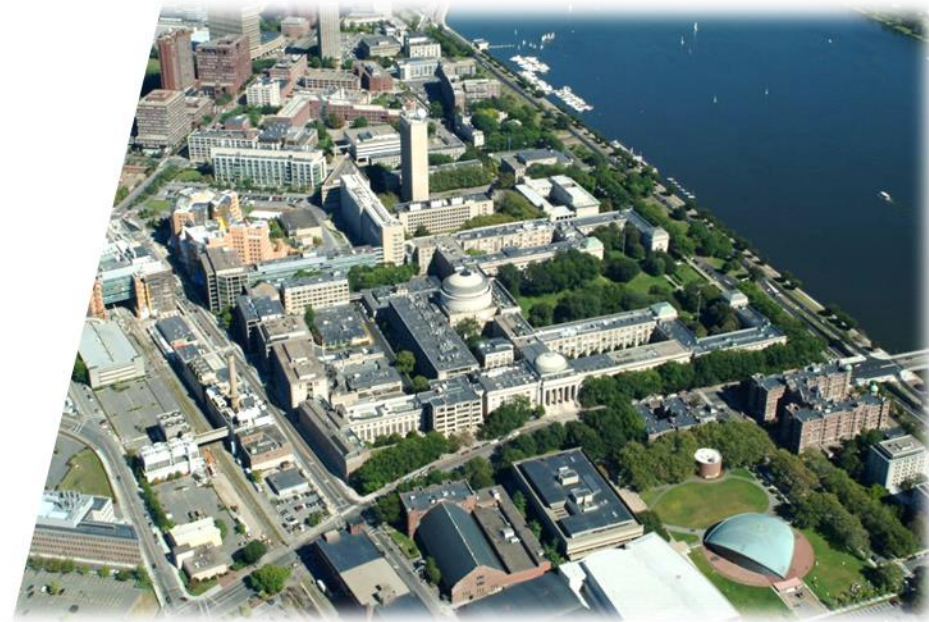


2016 Harvard vs. MIT Case Competition

Harvard Team 6

Vladislava Chalei | Kathryn McKeough | Jonathan Xu | Zishu Chen



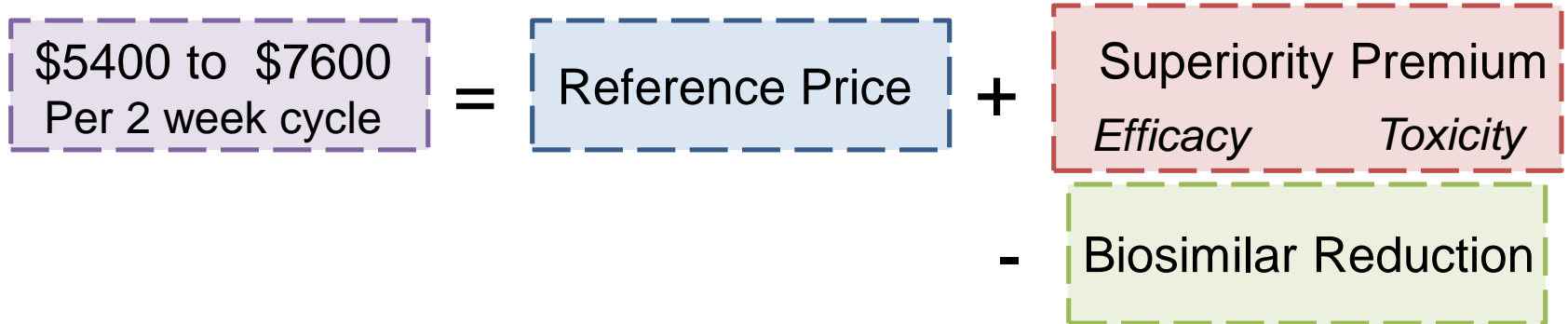
Purpose of Case

The purpose of this case was to help a Boston-based pharmaceutical company develop a pricing strategy for a new drug (“AB-123”) that treats colorectal cancer. The client is considering selling the AB-123 drug on a standalone basis or with another drug (“Multivide”).

Client and drug names have been withheld for privacy reasons.

