommendations

This appraisal reviews the additional evidence collected as part of the Cancer Drugs Fund managed access agreement for abemaciclib plus fulvestrant for treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy (<u>NICE technology appraisal guidance 579</u>). Abemaciclib with fulvestrant will no longer be available in the Cancer Drugs Fund for this indication after final guidance is published.

People with hormone receptor-positive, HER2-negative advanced breast cancer usually have exemestane plus everolimus after endocrine therapy.

Additional clinical trial evidence was collected while abemaciclib plus fulvestrant was in the Cancer Drugs Fund. But some people in the trial had a higher dose of abemaciclib than would normally be used, so it is uncertain how well the drug will work in clinical practice.

There is also uncertainty because there is no evidence directly comparing abemaciclib plus fulvestrant with exemestane plus everolimus. An indirect comparison suggests that people having abemaciclib plus fulvestrant have longer before their disease progresses and live longer than people having exemestane plus

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everolimus. Also, it is unclear how long people would have treatment for, and therefore how much the treatments would cost.

Because of these uncertainties the cost-effectiveness estimates vary. The most likely estimates are higher than what NICE considers a cost-effective use of NHS resources. Therefore, abemaciclib plus fulvestrant is not recommended.

## 2 Information about abemaciclib with fulvestrant

### Marketing authorisation indication

2.1 Abemaciclib (Verzenios, Eli Lilly) is indicated 'for the treatment of women with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy. In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.'

### Dosage in the marketing authorisation

2.2 The dosage schedule is available in the <u>summary of product</u> <u>characteristics</u>.

#### Price

- 2.3 The list price for abemaciclib is £2,950 per 28-day cycle: £1,475 per 28-tablet pack, or £2,950 per 56-tablet pack of 150 mg tablets; £1,475 per 28-tablet pack, or £2,950 per 56-tablet pack of 100 mg tablets; and £1,475 per 28-tablet pack, or £2,950 per 56-tablet pack of 50 mg tablets (excluding VAT; BNF online, accessed January 2021).
- 2.4 The list price for fulvestrant is £522.41 for two 250 mg/5 ml pre-filled syringes of solution for injection, which equates to £1,044.82 for the first cycle, and £522.41 for subsequent cycles (excluding VAT; BNF online, accessed January 2021).

Appraisal consultation document – Abemaciclib with fulvestrant for treating advanced hormone receptor-positive, HER2-negative breast cancer after endocrine therapy Page 4 of 19 2.5 The company has a commercial arrangement (simple discount patient access scheme). This makes abemaciclib available to the NHS with a discount and it would have also applied to this indication if the technology had been recommended. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

## 3 Committee discussion

The <u>appraisal committee</u> considered evidence submitted by Eli Lilly, a review of this submission by the evidence review group (ERG) and responses from stakeholders. See the <u>committee papers</u> for full details of the evidence.

The appraisal committee was aware that several issues were addressed during the technical engagement stage, and agreed that:

- Costs and resource use codes for the comparator, subsequent treatments, drug administration costs, treatment of adverse events, disease monitoring, terminal care and hospitalisation used in the model were acceptable after an update by the company and minor corrections made by the ERG.
- There was unresolvable heterogeneity in the indirect treatment comparison.
- The quality-of-life data from the previous analysis of MONARCH 2 are acceptable, since new data from MONARCH 2 were not available.
- The price of fulvestrant paid by the NHS was not available to the company and is confidential. It was provided to NICE by NHS England and used in the analyses presented to the committee in the closed session. It is lower than list price.

The committee recognised that there were remaining areas of uncertainty associated with the analyses presented (see ERG report table 1, page 11), and took these into account in its decision making. It discussed issues 1, 4 and 5, which were outstanding after the technical engagement stage, and the usefulness of the systemic anti-cancer therapy data collected through the Cancer Drugs Fund.

