Minutes of the SMC Committee Meeting

Tuesday 2 February 2021

Present:	Dr Mark MacGregor (Chairman) Dr Paul Catchpole Ms Alison Culpan Dr Jacob Dreyer Ms Clare Dunn Professor Michael Eddleston Dr Jane Goddard Professor Charlie Gourley Dr Roger Hardman Ms Alex Jones Ms Jennifer Laskey Mr Gordon Loughran Ms Dionne Mackison Dr Catriona McMahon Dr Scott Muir Dr Avideh Nazeri Dr Paul Neary Dr Robert Peel Ms Yvonne Semple Mr Colin Sinclair Ms Alison Stillie Professor Alison Strath Professor Marc Turner Mr Scott Urquhart Ms Carla Verschueren
Observers:	Ms Morag Alexander Mr Keith Charters Ms Irene Fazakerley Ms Jennifer Hislop Mr Thea Kellock Ms Sheela Upadhyaya Ms Helen Wright
In Attendance:	Ms Ailsa Brown

	Mrs Jennifer Dickson Mrs Noreen Downes Mr Scott Hill Mrs Anne Lee Mrs Donna Leith Mrs Lindsay Lockhart Ms Rosie Murray Mr Jonathan Sim Mrs Catherine Tait
Apologies:	Dr Graham Scotland Ms Alice Wilson

1.	**Welcome and Apologies for Absence**
1.1	The Chairman welcomed members to the meeting and apologies for absence were noted.
1.2	Welcome to the following observers: • **Ms Morag Alexander, newly appointed public partner**. Morag will take over from Clare Dunn whose term of membership ends in March. • **Mr Keith Charters,** Non-Executive Director/Whistleblowing Champion, Healthcare Improvement Scotland. • **Ms Jennifer Hislop**, Health economist, Healthcare Improvement Scotland. • **Mr Thea Kellock,** Pharmacy and Medicines Division, Scottish Government. • **Ms Sheela Upadhyaya,** Accelerated Access Collaborative Relationship & Delivery Lead, Centre for Health Technology Evaluation, NICE. • **Ms Helen Wright**, Principal Pharmaceutical Analyst, SMC.
2.	**Declarations of Interest**
2.1	The Chairman reminded members to declare interests in the products to be discussed and the comparator medicines as noted on the assessment reports.
3.	**Minutes of the Previous Meeting 12 January 2021**
3.1	The minutes of the SMC meeting held on 12 January 2021 were accepted as an accurate record of the meeting.
4	**Matters Arising**
4.1	**Amended advice**
	ozanimod 0.23mg, 0.46mg and 0.92mg hard capsules (Zeposia®) Celgene Ltd SMC 2309 Due to comments from a competitor company, minor amendments have been made to the Detailed Advice Document for ozanimod 0.23mg, 0.46mg and 0.92mg hard capsules (Zeposia®), for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease as defined by clinical or imaging features. The DAD will be published on Monday 8 February 2021.
	ravulizumab 300mg/30mL concentrate for solution for infusion (Ultomiris) Alexion Pharma UK Ltd SMC2305 Due to comments from the company, minor amendments have been made to the Detailed Advice Document for ravulizumab (Ultomiris), for the treatment of adult patients with paroxysmal nocturnal haemoglobinuria (PNH): • In patients with haemolysis with clinical symptom(s) indicative of high disease activity • In patients who are clinically stable after having been treated with eculizumab for at least the past 6 months. The DAD will be published on Monday 08 February 2021.

5	**Chairman's Business**
5.1	Nothing to report.
6.	**NDC ASSESSMENT REPORTS**
	FULL SUBMISSIONS
6.1	<u>entrectinib 100mg and 200mg hard capsules (Rozlytrek®) Roche Products Ltd. SMC2295</u> An interest was declared in relation to this product/comparator medicines. Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. Representatives of the Patient Groups were invited to the committee table to respond to specific queries regarding the Patient Group submissions, and provide clarification on any outstanding issues. The NDC Chairman provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented Patient Group submissions from GIST Cancer UK and Roy Castle Lung Cancer Foundation. Detailed discussion followed and, after a vote of the members, it was decided that entrectinib (Rozlytrek ®), should be accepted for use within NHSScotland. Indication under review: as monotherapy for the treatment of adult and paediatric patients 12 years of age and older with solid tumours expressing a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, • who have a disease that is locally advanced, metastatic or where surgical resection is likely to result in severe morbidity, and • who have not received a prior NTRK inhibitor • who have no satisfactory treatment options In a pooled analysis of three phase I/II studies in adults with metastatic or locally advanced NTRK fusion-positive solid tumours, 64% of patients achieved an objective response with entrectinib treatment. The median duration of response in these patients was 12.9 months. Positive objective response rate results were also reported in a phase I/Ib paediatric study.

