National Cancer Control Programme

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**Nov 16th 2020 at 4.30pm**
Venue :	**Teleconference / NCCP Offices**
Assessment:	Apalutamide (Erleada)
	Axicabtagene ciloleucel (Yescarta)-not discussed due to time pressures
	Atezolizumab (Tecentriq)
	Olaparib (Lynparza)

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. Oscar Breathnach	Medical Oncologist, Beaumont: ISMO nominee	By 'phone
Dr. Gerard Crotty	Consultant Haematologist, MRH Tullamore: IHS representative	By 'phone
Dr. Michael Fay	Consultant Haematologist, Mater Hospital: IHS representative	By 'phone
Dr. Patricia Harrington	Head of Assessment, HTA Directorate: HIQA nominee	By 'phone
Ms. Patricia Heckmann	NCCP Chief Pharmacist **- Chair**	By 'phone
Ms. Ellen McGrath	Chief Pharmacist; HSE Corporate Pharmaceutical Unit	By 'phone
NCPE representative	National Centre for Pharmacoeconomics (NCPE)	By 'phone
Dr. Deirdre O'Mahony	Medical Oncologist, Bon Secour Hospital, Cork: ISMO nominee	By 'phone
Dr. Dearbhaile O'Donnell	Medical Oncologist, St. James's Hospital: ISMO nominee	By 'phone

Non-member invited specialists present

Apologies (members)	
Dr. Deirdre Murray	NCCP Health Intelligence
Dr. Eve O'Toole	Research Group Lead, NCCP
Dr. Linda Coate	Medical Oncologist, University Hospital Limerick: ISMO nominee
Dr. Ronan Desmond	Consultant Haematologist, Tallaght University Hospital: IHS representative

Observers present	
Ms. AnneMarie De Frein	Deputy Chief Pharmacist, NCCP
Dr. Susan Spillane	HIQA Nominee to commence from next meeting

Item	Discussion	Actions
1	**Introduction & reminder re. conflict of interest & confidentiality**	
	It was noted that Dr. P. Harrington is to step down from the TRC as the HIQA representative and Dr. S. Spillane has been nominated as the replacement HIQA representative. Dr. Spillane was welcomed to the group. Dr. Harrington was thanked for her contribution to the group Members were reminded of the confidentiality of documentation and discussions. It is proposed to trial HSE Share File to share documentation for the next meeting. In addition to the conflict of interest forms signed by all members previously, 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. DOD declared receipt of a travel grant in 2017 from one of the companies. The Chair considered this declaration sufficient and is satisfied that the member would continue engage in the group's discussions.	
2	**Notes of previous meeting and matters arising**	
	The notes of the previous meeting on July 6th 2020 and of September 22nd were approved.	
3	**Drugs/Technologies for consideration**	
	Apalutamide (Erleada®) (Ref. TRC 077) *Treatment of adult men with non-metastatic castration resistant prostate cancer (nmCRPC) who are at high risk of developing metastatic disease* The clinical aspects of this indication were outlined, including that there is a clear benefit shown to be associated with this treatment for patients in delaying the progression to metastatic disease. The side effects are as would be anticipated for a hormone blockade agent. It was noted that this benefit is important in terms of improved quality of life and wellbeing of this patient cohort. The pharmacoeconomic considerations were outlined, including that the HTA had identified that enzalutamide was seen as a comparator as well as ant-androgen therapy (ADT) alone, noting that enzalutamide is not currently reimbursed by the HSE for this indication. An additional medicine, darolutamide, is also pending in this space. As detailed in the HTA assessment carried out by the NCPE, the SPARTAN study was used to inform the comparative effectiveness against ADT and in the absence of direct head-to-head evidence for the comparison with enzalutamide, a matched-adjusted indirect comparison (MAIC) was performed using data from SPARTAN and the randomised-controlled PROSPER trial. It was noted that there were three interim analyses carried out and that there were concerns raised about the immaturity of the data. The ICERS were detailed as per the HTA assessment and the 5 year cumulative BI was noted to be €7.2m. Commercial negotiations are ongoing with the company for this indication. The group had a robust discussion, including that there were concerns around cost effectiveness as well as a number of uncertainties, whilst noting that the clinical data was impressive for the patient cohort. Having considered the clinical efficacy of the indication and that the commercial negotiation is ongoing, it was agreed by majority to recommend approval of this indication to the HSE Drugs Group, subject to an	NCCP to communicate recommendations to HSE Drugs Group.

improvement in cost effectiveness being achieved.

(Decision; TRC 077)

Atezolizumab (Tecentriq®) (Ref. TRC 078)

In combination with nab-paclitaxel is indicated for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumours have PD-L1 expression ≥ 1% and who have not received prior chemotherapy for metastatic disease

The committee members considered that the health technology assessment identified that the place in therapy for this indication is quite well defined and that the comparators in the pharmacoeconomic assessment included paclitaxel and capecitabine. PARP inhibitors were not included as not yet reimbursed in this indication or accepted as standard of care for this patient cohort. The phase 3 trial utilised PFS and OS as the primary endpoints, noting that the PFS was investigator assessed. Final analysis showed an OS benefit of 25months for the investigative arm versus 15.5 months in the standard of care arm. The ICERS were detailed and it was noted that there is zero probability of cost effectiveness at the €45k threshold. There is a significant budget impact associated with the net BI estimated at €25m.

From a clinical consideration, there is experience with this drug in lung cancer and so clinicians are experienced in managing the associated toxicities. The trial showed a clear PFS/ OS benefit in the PDL1 positive population. It was noted that Triple Negative Breast Cancer (TNBC) is a subset of breast cancer that is aggressive and very difficult to treat.

The commercial negotiations for this indication are ongoing. This drug is administered in combination which may be challenging from a cost effectiveness consideration.

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

(Decision: TRC078)

Axicabtagene ciloleucel (Yescarta®)

For the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) and primary mediastinal large B-cell lymphoma (PMBCL), after two or more lines of systemic therapy

This item was not discussed due to time pressures and will be added to the agenda of the next meeting.

Olaparib (Lynparza®) (Ref. TRC 079)

As monotherapy for the maintenance treatment of adult patients with platinum-sensitive relapsed high grade epithelial ovarian, fallopian tube or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy

It was noted that this medicine is already approved for reimbursement for an alternate indication for BRCA mutated patients. That is for a capsule formulation which represents a significant pill burden on patients. Reimbursement of this tablet formulation would significantly reduce that pull burden. The clinical benefit were outlined as seen in the SOLO2 and Study 19, and the discussion highlighted that this patient group have received first line treatment but relapse is perceived to be inevitable. It was

	discussed that this treatment would likely replace the current use of bevacizumab in this patient cohort. From the pharmacoeconomic assessment, a number of critiques were discussed, including that SOLO2 is a subgroup on the indication and that the outcomes are still immature. Longer term data is not yet available for the tablet formulation. The OS data is relatively mature but not adequately powered and in SOLO2, OS has not been reached in either arm. The ICERS were detailed, including that there is a low probability of achieving cost effectiveness at the €45k threshold. There is a significant budget impact associated with this indication. It was highlighted that this is felt to be a very important clinical option for ovarian cancer patients, associated with a definite benefit and is an internationally accepted standard of care. It was also discussed that the BRCA positivity rate in the Study 19 was not felt to be reflective of the anticipated positivity rates in Ireland. 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: TRC079)	
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 in December, details to be circulated to the group.	
6	**Any other business / Next meeting**	
	There was no other business.	

The meeting concluded at 6.00pm.

Actions arising from meeting:

Ref.	Date of meeting	Details of action	Responsible	Update
20/05	16/11/2020	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	