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## **Clinical pathway**

## There is a population who could benefit from abemaciclib plus fulvestrant

- 3.1 Advanced breast cancer is an incurable condition and the aim of treatment is to delay progression and extend survival. Most people who do not need urgent treatment with chemotherapy are offered endocrine therapy as initial treatment, in line with NICE's guideline on advanced breast cancer. After initial endocrine therapy, people can have exemestane plus everolimus before progressing to chemotherapy, though adverse events limit the use of everolimus. People who have had endocrine therapy and are eligible for exemestane plus everolimus as their next treatment may instead have 1 of 3 CDK4/6 inhibitor treatments, each with fulvestrant, through the Cancer Drugs Fund (see NICE's technology appraisal guidance on abemaciclib, ribociclib and palbociclib). In NICE's original technology appraisal guidance on abemaciclib for advanced disease after endocrine therapy, clinical experts explained that CDK4/6 inhibitors would not be used twice in the treatment pathway. This is because of the potential for tumours becoming resistant. The clinical experts said that the main groups of people who could benefit from abemaciclib plus fulvestrant after previous endocrine treatment for advanced disease are those whose:
  - disease has progressed on or within 12 months of neoadjuvant or adjuvant endocrine therapy (because they are not eligible for CDK4/6 inhibitors with aromatase inhibitors in the NHS)
  - advanced disease is progressing slowly on endocrine therapy.

They noted that, through the Cancer Drugs Fund, abemaciclib plus fulvestrant could also be offered later in the treatment pathway, after chemotherapy. The patient experts explained that it would be a backwards step if abemaciclib plus fulvestrant was not recommended for routine commissioning. The committee concluded that there is a

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population who could benefit from abemaciclib plus fulvestrant being routinely available.

## People with advanced breast cancer value a choice of CDK4/6 inhibitors after endocrine therapy

3.2 Patient and clinical experts explained that CDK4/6 inhibitors were welcomed by patients because they can delay disease progression and so delay or avoid the need for chemotherapy. This is desirable because chemotherapy side effects can substantially reduce quality of life. Extending survival can give people valuable extra time with family and friends. The patient experts explained that exemestane plus everolimus, the comparator, was poorly tolerated and used for only a small number of people, because it has similar effects to chemotherapy on quality of life. They also noted that although abemaciclib plus fulvestrant can cause debilitating diarrhoea and other side effects, these can usually be managed and are preferable to having chemotherapy. The patient and clinical experts preferred having a choice of CDK4/6 inhibitors because they have different side-effect profiles and people can change to a different option if needed. The committee concluded that having a choice of treatments that extend how long people live before their disease progresses and delay chemotherapy is valued by people who have already had endocrine therapy.

### **Clinical evidence**

## Data from the group who start on the licensed dose are the most relevant

- 3.3 MONARCH 2 is a phase 3, multinational, placebo-controlled, double-blind trial. It enrolled women with hormone receptor-positive, HER2-negative locally advanced or metastatic breast cancer whose disease had progressed on neoadjuvant or adjuvant endocrine therapy, either:
  - 12 months or less from the end of adjuvant endocrine therapy or

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• while having first-line endocrine therapy for metastatic disease.

Because of adverse events (diarrhoea), a protocol amendment was made after 26.6% of patients were enrolled. This changed the starting dose of abemaciclib from 200 mg to 150 mg, both twice per day. At the time of the protocol amendment anyone still on 200 mg had their dose reduced to 150 mg. In total, 446 patients were enrolled to have abemaciclib plus fulvestrant (pre-amendment n=121, post-amendment n=325) and 223 to have placebo plus fulvestrant (pre-amendment n=57, post-amendment n=166). The company considered it appropriate for the committee to use data from the full trial population in its decision making, rather than from separate pre- and post-amendment groups. The company provided:

- the median dose for the pre- and post- amendment groups
- · the median time to dose reduction and
- results from an interaction test after adjustments for multiplicity and baseline confounding factors.

