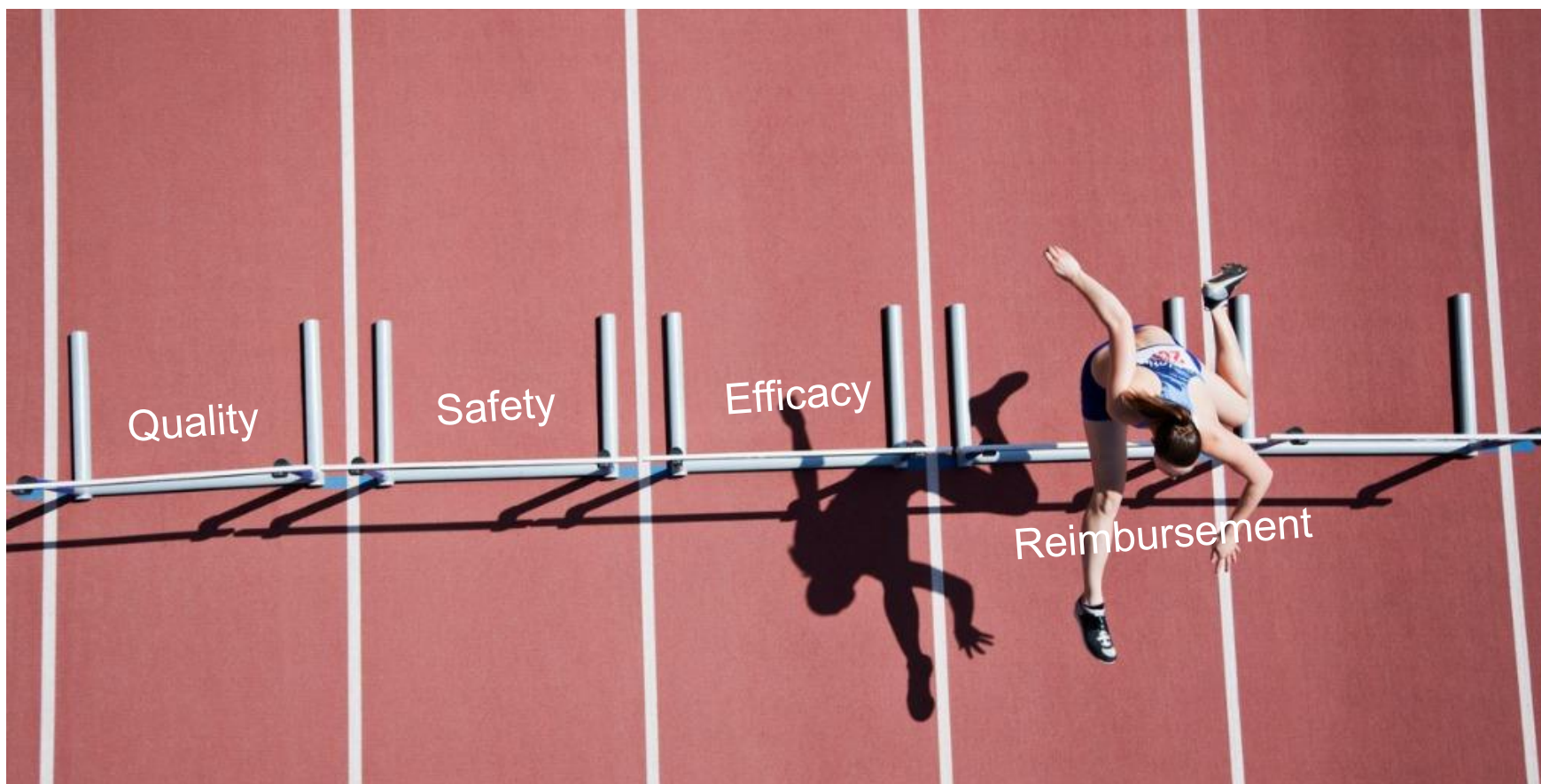




GLOBAL WORKSHOP MARKET ACCESS / EASTERN CONFERENCE

26.09.2020

BROAD AND FAST ACCESS FOR ALL PATIENTS AT A SUSTAINABLE PRICE



BROAD AND FAST ACCESS FOR ALL PATIENTS AT A SUSTAINABLE PRICE



Business Development **Early drug discovery & pipeline**

- 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

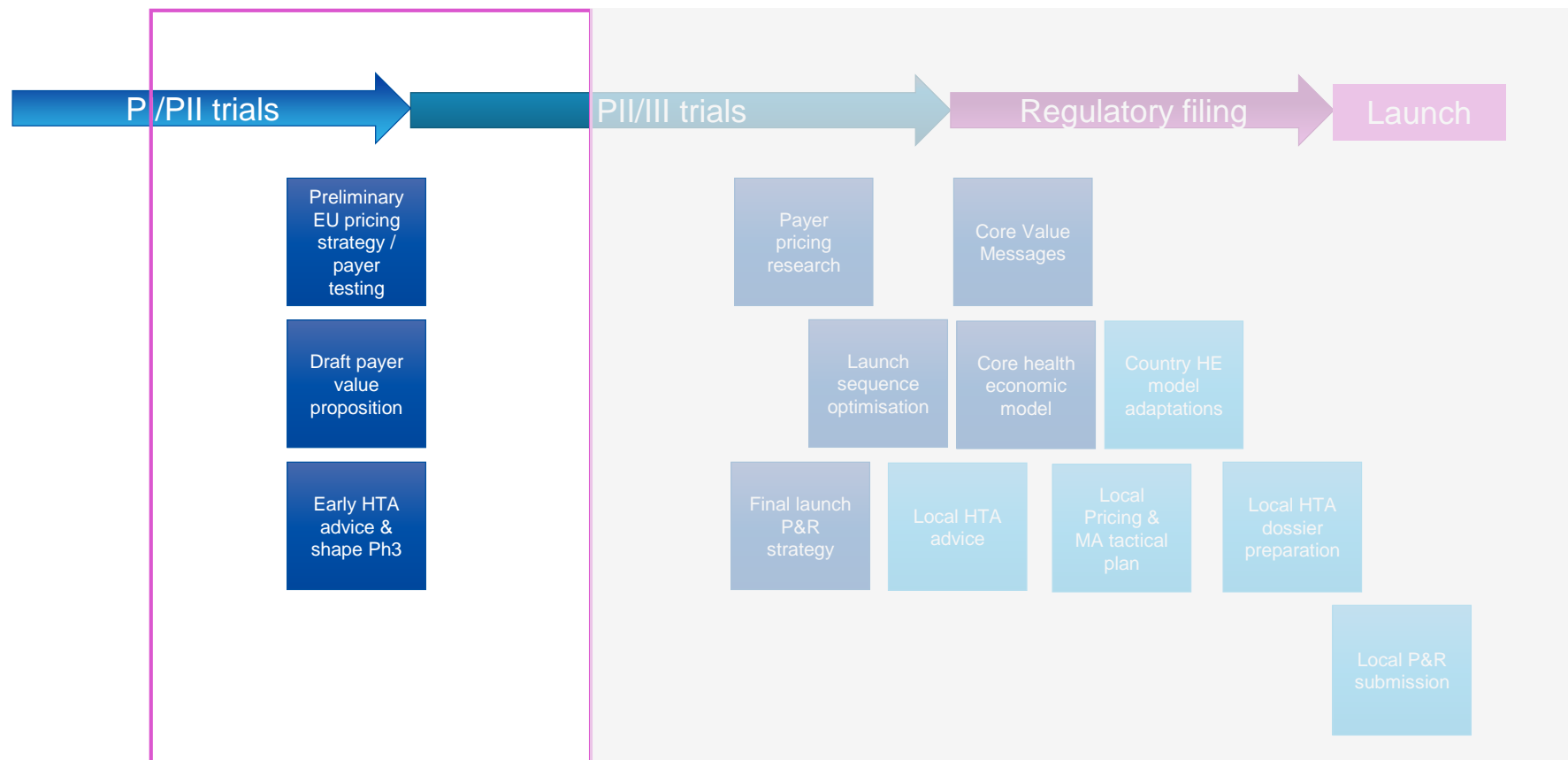


