National Cancer Control Programme

NCCP Technology Review Committee (TRC)

Meeting Notes

Date of Meeting:	**26th June 2023 at 4.30pm**
Venue :	**Teleconference**
Assessment:	Amivantamab (Rybrevant®)
	Atezolizumab (Tecentriq®)
	Relugolix (Orgovyx®)

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		
NCPE representative	National Centre for Pharmacoeconomics (NCPE)	By 'phone
Dr Dearbhaile Collins	Medical Oncologist, Cork University Hospital: ISMO nominee	By 'phone
Dr Ronan Desmond	Consultant Haematologist, Tallaght University Hospital: IHS representative	By 'phone
Ms Patricia Heckmann	AND NCCP (Chair)	By 'phone
Dr Adrian Murphy	Medical Oncologist, Beaumont: ISMO nominee	By 'phone
Prof Michael O'Dwyer	Consultant Haematologist, Galway: IHS representative	By 'phone
Dr. Hazel O'Sullivan	Medical Oncologist, Cork University Hospital: ISMO nominee	By 'phone
Dr Susan Spillane	HTA Directorate: HIQA nominee	By 'phone
Non-member invited specialists present		
Dr Megan Greally	Medical Oncologist, Beaumont:	By 'phone

Apologies (members)	
Dr Oscar Breathnach	Medical Oncologist, Beaumont: ISMO nominee
Dr Michael Fay	Consultant Haematologist, Mater Hospital: IHS representative
Ms Ellen McGrath	PCRS representative
Dr Dearbhaile O'Donnell	Medical Oncologist, St. James's Hospital: ISMO nominee

Observers present		
Ms Helena Desmond	Senior Pharmacist, NCCP	By 'phone
Mr David Cullinane	Department of Health (Mazars Report implementation group)	By 'phone
Mr Carl O'Gorman	Department of Health (Mazars Report implementation group)	By 'phone
Dr. Lesley Tilson	NCPE (Mazars Report implementation group)	By 'phone

Item	Discussion	Actions

1	**Introduction & reminder re. conflict of interest & confidentiality**	
	Members were reminded 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.	
2	**Notes of previous meeting and matters arising**	
	The notes of the previous meeting on May 22nd 2023 were agreed.	
3	**Drugs/Technologies for consideration**	
	Amivantamab (Rybrevant®) **(Ref. TRC 136)** *As monotherapy for the treatment of adult patients with advanced non-small cell lung cancer (NSCLC) with activating EGFR Exon 20 insertion (Exon20ins) mutations, after failure of platinum-based therapy.* The clinical aspects of this indication were discussed, the supporting evidence for this indication is the phase I, dose-escalation and dose expansion CHRYSALIS study which evaluated the safety and efficacy of amivantamab as monotherapy in patients with advance NSCLC activating *EGFR* Exon20ins mutations, after failure of platinum-based therapy. The study showed an objective response rate (ORR) of 37% and median duration of response (DoR) of 12.5%, with 64% of patients having a DoR of ≥6 months. Treatment with amivantamab also showed a progression free survival (PFS) of 6.9 months and an overall survival (OS) of 22.8months. The safety profile was discussed, noting that 30% of patients treated with amivantamab experienced a grade 3 toxicity, with the most the common toxicities being *EGFR* toxicities such as rash, which trends to be more severe than with other *EGFR* inhibitors, however these can be managed with prophylaxis antibiotics and emollients. Anivantamab is a drug that is clearly beneficial and there is a strong desire among clinicians to have this treatment option available for this cohort of patients, a cohort, who currently have no effective treatment. The pharmacoeconomic aspects as outlined in the HTA assessment carried out by the NCPE were discussed. The supporting evidence was outlined and the NCPE review group highlighted a number of limitations with the study, such as the open label, single arm nature of the study, the small patient population and lack of direct comparator evidence. It was noted that a number of adjustments to the model were made. In terms of the cost, based on the applicant assumption of a mean treatment duration of 10.1 months the cost per treatment course of amivantamab is estimated to be €116,291 including VAT and €92.982 excluding VAT. In the applicant base case analysis the ICER is estimated to be €150,242 per QALY and amivantamab is associated with an incremental QALY gain of 0.5. A number of changes were made to the NCPE adjusted base case and the NCPE adjusted base case the ICER is estimated to be €183,181 per QALY and amivantamab is associated with 0.54 additional QALYs. The probability of cost effectiveness at both the €20,000/QALY and €45,000/QALY threshold in the NCPE adjusted base case is 0%, with a total rebate of 77.9% inclusive of the frame work agreement rebate required to bring the ICER below the 45,000/QALY. In terms of patients numbers, based on the applicants estimates, [redacted] The applicant estimates that 26 patients will be treated over 5 years and is associated with an estimated gross budget impact (BI) of €3.2million and a net BI of €2.1million. [redacted] However feedback from clinicians regarding the incidence of patient to be treated is in line with the applicant's estimates. The recommendation of the NCPE review group was that amivantamab not be considered for reimbursement unless cost-effectiveness can be improved relative to existing treatments.	