These were marked confidential, and cannot be reported here. The company did not believe that the outcomes in the subgroups could reasonably be attributed to the starting dose used. It stated that starting dose is not a treatment effect modifier. The company further explained that worldwide regulators have used data that included all patients. Also, clinical advice to the company was that it would be inappropriate to analyse the groups separately, or exclude patients recruited before the amendment. The clinical experts said that they would not expect abemaciclib's efficacy to differ between the 150 mg and 200 mg doses, and clinical outcomes with the 2 doses were similar in practice. A larger study of 150 mg abemaciclib plus an aromatase inhibitor, which is now routinely commissioned, showed clear efficacy at that dosage. They also explained that a higher dose for a short time at the start of treatment was not likely to confer a long-term advantage, because CDK4/6 inhibitors work through long-term suppression of tumour growth. The ERG noted

that the 150 mg starting dose is in the marketing authorisation and will be Appraisal consultation document – Abemaciclib with fulvestrant for treating advanced hormone receptor-positive, HER2-negative breast cancer after endocrine therapy Page 8 of 19

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used in clinical practice. It emphasised that the post-amendment group is methodologically robust since the trial was redesigned to be powered to detect a difference in progression-free survival between abemaciclib plus fulvestrant and placebo plus fulvestrant in this group. The committee did not consider that the company's interaction test was sufficient evidence to support using the full trial population. It also noted that the patient baseline characteristics provided by the company were not likely to account for the difference in efficacy reported, but that not all characteristics were provided. The committee considered that the ERG had made a coherent case that the post-amendment group was methodologically robust. It discussed whether there was a genuine dose effect, or whether differences between the groups were because of chance or baseline imbalances. It considered whether the differences might be greater in the placebo arm than in the treatment arm, but this was difficult to determine. The committee understood the challenges of interpreting the MONARCH 2 clinical data given the protocol amendment. It preferred to use the post-amendment group data to estimate the clinical effectiveness of abemaciclib plus fulvestrant because:

- this group included only people who had the licensed dose of abemaciclib
- the trial was redesigned and adequately powered to detect a treatment effect for progression-free survival in this group.

The committee considered that excluding data from the 26.6% of people who were recruited before the amendment was justified. It concluded that data from those recruited after the amendment, who started on the licensed dose, were more relevant than data for the full trial population.

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## **Clinical effectiveness**

## Abemaciclib plus fulvestrant improves progression-free survival but the improvement in overall survival is less certain

- 3.4 In the <u>original NICE technology appraisal guidance for abemaciclib plus</u> <u>fulvestrant</u>, abemaciclib plus fulvestrant statistically significantly improved progression-free survival compared with placebo plus fulvestrant in the full trial population. The effect of abemaciclib plus fulvestrant on overall survival was not statistically significant. It was concluded that more mature data from MONARCH 2 could resolve uncertainty around this outcome. More data from MONARCH 2 have now been collected, and were analysed in June 2019. This analysis included an additional 28 months of data compared with the original appraisal:
  - Median follow up was 47.7 months.
  - Median progression-free survival was 16.87 months with abemaciclib plus fulvestrant compared with 9.27 months with placebo plus fulvestrant.
  - Median overall survival was 46.72 months for abemaciclib plus fulvestrant and 37.25 months for placebo plus fulvestrant.

This analysis confirmed the previous progression-free survival results for the full trial population. The progression-free survival data for the pre- and post-amendment groups were marked academic in confidence and cannot be reported here. The updated data from MONARCH 2 also showed that abemaciclib plus fulvestrant statistically significantly improved overall survival compared with placebo plus fulvestrant (hazard ratio [HR] 0.757, 95% confidence interval [CI] 0.606 to 0.945). The improvement in overall survival was smaller in the post-amendment group than in the preamendment group. The company explained that it was likely that any differences in outcomes seen when comparing subgroups were the result of differences in baseline characteristics between subgroups, and random variation. The committee agreed that the explanation for the different

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clinical results between the pre- and post-amendment groups was uncertain. This was because it could not be determined if the differences were because of a genuine dose effect, or because of chance or baseline imbalances. It concluded that abemaciclib plus fulvestrant improved progression-free survival compared with placebo plus fulvestrant. But the improvement in overall survival was less certain in the post-amendment group data, which the committee preferred (see section 3.3).