	This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 February 2021.
6.2	<u>onasemnogene abeparvovec 2 × 1013 vector genomes/mL solution for infusion (Zolgensma®) Novartis Gene Therapies SMC2311</u> An interest was declared in relation to this product/comparator medicines. Representatives of the submitting company were invited to the committee table to respond to specific queries regarding this submission, comment on matters of factual accuracy and provide clarification on any outstanding issues. Representatives of the Patient Groups were invited to the committee table to respond to specific queries regarding the Patient Group submissions, and provide clarification on any outstanding issues. The NDC Co-Vice Chair provided an overview of the assessment, draft advice, expert comments, revised data/analysis, and comments received from the company. A member of the Public Involvement Team presented Patient Group submissions from (Joint submission SMA UK and Muscular Dystrophy UK) and TreatSMA. Detailed discussion followed and, after a vote of the members, it was decided that onasemnogene abeparvovec (Zolgensma®), should be accepted for restricted use within NHSScotland. Indication under review: treatment of patients with 5q spinal muscular atrophy (SMA) with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA type 1, or patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene. SMC restriction: for the treatment of - patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and a clinical diagnosis of SMA type 1, or - pre-symptomatic patients with 5q SMA with a bi-allelic mutation in the SMN1 gene and up to 3 copies of the SMN2 gene, where patients are expected to develop SMA type 1

	In a phase III study of patients with symptomatic SMA type 1 treated with onasemnogene abeparvovec, survival was significantly better than a historical control cohort. In addition, motor milestones achieved generally exceeded the natural history of SMA type 1. This advice applies only in the context of an approved NHSScotland Patient Access Scheme (PAS) arrangement delivering the cost-effectiveness results upon which the decision was based, or a PAS/ list price that is equivalent or lower. This advice takes account of the views from a Patient and Clinician Engagement (PACE) meeting. The SMC advice will be issued to the NHS Boards and ADTCs on Friday, 5 February 2021.
7.	**SMC User Group Forum (UGF)**
7.1	The SMC UGF met on 19 January, key topics discussed were: • The recognition that SMC continues to have interim measures in place to support remobilisation and business recovery during the COVID-19 pandemic, which has been very productive. • Discussion on collaborative working with the MHRA. The next meeting is on 20 April 2021 and an update will be provided at SMC meeting on 4 May 2021.
8.	**Forthcoming Submissions**
8.1	Noted
9.	**Area Drug & Therapeutics Committee (ADTC) Issues**
9.1	Nothing to report.
10.	**Any Other Business**
10.1	Nothing to report.
11.	**Closed Session**
11.1	Nothing to report.
12.	**Any Other Business in Closed Session**
12.1	**Update on the interim assessment approach in response to COVID-19** This is a pragmatic approach to minimise delay in patient access as a result of the COVID-19 pandemic. Following review by the SMC executive, SMC advice for **five abbreviated submissions,** will be issued in confidence to NHS Boards on Friday 5 February 2021, and published on the SMC website on Monday 8 March 2021.

	• **beclometasone dipropionate / formoterol fumarate dehydrate / glycopyrronium bromide (Trimbow)** SMC2335 **-** for maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and **medium dose** of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year. • **doravirine (Pifeltro),** SMC2332 - in combination with other antiretroviral medicinal products, for the treatment of adults infected with human immunodeficiency virus 1 (HIV-1) without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class. • **doravirine / lamivudine / tenofovir disoproxil fumarate (Delstrigo),** SMC2333 - for the treatment of adults infected with human immunodeficiency virus 1 (HIV-1) without past or present evidence of resistance to the non-nucleoside reverse transcriptase inhibitor (NNRTI) class, lamivudine, or tenofovir. • **trametinib (Mekinist),** SMC2328 - for treatment in combination with dabrafenib (Tafinlar) for the treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation. This is an abbreviated submission to remove the SMC restriction to first-line treatment. • **beclometasone dipropionate / formoterol fumarate dehydrate / glycopyrronium bromide (Trimbow)** SMC2334 **-** for maintenance treatment of asthma, in adults not adequately controlled with a maintenance combination of a long-acting beta2-agonist and **high dose** of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year. **Please note** advice for beclometasone dipropionate / formoterol fumarate dehydrate / glycopyrronium bromide (Trimbow) SMC2334 will be witheld awaiting available launch date. Advice will be distributed to Boards once launch has been confirmed.
13.	**Date of the Next Meeting**
13.1	The date of the next meeting was confirmed as Tuesday 2 March 2021.