National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**March 1st 2021 at 4.30pm**
Venue :	**Teleconference / NCCP Offices**
Assessment:	Abemaciclib (Verzenio)
	Atezolizumab (Tecentriq)
	Midostaurin (Rydapt)
	Dabrafenib and Trametinib (Tafinlar and Mekinist)

TEXT FOR REDACTION DUE TO DELIBERATIVE PROCESS HIGHLIGHTED IN YELLOW

TEXT FOR REDACTION DUE TO COMMERCIAL SENSITIVITY IS HIGHLIGHTED IN PINK

TEXT FOR REDACTION DUE TO CONFIDENTIALITY IS HIGHLIGHTED IN BLUE

Attendance:

Members present		
Dr. Gerard Crotty	Consultant Haematologist, MRH Tullamore: IHS representative	By 'phone
Dr. Michael Fay	Consultant Haematologist, Mater Hospital: IHS representative	By 'phone
Ms. Patricia Heckmann	NCCP Chief Pharmacist - **Chair**	By 'phone
Prof. Michaela Higgins	Medical Oncologist, St. Vincent's University Hospital: ISMO nominee	By 'phone
Ms. Ellen McGrath	Chief Pharmacist; HSE Corporate Pharmaceutical Unit	By 'phone
NCPE Representative	National Centre for Pharmacoeconomics (NCPE)	By 'phone
Dr. Dearbhaile O'Donnell	Medical Oncologist, St. James's Hospital: ISMO nominee	By 'phone
Dr. Oscar Breathnach	Medical Oncologist, Beaumont: ISMO nominee	By 'phone

Non-member invited specialists present	

Apologies (members)	
Dr. Eve O'Toole	Research Group Lead, NCCP
Dr. Linda Coate	Medical Oncologist, University Hospital Limerick: ISMO nominee
Dr. Susan Spillane	HTA Directorate: HIQA nominee

Observers present	
Ms. AnneMarie De Frein	Deputy Chief Pharmacist, NCCP
Dr Clare Meaney	Senior Pharmacist, NCCP

Item	Discussion	Actions
1	**Introduction & reminder re. conflict of interest & confidentiality**	
	Members were reminded of the confidentiality of documentation and discussions and asked to submit completed conflict of interest form for 2021 which had been circulated. Members were asked to raise any conflicts of interest that they had in relation to any drug for discussion prior to the commencement of the discussion of that item.	COI form to be returned by all members for 2021
2	**Notes of previous meeting and matters arising**	
	The notes of the previous meeting on February 1st were approved.	
3	**Drugs/Technologies for consideration**	
	Abemaciclib (Verzenio®) (Ref. TRC 083) *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.* This application for reimbursement is being progressed as a cost minimisation piece by the PCRS as an alternate CDK 4/6 inhibitor. The committee members recommended approval for reimbursement subject to cost minimisation with other agents in this indication. *(Decision:TRC 083)* *D O Donnell not present for vote. Quorum still in place* **Atezolizumab (Tecentriq®) (Ref. TRC 084)** *In combination with carboplatin and etoposide (CE) for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)* The clinicians agreed that this treatment represented the first real advance in the treatment of SCLC in 40 years. It was discussed that the trial data showed a modest improvement in median survival and that this treatment would meet an unmet need in an area where there are currently limited options available for this patient cohort. It was noted that the EMA had considered that the relatively small degree of overall benefit would need to be balanced in terms of the side effect profile. The ICERS were outlined by the NCPE representative and it was recognised that there was difficulty with Applicant achieving commercially achievable ICER due to the low cost comparators but there are other considerations including that the CPU recognise unmet need in this patient population. Having considered the unmet need in this patient cohort the committee members agreed by majority to recommend approval of this indication to the HSE Drugs Group, subject to an improvement in cost effectiveness being achieved *(Decision:TRC 084)*	NCCP to communicate recommendations to HSE Drugs Group.

Midostaurin (Rydapt®) (Ref. TRC 085)

Midostaurin is indicated in combination with standard DAUNOrubicin and cytarabine induction and high dose cytarabine consolidation chemotherapy, and for patients in complete response followed by midostaurin single agent maintenance therapy, for adult patients with newly diagnosed acute myeloid leukaemia (AML) who are FLT3 mutation positive

This is a new agent for the FLT3 positive subgroup of AML patients which is added on to the current DAUNOrubicin cytarabine backbone therapy. The clinical evidence for this indication is based on phase III RATIFY trial of 750 patients which demonstrated greater overall survival and event free survival rates in the midostaurin arm. It was acknowledged that a clinical trial was due to start in Ireland involving midostaurin which many of the patients eligible for treatment with midostaurin would potentially benefit from but noted that this was an important option to have available for those who would not be eligible for this trial.

The principle licensing study was in patients aged 60 or under. Clinical opinion was that there would not be a significant number of patients outside this age profile per year in Ireland suitable for the treatment and not necessary to restrict age in regimen

The HTA was considered and the ICERs were outlined. It was noted that the CPU were still awaiting a finalised commercial offer from the company.

Having considered the clinical efficacy of the indication and the unmet clinical need in this patient cohort, the committee members agreed by majority to recommend approval of this indication to the HSE Drugs Group, subject to an improvement in cost effectiveness.

(Decision:TRC 085)

Dabrafenib in combination with Trametinib (Tafinlar and Mekinist ®) (Ref. TRC 086)

Dabrafenib in combination with trametinib for the adjuvant treatment of adult patients with stage III melanoma with a BRAF V600 mutation, following complete resection.

The committee members discussed that this represented an oral treatment option for adjuvant treatment in melanoma albeit for a subset of patients with BRAF V600 mutation. The clinical evidence for this application is based on a phase III trial involving 870 patients using the surrogate marker relapse free survival as primary endpoint. The primary endpoint was not reached in the treatment group v 16.6.months for placebo.

From a clinical consideration, there is experience with this drug in metastatic melanoma and so clinicians are experienced in managing the associated toxicities

The HTA evaluation carried out by the NCPE recommends that this indication be considered for reimbursement if cost-effectiveness can be improved relative to existing treatments. The pharmaceconomic assessment considered the relative effect of the different options available for adjuvant melanoma using network meta-analyses (indirect comparisons). Due to small differences between the trials e.g. differences in staging, BRAF status the uncertainty is such that it was felt to be reasonable to think of these agents as relatively comparable in benefit. The ICERS were outlined, at list price, this treatment is significantly more expensive than the alternate immunotherapy options recently considered by NCPE for adjuvant treatment of melanoma. Commercial negotiations have been held with the company and the details will form a component of the details to be provided to HSE Drugs Group for consideration.

There was some discussion around sequencing of immunotherapy which is in place for metastatic melanoma. It was agreed by the clinicians that choice

	of treatment following relapse after adjuvant treatment in melanoma will depend on factors including length of time to relapse and performance status of the individual patients. The committee members agreed unanimously to recommend approval of this indication to the HSE Drugs Group, subject to an improvement in cost effectiveness being achieved (Decision: TRC086) *D O Donnell not present for vote. Quorum still in place*	
4	**Update on other drugs in the reimbursement process**	
	An update on the drugs that are in the reimbursement process was circulated to members in advance of the meeting.	
5	**Next meeting**	
	The proposed date for the next meeting dates is March 29th 2021	
6	**Any other business / Next meeting**	
	There was no other business.	

The meeting concluded at 5.30pm.

Actions arising from meeting:

Ref.	Date of meeting	Details of action	Responsible	Update
21/02	1.3.2021	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	