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## MAPPs Webinar

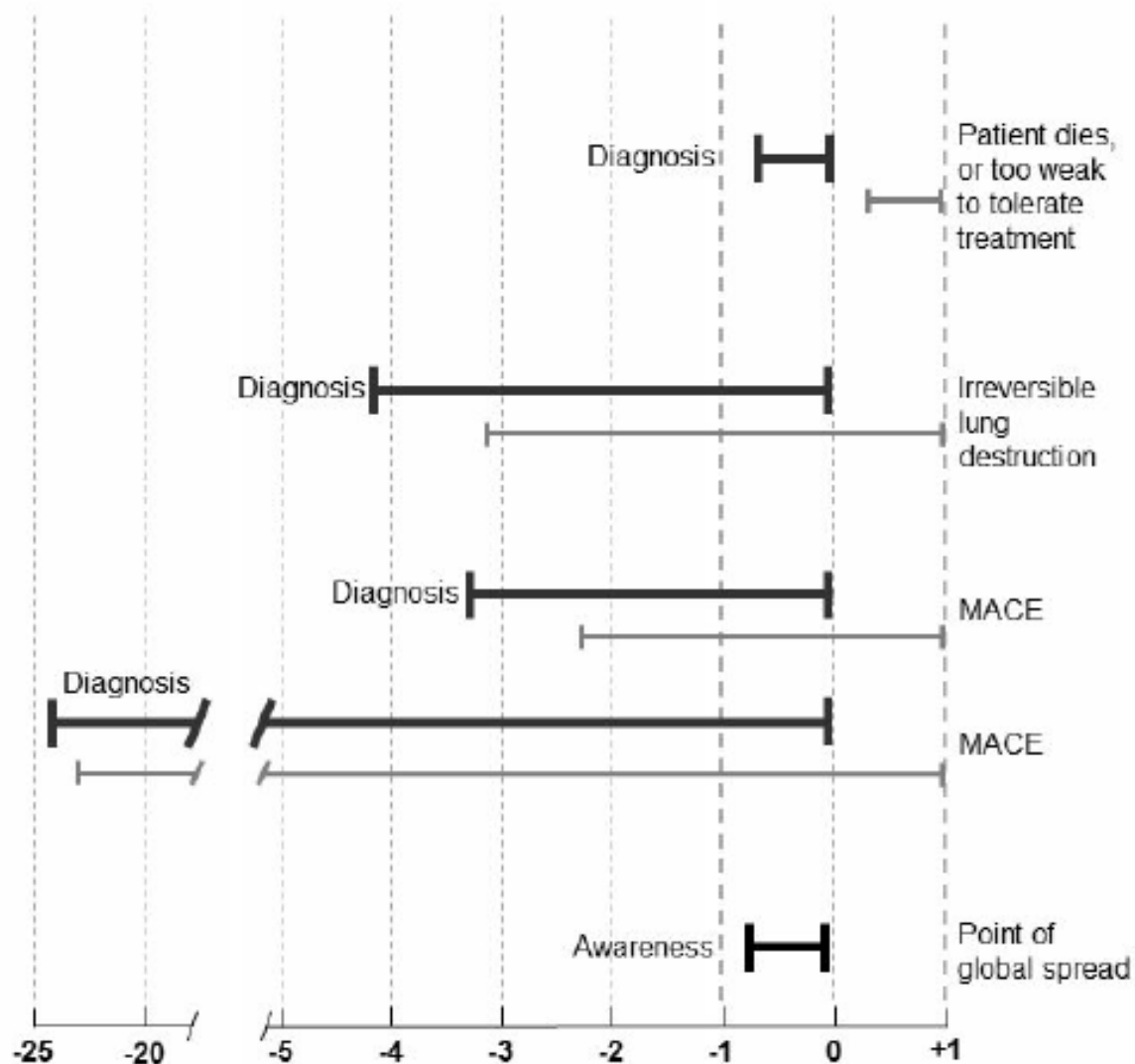
14 April, 2015

James Anderson, Head of Corporate  
Government Affairs, GSK

# Why MAPPs is Important – “Treatment Window of Opportunity”

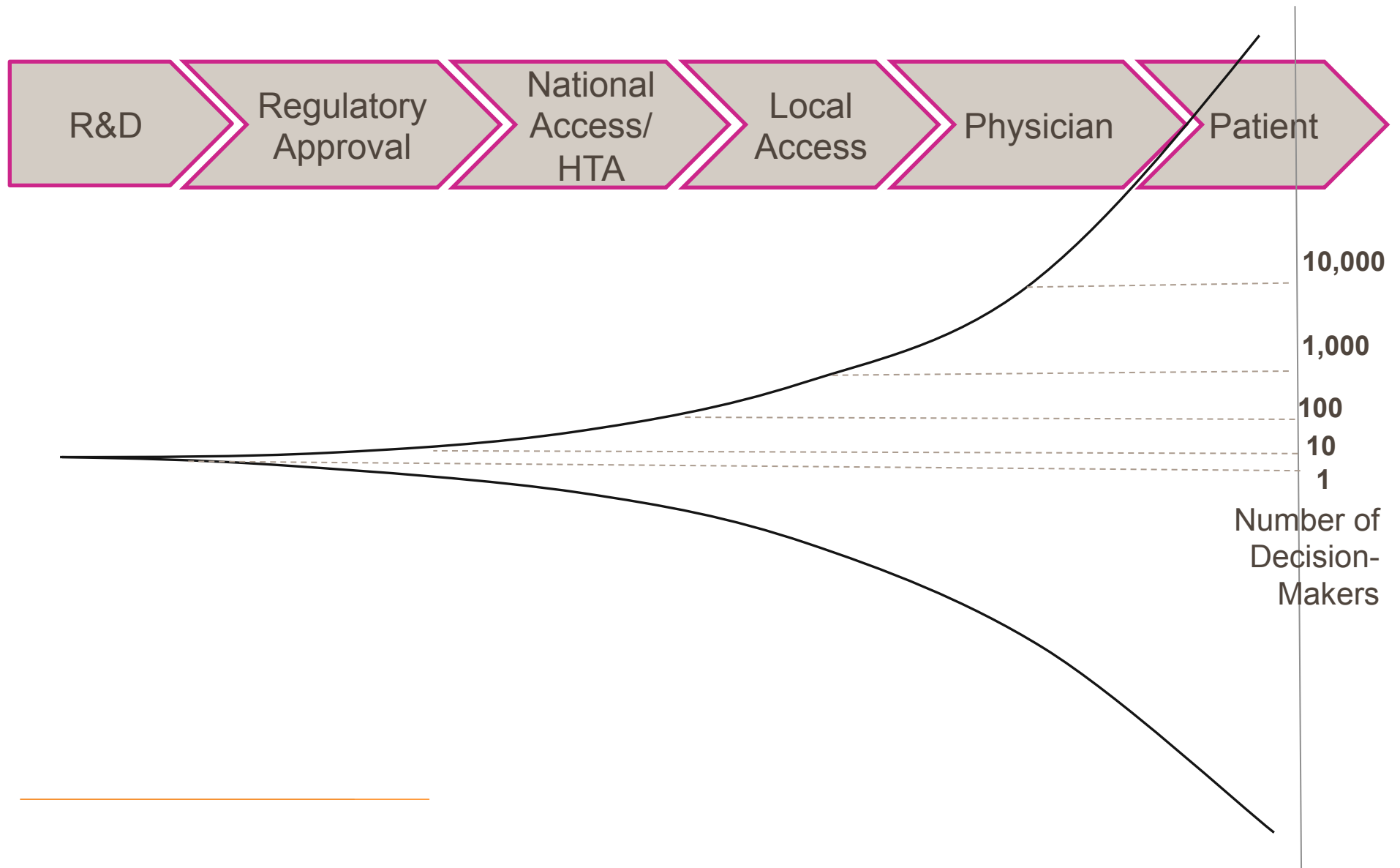


Condition / Patient Population	Therapeutic Goal
Metastatic melanoma	Prolong overall survival
Cystic fibrosis	Prevent irreversible lung destruction
<b>Hypercholesterolemia / dyslipidemia</b> Top: Patients with genetically defined FH Bottom: patients with primary hypercholesterolemia and mixed dyslipidemia, moderate risk of MACE	Prevent MACE
Flu (or similar) pandemic	Achieve herd immunity



Ref: Eichler HG, et al. From adaptive licensing to adaptive pathways: delivering a flexible life span approach to bring new drugs to patients. Clin Pharmacol Ther. 2015 Mar;97(3):234-246

# How Much Evidence is Enough? And Who Needs to Agree?



# 3 Myths we Need to Work Through Together, to Avoid Falling into Traps

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- MAPPs only “works” in Rare Diseases
  - Many aspects of Rare Disease R&D fit with MAPPs
  - But other diseases and development challenges also fit well:
    - Science enables risk or benefit based patient targeting
    - Traditional development infeasible: too long/too many patients needed/can’t generate required evidence
    - Traditional development not economically viable
- R&D investments will be lower under MAPPs than Traditional development pathways
  - Investments before first approval lower, but higher post-launch – company may need to build monitoring infrastructure
  - Costs of failure may increase due to accelerated investments (eg manufacturing, parallel work)
- Product prices will be lower under MAPPs than Traditional development pathways
  - More targeted patient populations may gain greater health benefits (and therefore value) – even if not fully demonstrated at launch.
  - Investments and risks may increase or decrease
  - Value provided to patients who are within treatment window.



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Thankyou

