

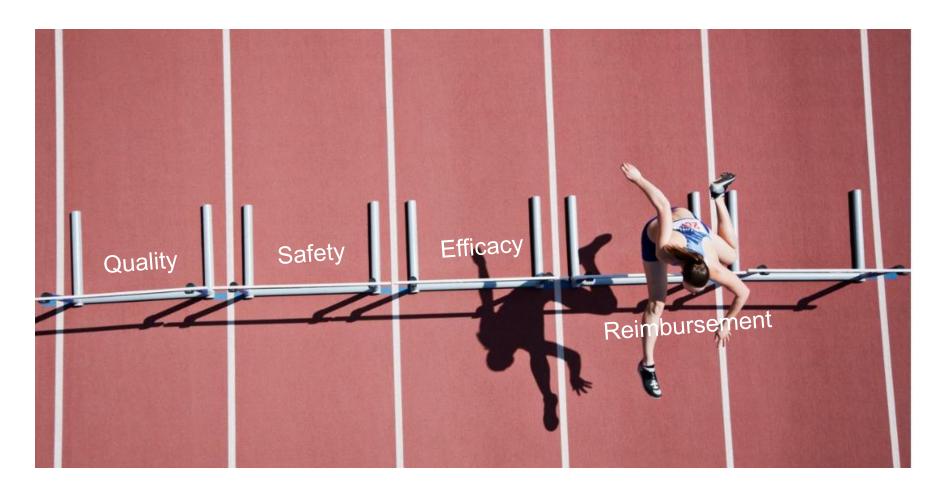
GLOBAL WORKSHOP MARKET ACCESS

26.09.2020

Together we know more. Together we do more

BROAD AND FAST ACCESS FOR ALL PATIENTS AT A SUSTAINABLE PRICE





BROAD AND FAST ACCESS FOR ALL PATIENTS AT A SUSTAINABLE PRICE







- Develop target product value
- Estimate optimal price corridor
- Adapt studies to achieve access
- · Develop value based positioning
- Interact early with payers & HTA bodies



International HTA & reimbursement

- Develop Global value story
- Support local reimbursement processes
- Implement price and launch strategies

Germany AMNOG & reimbursement

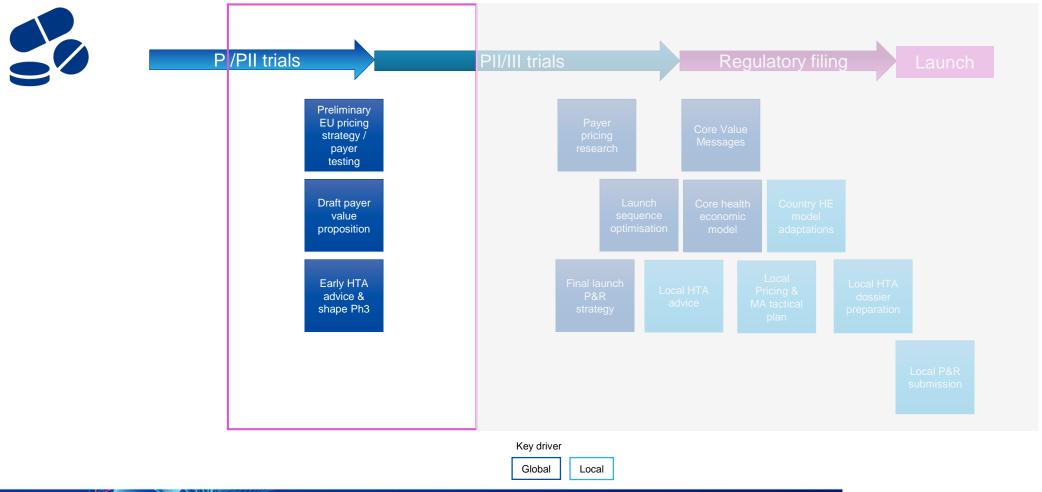
- Develop value dossier for AMNOG
- Pricing & Negotiation for portfolio
- Contracting to substain business