## Clinical effectiveness data from the SACT dataset is less relevant than the updated MONARCH 2 data for decision making

- 3.5 The company presented observational data from the systemic anti-cancer therapy (SACT) dataset for 876 people who had abemaciclib plus fulvestrant through the Cancer Drugs Fund:
  - Median follow up was only 4.4 months, because more mature MONARCH 2 data became available, which were suitable for decision making.
  - Median treatment duration was 10.2 months and the median overall survival was not reached.
  - Fewer people were alive at 12 months after having abemaciclib plus fulvestrant compared with those who had treatment in MONARCH 2.

The SACT data were not included in the company's economic analysis. The company explained that the difference in the number of people alive at 12 months may be because people having treatment through the Cancer Drugs Fund were generally older and frailer than those in MONARCH 2. Also, they may have had treatment later in the pathway or when disease was more advanced. The company also highlighted that people with visceral disease may be offered abemaciclib plus fulvestrant over other CDK4/6 inhibitors because there is evidence of efficacy for this group. The company noted that the data were immature, and since there was no comparator arm, the relative efficacy was unknown. The ERG agreed with most points and considered that MONARCH 2 was the more

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robust evidence source. The clinical experts agreed that the relative efficacy from MONARCH 2 was generalisable and provided the most robust clinical evidence for decision making. The committee concluded that the SACT data were too immature and that clinical effectiveness data from MONARCH 2 were more appropriate for decision making.

#### Indirect treatment comparison

## Data from the post-amendment group from MONARCH 2 should be used to estimate the clinical effectiveness of abemaciclib plus fulvestrant

3.6 There were no trials directly comparing abemaciclib plus fulvestrant with exemestane plus everolimus. So, the company presented fractional polynomial network meta-analyses in line with the committee's preferred assumptions. These meta-analyses incorporated the updated MONARCH 2 data for progression-free and overall survival for the full trial population. The results were based on the post-amendment group at technical engagement, at the ERG's request. The fractional polynomial network meta-analyses for progression-free and overall survival showed that abemaciclib plus fulvestrant improved progression-free and overall survival compared with exemestane plus everolimus for the full trial population. The ERG highlighted that progression-free and overall survival with abemaciclib plus fulvestrant were shorter in the post-amendment group than for the full trial population. So, taking into account the heterogeneity and uncertainty across the network, the size of these benefits was highly uncertain. The committee recalled its preference to use the post-amendment group data to estimate the clinical effectiveness of abemaciclib with fulvestrant (see section 3.3). It concluded that data from the post-amendment group from MONARCH 2 should be used to estimate the clinical effectiveness of abemaciclib plus fulvestrant compared with exemestane plus everolimus.

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## The company's economic model

## Data from the post-amendment group from MONARCH 2 should be used to estimate the cost effectiveness of abemaciclib plus fulvestrant

3.7 The company used fractional polynomial network meta-analysis data that used the full trial population from MONARCH 2 in its economic model for progression-free and overall survival (see section 3.6). The ERG was concerned that this may have overestimated the treatment effects compared with clinical practice. It emphasised that this did not fully reflect the licensed dose that would be used in clinical practice. The ERG preferred to use fractional polynomial network meta-analysis data that used the post-amendment group from MONARCH 2 in the economic model. The committee was aware that the results of the model were highly sensitive to the choice of clinical effectiveness data for abemaciclib plus fulvestrant. Also, using only the post-amendment group data gave a much lower estimate of abemaciclib's clinical effectiveness compared with using the full trial population data. The committee was not persuaded that the company's approach was more appropriate, since the trial was redesigned and powered to detect an effect in progression-free survival in the post-amendment group (see section 3.3). The committee concluded that the post-amendment group data should be used in the economic model. But it recognised that the cost-effectiveness results were highly sensitive to the choice of clinical effectiveness data for abemaciclib plus fulvestrant.