Germany **AMNOG & reimbursement**

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



EARLY DRUG DEVELOPMENT & PIPELINE ACTIVITIES



Key driver

Global

Local

BROAD AND FAST ACCESS FOR ALL PATIENTS AT A SUSTAINABLE PRICE



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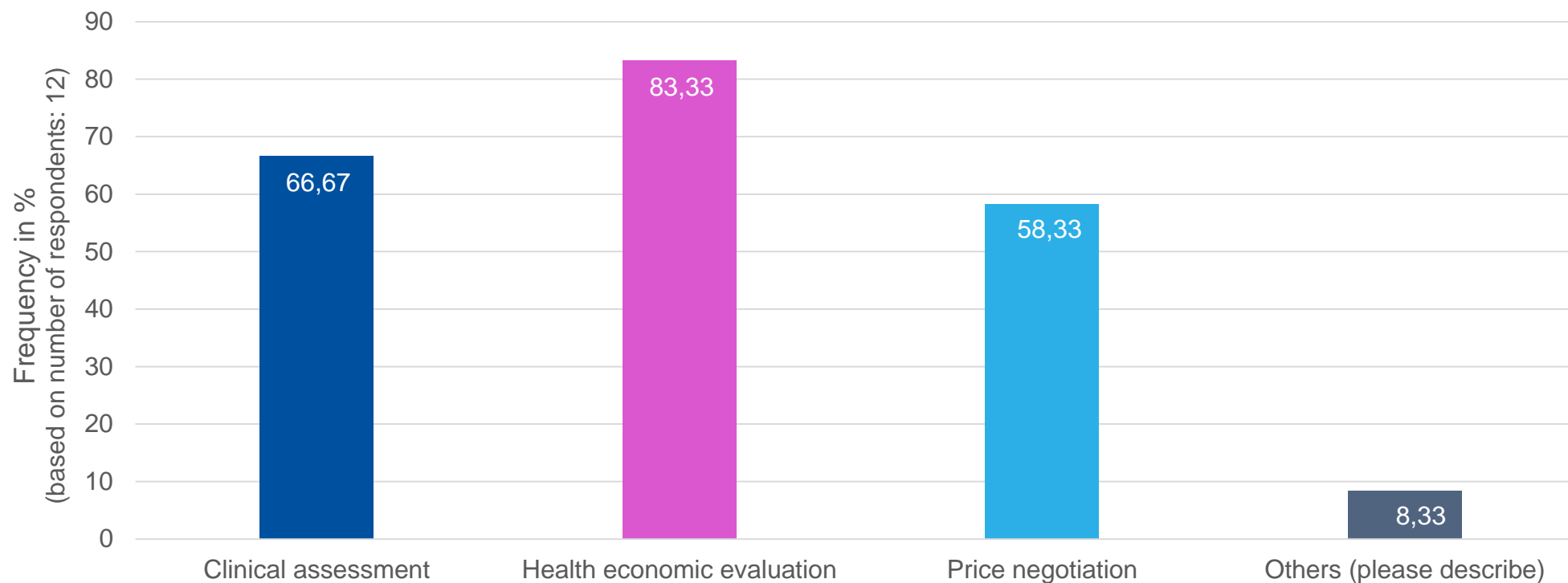


Germany AMNOG & reimbursement

- Develop value dossier for AMNOG