EARLY DRUG DEVELOPMENT & PIPELINE ACTIVITIES





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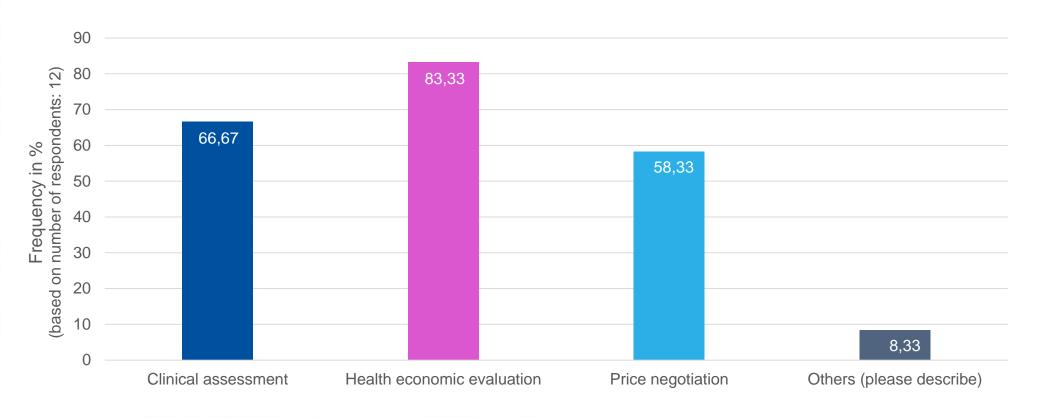
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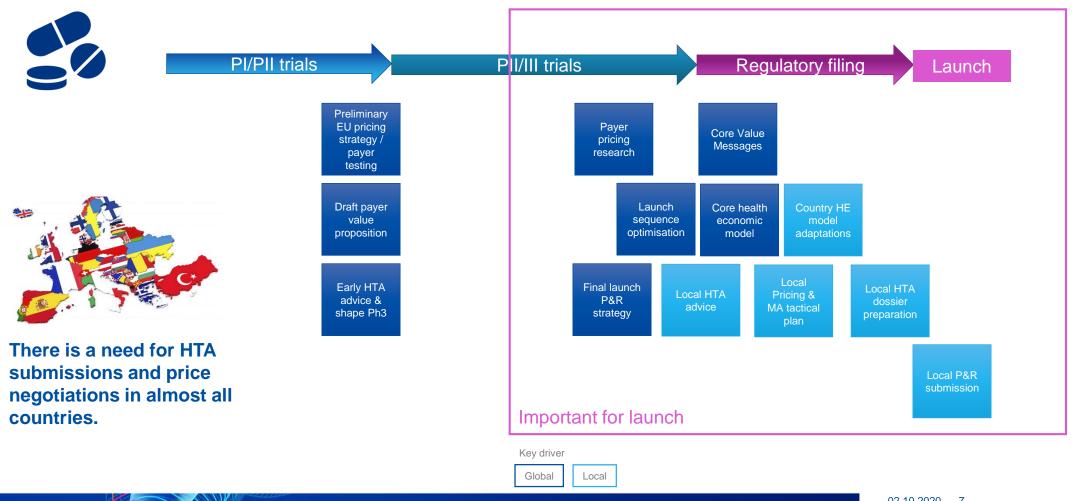
WHAT KIND OF HTA PROCEDURE DO YOU NEED TO COMPLETE TO ACHIEVE REIMBURSEMENT OF A NEW DRUG?





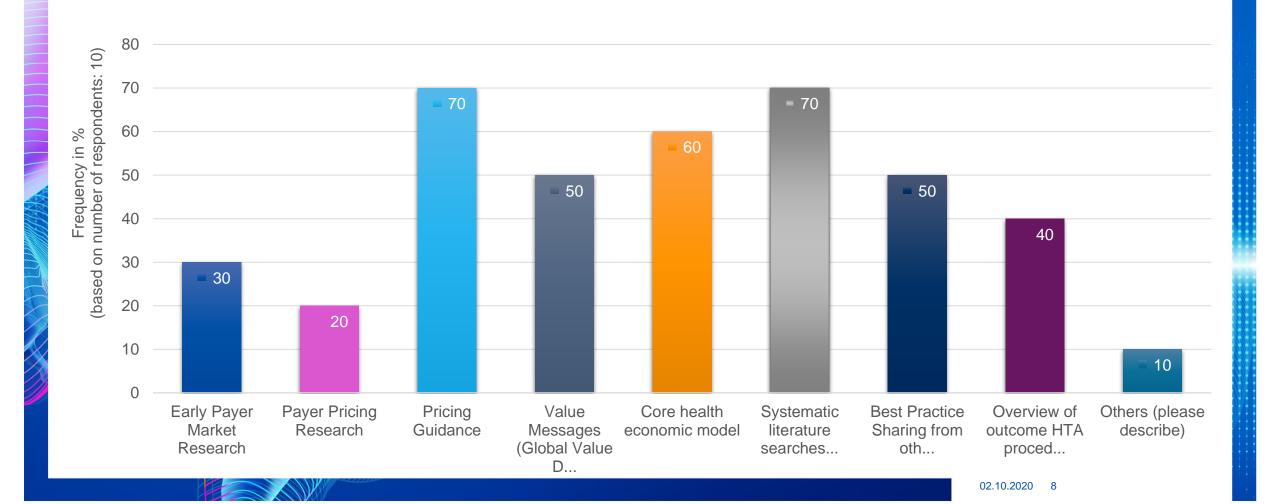
MARKET ACCESS ACTIVITIES FOR A SUCCESSFUL PRODUCT LAUNCH FROM A GLOBAL AND LOCAL PERSPECTIVE





WHAT KIND OF GLOBAL TOOLS WOULD SUPPORT YOU BEST IN A SUCCESSFUL MARKET ACCESS?