	Having considered the clinical efficacy of the indication in this patient cohort the committee members agreed by majority to recommend approval of this indication to the HSE Drugs Group. *(Decision: TRC 136)* **Relugolix (Orgovyx®)(Ref. TRC 137)** *For the treatment of adult patients with advanced hormone-sensitive prostate cancer (HSPC).* The clinical aspects of this indication were discussed, relugolix is unique in that it is an oral formulation of a GnHR antagonist. The supporting evidence for this indication is the phase III, open label HERO trial, which evaluated the safety and efficacy of oral relugolix versus injectable leuprorelin for advanced prostate cancer. The trial demonstrated that relugolix was non-inferior to leuprorelin with a sustained castration rate of ~ 97% in the relugolix group vs ~89% in the leuprorelin group. The trial also showed that treatment with relugolix demonstrated more rapid response compared to leuprorelin. The safety profile was discussed, overall the safety profile of relugolix was comparable to leuprorelin, with a lower incidence of major cardiovascular events. There is desire among clinicians to have an oral GnHR antagonist available for this cohort of patients. The pharmacoeconomic aspects as outlined in the rapid review assessment carried out by the NCPE were discussed, noting that a full HTA was not recommended. The supporting evidence for this indication was outlined, the NCPE review group highlighted a number of limitations of the trial including, concurrent use of novel hormone treatment or docetaxel in participants upon raising PSA levels, the heterogeneity and the absence of direct comparator evidence with the other comparators of interest. In terms of cost effectiveness, the cost to the HSE per pack of tablets is €155.35 with the total cost per patient in year 1 estimated to be €2,646 and in year 2 reducing slightly to €2,635. In terms of the budget impact (BI) and patient numbers, it is anticipated that 58 patients will be treated in year 1 rising to 1,198 in year 5.The BI was outlined with an a 5-year gross BI estimated to be €7million and the 5-year net BI estimated to be €1.82 million including VAT. The recommendation of the NCPE review group was that relugolix not be considered for reimbursement at the submitted price. Commercial negotiations with the company are ongoing. Having considered the clinical efficacy of the indication in this patient cohort the committee members agreed unanimously to recommend approval of this indication to the HSE Drugs Group. *(Decision: TRC 137)* **Atezolizumab (Tecentriq®) (Ref. TRC 138)** *In combination with bevacizumab for the treatment of adult patients with advanced or unresectable hepatocellular carcinoma (HCC) who have not received prior systemic therapy.* Discussion of this item was deferred and will be added to the agenda for the next meeting.	
4	**Update on other drugs in the reimbursement process**	
	An update had been shared with the group in the documentation for the meeting	
5	**Next meeting**	
	The proposed date for the next meeting is July 24th 2023	

6	Any other business / Next meeting	
	New members - the Chair welcomed Dr Hazel O'Sullivan, a new ISMO nominee alternative member. Members of the Mazars Report implementation group (Mr David Cullinane, Mr Carl O'Gorman and Dr. Lesley Tilson) attended as observers to inform their knowledge of the current reimbursement pathway and were welcomed by the Chair.	NCCP

The meeting concluded at 5.40pm.

Actions arising from meeting:

Ref.	Date of meeting	Details of action	Responsible	Update
23/01	27/03/2023	NCCP to communicate recommendations to HSE Drugs Group.	NCCP	Complete
23/01	27/03/2023	Apply for CPD	NCCP	Complete