Project Orbis & the UK: 18-month report card

Implications of UK Market Access for Oncology Medicines Prior to the EMA approval

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Introduction

- In January 2021, the UK joined Project Orbis, a multi-nation programme coordinated by the FDA that provides a framework for concurrent submission and review of innovative oncology products to deliver faster patient access
- This research evaluates all medicines approved by the MHRA under Project Orbis compared to EU, and how these were reimbursed in England by NICE and NHSE

Methods

- All medicines approved by the MHRA under Project Orbis were identified from https://www.gov.uk/guidance/guidance-on-project-orbis, their corresponding reimbursement status in England from https://www.nice.org.uk/ and https://www.england.nhs.uk/, and their EMA regulatory status from https://www.ema.europa.eu/en (28-JUN-2022)

Results

- 11 oncology medicines have been authorised in the UK under Project Orbis, beginning in May 2021 (6: 2021, 5: 2022)
- 4/11 were new indications for already licensed therapies and 7/11 were new marketing authorisation applications
- The EMA has authorised 10/11 (91%) of these medicines, 7/10 after the MHRA (mean delay: 31 days (range: -103 to +51 days)
- Only 3/11 (25%) have had a completed NICE appraisal, an average of 218 days after MHRA approval (range: 174 to 258 days)
  - All three were recommended (2/3 via the CDF)
  - However, 4/11 (36%) have been subject to a NHSE press release prior to NICE appraisal, all four confirming funding (an average of 16 days after MHRA approval [range: 1-27])
- 3/4 NHSE agreements confirming funding were on a budget neutral basis whilst NICE undertakes its appraisal.

Table 1: Medicines MHRA-approved under Project Orbis

Brand	Generic name	Indication	MHRA approval	EC approval	Time from MHRA=>EC (days)	NICE	NHSE
Tagrisso	Osimertinib	EGFR M+ NSCLC	06 May 2021	22 April 2022	351	19 January 2022 Recommended (CDF)	07-May-21 Budget neutral access whilst NICE appraisal ongoing
Lumykras	Sotorasib	KRAS M+ NSCLC	08 September 2021	11 November 2021	64	30 March 2022 Recommended (CDF)	10-Oct-21 Budget neutral access whilst NICE appraisal ongoing
Trovdelvy	Sacituzumab govitecan	3L+ mTNBC	08 September 2021	14 October 2021	36	*01 March 2022 Not recommended (Draft)*	N/A
Lorviqua	Lorlatinib	1L ALK+ NSCLC	23 September 2021	16 December 2021	84	Ongoing	N/A
Tepmetko	Tepotinib	METex14 NSCLC	24 September 2021	16 December 2021	83	18 May 2022 Recommended	N/A
Rybrevant	Amivantamab	EGFR M+ NSCLC	15 November 2021	14 October 2021	-32	Ongoing	N/A
Tecentriq	Atezolizumab	PD-L1+ NSCLC	01 January 2022	22 April 2022	111	Ongoing	28-Jan-22 Early access whilst NICE completes appraisal
Exkivity	Entrectinib	EGFR M+ NSCLC	17 March 2022	N/A	N/A	N/A	21-Mar-22 Budget neutral access whilst NICE appraisal ongoing
Jakavi	Ruxolitinib	GvHD	23 March 2022	24 March 2022	1	N/A	N/A
Welireg	Belzutifan	VHL-associated cancers	31 May 2022	20 August 2021	-284	Ongoing	N/A
Kimmtrak	Tebentafusp	(HLA)-A*02:01 uveal MEL	07 June 2022	24 February 2022	-103	Ongoing	N/A

Conclusions

- Project Orbis has provided an opportunity for oncology medicines to be licensed in the UK several months before the EU
- However, these earlier MHRA approvals have not translated into expedient NICE appraisals
- Nevertheless, patient access is being achieved for some of these medicines in the interim through NHSE
- Manufacturers should accordingly tailor their early engagement and pricing strategies to leverage the potential for expedient UK access through Project Orbis

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