## The appropriate modelling approach for time to treatment discontinuation for abemaciclib plus fulvestrant is uncertain

3.8 In the <u>original NICE technology appraisal guidance for abemaciclib with</u> <u>fulvestrant</u> there was uncertainty around how long people had treatment with abemaciclib plus fulvestrant (time to treatment discontinuation). Also, the company's model underestimated the treatment duration and therefore the treatment costs of abemaciclib plus fulvestrant. This was

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because the company used data from the full trial population, including those who were enrolled before the protocol amendment. Also, people on the lower dose stopped treatment less often because they had fewer adverse events. During that appraisal, the committee suggested that discontinuation should be estimated using the post-amendment group data, because this used the lower licensed dose with fewer side effects, and more data could be collected on this outcome. In the current appraisal, the company used updated discontinuation data from the postamendment group as requested. It calculated a hazard ratio to apply to the progression-free survival curve for abemaciclib plus fulvestrant. The progression-free survival curve was generated by the fractional polynomial network meta-analysis for use in the model (see section 3.6). The hazard ratio was calculated using the discontinuation data from the post-amendment group and the progression-free survival data from the full trial population. The ERG was concerned that the inconsistency in data sources could overestimate the hazard ratio. This was because it considered that progression-free survival was shorter in the postamendment group. Also, the curves for the time to treatment discontinuation in the post-amendment group and progression-free survival in the full trial population were close together. At technical engagement, the company calculated 6 potentially useful hazard ratios using a lifetime survival model or a restricted means methodology. These hazard ratios were based on:

- progression-free survival data and time to treatment discontinuation data from the full trial population, and separately from the postamendment group or
- using full trial progression-free survival data and post-amendment time to treatment discontinuation data.

The company continued to prefer using the hazard ratio generated by the lifetime survival model. It also continued to use the full trial progression-free survival data and post-amendment time to treatment discontinuation

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data, as it had used in its base case. The ERG preferred the restricted means analysis using the post-amendment data, because it had a better visual fit with the Kaplan–Meier curves from MONARCH 2. The company explained that the trial data could not be used directly in the model because data were not available for all the comparators. The committee concluded that the most appropriate modelling approach to estimate time to treatment discontinuation for abemaciclib plus fulvestrant was uncertain.

## The appropriate modelling approach for time to treatment discontinuation for exemestane plus everolimus is uncertain

3.9 In the original NICE technology appraisal guidance for abemaciclib with fulvestrant, the company estimated a hazard ratio for the time to treatment discontinuation for exemestane plus everolimus compared with progression-free survival. To do this, it used the median progression-free survival and median time to treatment discontinuation from BOLERO 2, a phase 3 randomised controlled trial comparing exemestane plus everolimus with exemestane alone. The hazard ratio was applied to the progression-free survival curve for exemestane plus everolimus generated by the fractional polynomial network meta-analysis, which was used in the model. The company's original model was not set up to model time to treatment discontinuation for exemestane and everolimus separately. This was a limitation because people tended to stop treatment with everolimus because of adverse events but continued to have exemestane. This affected cost effectiveness because everolimus is considerably more expensive than exemestane. In this appraisal, the ERG preferred to use a different approach. It calculated a hazard ratio and applied it to the fractional polynomial network meta-analysis progression-free survival curve to estimate the exemestane plus everolimus time to treatment discontinuation curve in the model. The ERG and the company agreed on the method used to derive the hazard ratio of 1.58 from the BOLERO 2 data at technical engagement. The company used the hazard ratio of 1.58

in its base case but also presented 3 alternative scenarios. The ERG Appraisal consultation document – Abemaciclib with fulvestrant for treating advanced hormone receptor-positive, HER2-negative breast cancer after endocrine therapy Page 15 of 19

