UK PharmaScan

Example of 'ideal' record when a product is first added to UK PharmaScan (in phase III or 3 years from launch in the UK)

Assura

Rifamilumab

Moderate to severe rheumatoid arthritis

Drug	
Manufacturer	Assurent Pharma Ltd
Branded name	Assura
Generic name	Rifamilumab
Synonyms	PC701, rifpuramab
Indication	
Proposed	In combination with methotrexate for the treatment of early arthritis.
Final	
Abbreviated	Early rheumatoid arthritis
Identified sub groups	Adults with RA and a symptom duration of 3-6 months
Proposed place in therapy	First-line treatment
Stage of disease	Early RA
Is paediatric	No
Formulation	
Formulation	Subcutaneous injection
Details	
Mode of action	Inhibitor of northodeconate dehydrogenase (NDDH), a key enzyme involved in joint destruction. First in class biological.
Technology status	New indication
Nature of SPC amendment	
Route	Parenteral
Presentation	Self-administered autoinjector containing 300mg rifamilumab in 1mL solution. Requires fridge storage.
Proposed dose	300mg

Proposed dosing regimen	Given by subcutaneous injection, initially 300mg at weeks 1 and 4, then every 6 months.
BNF Chapter	10 – Musculoskeletal and joint diseases
Disease state	Rheumatoid arthritis
Is the drug considered a personalised medicine?	No
Is there a companion diagnostic test?	No
Please provide details	
Current treatment options	Methotrexate; other DMARDs
Likely Comparators	As above
Has this medicine been formally selected for an AWMSG TDA?	Unknown
Comments	
Has this medicine been formally selected for a NICE HTA?	Unknown
Comments	
Will this medicine be appraised by the SMC?	Yes
Comments	
Who is the originating company?	Assurent Pharma Ltd
Is the drug being co-marketed?	No
Co-marketing company	
Clinical trial information	
Study Name	AS-104/9
National Clinical Trial number from ClinicalTrials.gov	NCT02101234
Phase	Phase III
Trial start date	
Participating countries	
Patient population	
Study design	
Primary objective	
Primary outcomes	
Secondary outcomes	
Anticipated date of study completion	Q1/2020
Anticipated date of study publication	Q4/2021
Publications	

Regulatory information	
Current EU stage of development	Phase III
Orphan drug status in EU	Unknown
Date Eu orphan drug status granted	
EU orphan status number	
Classified by EMA as an Advanced Therapy Medicinal Product (ATMP)?	
MHRA Promising Innovative Medicine (PIM) designation granted?	No
Estimated Early Access to Medicines Scheme (EAMS) submission date	
Actual EAMS submission date	
Estimated EAMS scientific opinion date	
Actual EAMS scientific opinion date	
EAMS scientific opinion decision	
Regulatory procedure	EU Centralised
Estimated regulatory submission date (quarter)	Q1/2023
Estimated regulatory submission date (month)	January
Estimated licence date (quarter)	Q3/2023
Estimated licence date (month)	August
Estimated UK availability date (quarter)	Q3/2023
Estimated UK availability date (month)	August
EU Fast track application anticipated	No
EU Conditional approval anticipated	
Regulatory dossier submitted	
Estimated CHMP opinion date	
Actual CHMP opinion date	
CHMP opinion	
Actual regulatory submission date	
EU Reference Member State	
Licence date for Reference Member State	
Actual licence date	
Actual UK availability date	
Information on EMA/MHRA decisions	
MAA EU withdrawal date	
MAA EU withdrawal reason	
If suspended, date of suspension	
Reason for suspension	

Are there further plans for trials/refiling?	
If development in EU discontinued, date of discontinuation	
Reason for EU discontinuation	
If other reason for archival, date of decision to archive	
Other reason to archive	
Development in the US	Phase III
Response letter issued	
Date response letter issued	
FDA fast tracked	
FDA orphan drug status	No
General comments	
Cost and budgetary information	
Proposed average dose	300mg 6 monthly.
Place in therapy	Substitute for DMARDs
Estimated length of treatment	Ongoing
Drug cost range (per patient per year or patient per episode if less than one year)	£30,000 and £40,000
Drug cost notes	Excl. VAT, per patient per year
Is a Patient Access Scheme or alternative discount arrangement planned for this indication?	
Comments	
Is the technology available on a compassionate basis pre-licence in the UK other than clinical trials?	No
Service impact	Delayed radiographic progression may improve long-term prognosis. This may reduce burden on NHS.
Impact on patients and carers	It is anticipated that, if licensed, rifamilumab will decrease pain associated with early rheumatoid arthritis and potentially increase quality of life.
UK patient population range	Between 1,000 and 1,500 per 100,000
UK patient population notes	RA is the most common inflammatory polyarthropathy in the UK, affecting around 1% of the population (over 400,000 people in England and Wales). Ref: www.nice.org.uk/XX

Estimated eligible patient population	The disease is severe in around 15% of patients and its peak age of onset is 40-70 years Ref: www.nice.org.uk/XX
Is the drug an orphan drug?	No
Is the drug likely to have a significant service impact?	Unknown
Is the net budget impact for the UK greater than £5million at year 5?	Yes.
Estimated uptake	Details not available at this stage.
Estimated net incremental drug acquisition costs per annum at year 1 and 5	
What will be the net budget impact at year 1 and 5?	
Budget impact model available from the company on request	Unknown