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WHAT KIND OF HTA PROCEDURE DO YOU NEED TO COMPLETE TO ACHIEVE REIMBURSEMENT OF A NEW DRUG?



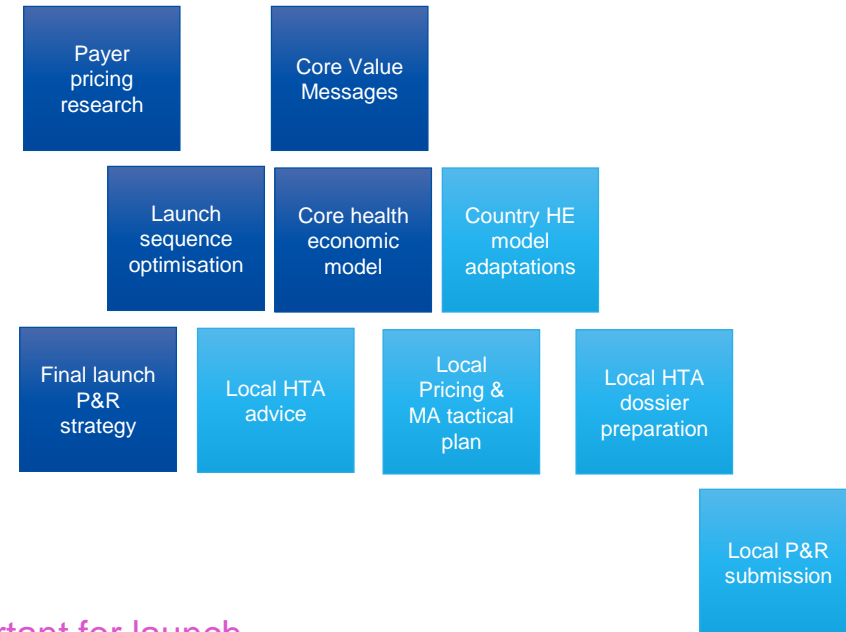
MARKET ACCESS ACTIVITIES FOR A SUCCESSFUL PRODUCT LAUNCH FROM A GLOBAL AND LOCAL PERSPECTIVE



There is a need for HTA submissions and price negotiations in almost all countries.