INTERNATIONAL MARKET ACCESS COUNCIL TO ALIGN ON VALUE AND PRICE IS IN PLACE AND WORKING





Team Member:



Market Access
Justus Kofler



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Austria Elke Liebhart



Nordics
Yvonne Thomson



- Meetings on request
- Frequent Update TC
- Tracker information

SUPPORT FOR JORVEZA IS CO-DEVELOPED AND SECURED



- Comprehensive overview of value messages for Jorveza:
 - Helps to speak with one voice to authorities
 - > Helps to use synergies and reduce costs and efforts
 - Co-developed with the international market access council

Value Messages for Jorveza

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L	Hov	How to use this document		
2	Clin	ical Value Messages (Efficacy and Safety)	3	
	2.1 histolo	Acute treatment with Jorveza resulted in 58% of patients achieving combined clinical and gical remission at 6 weeks and 85% at 12 weeks.	3	
	2.2 weeks	Acute treatment with Jorveza resulted in 93% of patients achieving histologic remission at .5 $$	6	
	2.3 weeks	Acute treatment with Jorveza resulted in 59% of patients achieving clinical remission at 6 $$ 5 $$		
	2.4 resolu	Acute treatment with Jorveza resulted in 64% of patients achieving overall symptoms tion at 6 weeks.	6	
	2.5 weeks	Maintenance treatment with Jorveza resulted in 74% of patients being in remission at 48 $^\circ$. 6		
	2.6 while	Patients on Jorveza maintenance treatment relapsed on average after more than 350 days patients on placebo relapsed after 87 days		
	2.7 featur	Maintenance treatment with Jorveza resulted in approx. 70% of patients having no visible es of EoE activity	0	
	2.8	Acute, as well as maintenance treatment with Jorveza was safe and well tolerated 1	0	
	2.9 under	Indirect treatment comparisons have shown the rate of histological remission to be higher acute treatment with Jorveza compared to all other off-label and diet treatments		
	2.10 treatm	Maintenance treatment with Jorveza appears to be more efficacious than maintenance nent with other treatments based on a qualitative comparison of available studies	5	
3	Eco	nomic Value Messages 1	8	
	3.1	EoE is associated with substantial health care utilization and costs	8	
	3.2 reimbi	Treatment with Jorveza has been accepted as being cost-effective by pricing and ursement authorities and HTA agencies in (insert relevant countries)	9	
ļ	Refe	erences	0	

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Single technology appraisal

Budesonide for treating eosinophilic oesophagitis [IDxxx]

Document B - APPENDICES Company evidence submission

August 2020

File name	Version	Contains confidential information	Date
IDxxx-Jorveza- DocB-Appendices	x	NO	14th August, 2020

PRICING GUIDANCE FOR JORVEZA MAINTENANCE SECURES SUBSTAINABLE PRICES IN EUROPE



- Pricing guidance for Jorveza Maintenance Europe:
 - Developed based on pricing study and country feedback
 - Helps countries to adapt the negotiation strategy to the target price
 - Further individual country agreements need alignment with Falk Freiburg

Launch timelines for the 0.5 mg for Europe



Maintenance Pricing Guidance: Jorveza

Tablet strength	Tablet price (Price after negotiation, ex-manufacturer)	Daily tx costs (2x)	
1 mg	3,67 EUR	7,34 EUR (no change)	
0.5 mg	3,12 EUR	6,24 EUR (-15 % of 2x 1mg)	

- Price of Jorveza reflects high efficacy and tolerability of 0.5 mg and 1.0 mg in maintenance
- Payers should consider tha
- High efficacy and tolerability for both strengths
- Different dosing is required to achieve the best possible individual outcome for the patient
- Choice of dosage should be guided by the individual needs of a patient and not by the price
- Orphan drug with very limited patient population
- Limited uptake of maintenance indication expected (20-30 % increase of sales, based on German forecast
- Individual country agreements need to be aligned before payer negotiations with Falk Freiburg and any difference to the target price needs to be approved by Dr. Falk Freiburg
- Please reach out to us for any support



SUCCESSFUL REIMBURSEMENT IN MANY COUNTRIES AND ONGOING PROCEDURES FOR THE MAINTENANCE



- Jorveza has **successfully gained reimbursement** in many countries:
 - Germany (no HTA)
 - > NORDICS
 - Netherlands, Luxembourg
 - Austria, Croatia, Slovenia, Scotland



- Already **ongoing submissions** in the following countries:
 - France (already positive assessment!)
 - Italy
 - UK
 - Spain
 - Switzerland
 - Hungary
 - Australia
 - Canada
 - And more countries for the maintenance treatment



MARKET ACCESS INTL: PRIORITIES FOR 2021



I. Achieve full reimbursement: Jorveza induction and maintenance across Europe



II. Prepare pipeline: Set up strategies and action plan to prepare for upcoming pipeline products (e.g. HTA advices)



III. Increase transparency: Create and live a digital platform for affiliates to get an overview, exchange and learning opportunity