agreed that 1 of these was potentially plausible. The plausible scenario was based on clinical opinion from the Cancer Drugs Fund review of NICE's technology appraisal guidance on ribociclib with fulvestrant for hormone receptor-positive, HER2-negative, advanced breast cancer. It assumed that 20% of people stopped everolimus after 6 months, and 70% of those remaining on treatment had a dose reduction (10 mg to 5 mg) but continued exemestane until disease progression. The clinical experts noted that the change at 6 months seemed implausible because people would be more likely to stop gradually throughout the first 6 months. The committee said that BOLERO 2 data, even if not based on individual patient data from the trial, were preferable to the opinion of 1 clinician. The committee was aware that the results of the economic model were highly sensitive to the assumption used to estimate the time to treatment discontinuation for exemestane plus everolimus. It concluded that there was uncertainty about the most appropriate method to estimate time to treatment discontinuation for exemestane plus everolimus.

#### **Cost-effectiveness results**

## The cost-effectiveness estimates are uncertain, but are higher than what NICE considers cost effective

3.10 The company's base-case incremental cost-effectiveness ratio (ICER) was within what NICE considers a cost-effective use of NHS resources when the relevant confidential discounts were applied. These were the patient access scheme discounts for abemaciclib and everolimus, and the NHS England price for generic fulvestrant. Using the ERG's preferred assumptions, the ICER increased to above the range NICE normally considers a cost-effective use of NHS resources. This was irrespective of the approach used to estimate time to treatment discontinuation for exemestane plus everolimus (see section 3.9). Its preferred assumptions were:

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- applying the hazard ratio to generate the time to treatment discontinuation curve for abemaciclib plus fulvestrant (see section 3.8)
- using the post-amendment group efficacy data for abemaciclib plus fulvestrant (see section 3.7) and
- removing the half-cycle correction.

Taking into account the confidential discounts and the committee's preference for using the post-amendment group efficacy data for abemaciclib plus fulvestrant, the ICERs were all over £30,000 per quality-adjusted life year (QALY) gained. The committee concluded that all the ICERs were higher than what NICE considers a cost-effective use of NHS resources.

### **Cancer Drugs Fund**

#### Abemaciclib plus fulvestrant cannot remain in the Cancer Drugs Fund

3.11 The aim of a Cancer Drugs Fund guidance review is to decide whether or not the drug can be recommended for routine use. Abemaciclib plus fulvestrant for treating advanced hormone receptor-positive, HER2negative breast cancer after endocrine therapy cannot remain in the Cancer Drugs Fund once the guidance review has been completed (see section 6.19 of the guide to the processes of technology appraisal).

#### **Other factors**

3.12 NICE's advice about life-extending treatments for people with a short life expectancy did not apply.

#### Conclusion

#### Abemaciclib plus fulvestrant is not recommended for routine use

3.13 The committee concluded that the most plausible cost-effectiveness estimates are higher than what NICE considers a cost-effective use of NHS resources. So, abemaciclib with fulvestrant is not recommended for

Appraisal consultation document – Abemaciclib with fulvestrant for treating advanced hormone receptor-positive, HER2-negative breast cancer after endocrine therapy Page 17 of 19 treating hormone receptor-positive, HER2-negative advanced breast cancer after endocrine therapy.

## 4 Proposed date for review of guidance

4.1 NICE proposes that the guidance on this technology is considered for review by the guidance executive 3 years after publication of the guidance. NICE welcomes comment on this proposed date. The guidance executive will decide whether the technology should be reviewed based on information gathered by NICE, and in consultation with consultees and commentators.

Jane Adam Chair, appraisal committee February 2021

# 5 Appraisal committee members and NICE project team

## Appraisal committee members

The 4 technology appraisal committees are standing advisory committees of NICE. This topic was considered by committee A. The names of the members who attended are in the <u>minutes of the appraisal committee meeting</u>, which are posted on the NICE website.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

## NICE project team

Each technology appraisal is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the appraisal), a technical adviser and a project manager.

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