- Preliminary EU pricing strategy / payer testing
- Draft payer value proposition
- Early HTA advice & shape Ph3

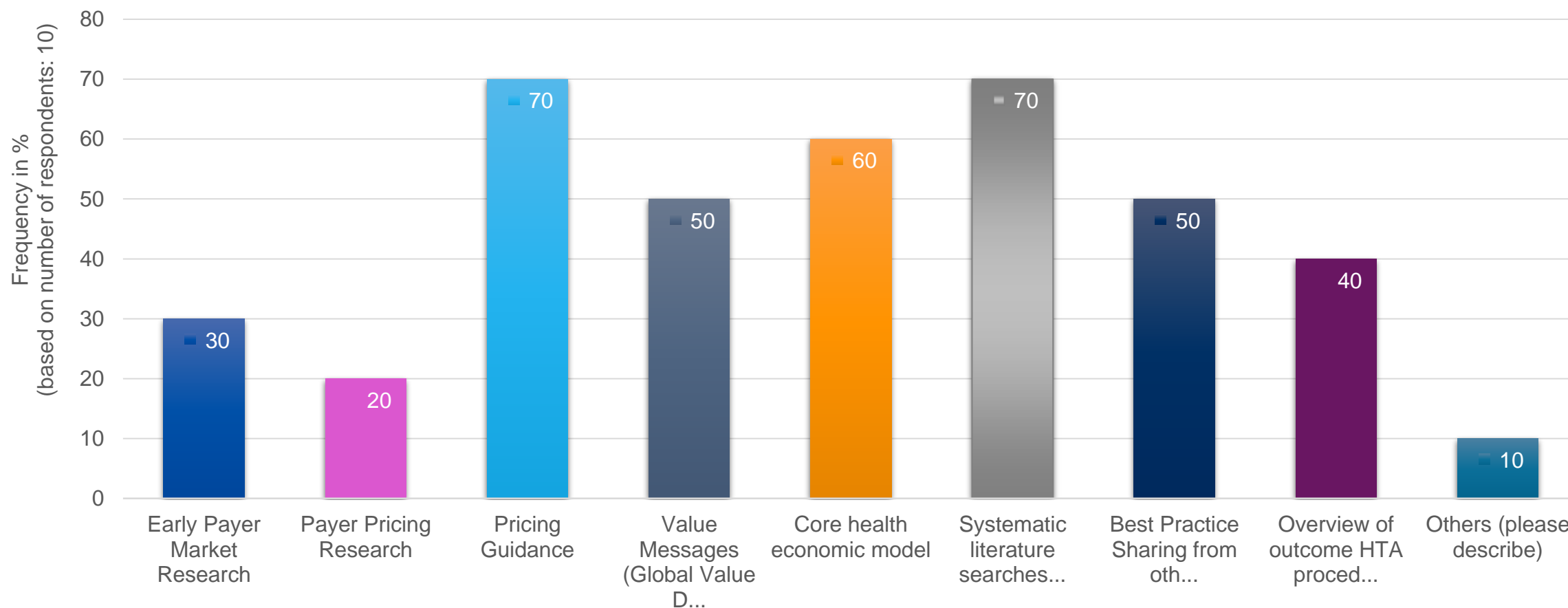


Important for launch

Key driver

- Global
- Local

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



Intl. Sales

Christian Schmolck



Medical

Ralph Müller



Germany

Martin Strünkelnberg



UK

Sarah Siple



Benelux

Johan van Ieperen



Spain

Miguel Gonçalves



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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2.1	Acute treatment with Jorveza resulted in 58% of patients achieving combined clinical and histological remission at 6 weeks and 85% at 12 weeks.	3
2.2	Acute treatment with Jorveza resulted in 93% of patients achieving histologic remission at 6 weeks.	5
2.3	Acute treatment with Jorveza resulted in 59% of patients achieving clinical remission at 6 weeks.	5
2.4	Acute treatment with Jorveza resulted in 64% of patients achieving overall symptoms resolution at 6 weeks.	6
2.5	Maintenance treatment with Jorveza resulted in 74% of patients being in remission at 48 weeks.	6
2.6	Patients on Jorveza maintenance treatment relapsed on average after more than 350 days while patients on placebo relapsed after 87 days.	9
2.7	Maintenance treatment with Jorveza resulted in approx. 70% of patients having no visible features of EoE activity.	10
2.8	Acute, as well as maintenance treatment with Jorveza was safe and well tolerated.	10
2.9	Indirect treatment comparisons have shown the rate of histological remission to be higher under acute treatment with Jorveza compared to all other off-label and diet treatments.	13
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3	Economic Value Messages.....	18
3.1	EoE is associated with substantial health care utilization and costs	18
3.2	Treatment with Jorveza has been accepted as being cost-effective by pricing and reimbursement authorities and HTA agencies in ... (insert relevant countries).....	19
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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	14 th August, 2020

PRICING GUIDANCE FOR JORVEZA MAINTENANCE SECURES SUSTAINABLE 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 that
 - 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