3 year Pricing strategy (AB-123)

Year 1



Years 2 and 3

- Natural inflation
- Adjust based on true clinical performance
- Any additional FDA approvals

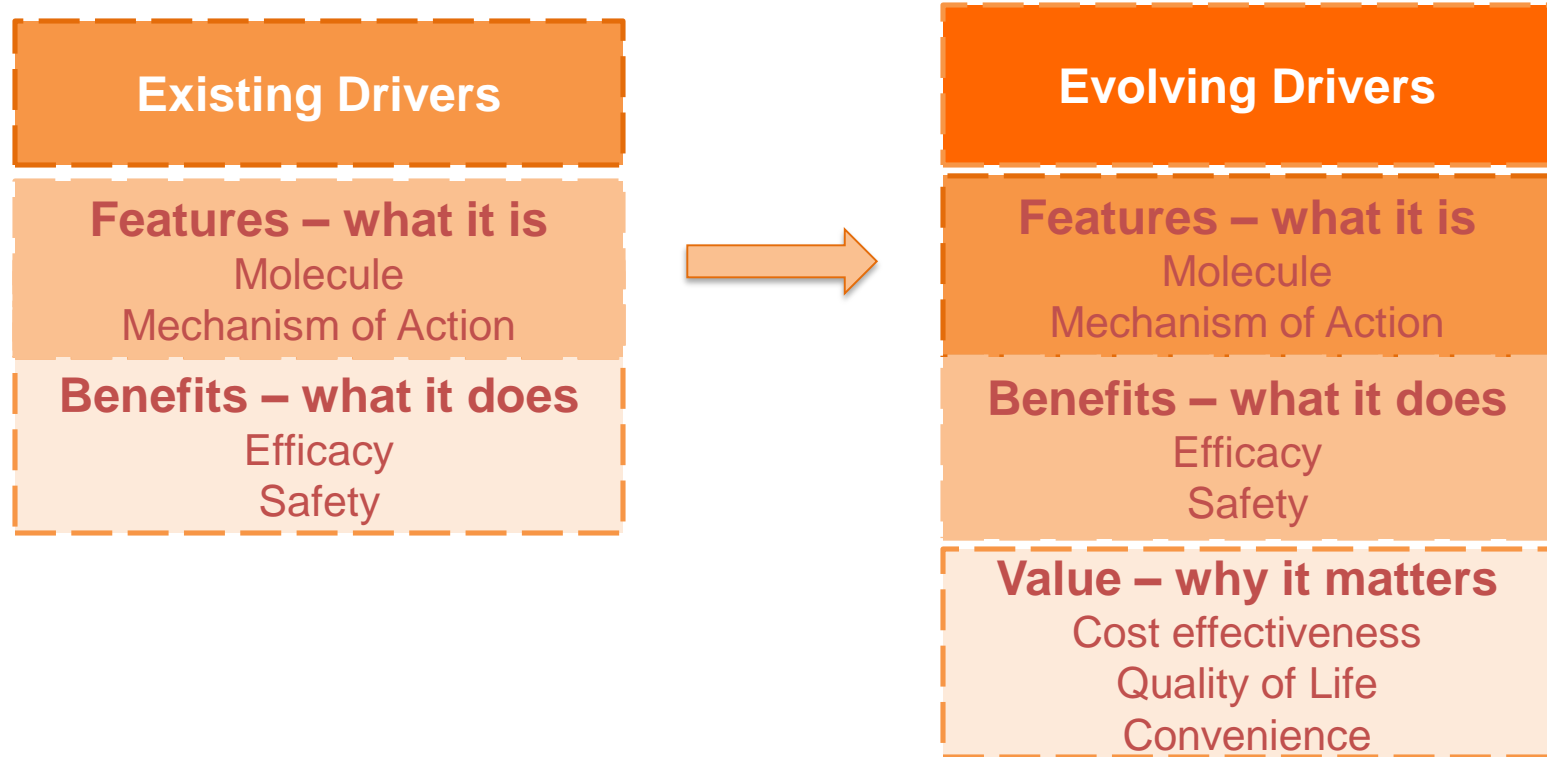
Value price: stakeholder-informed, evidence-based

Value = characteristics and attributes customers are willing to pay for

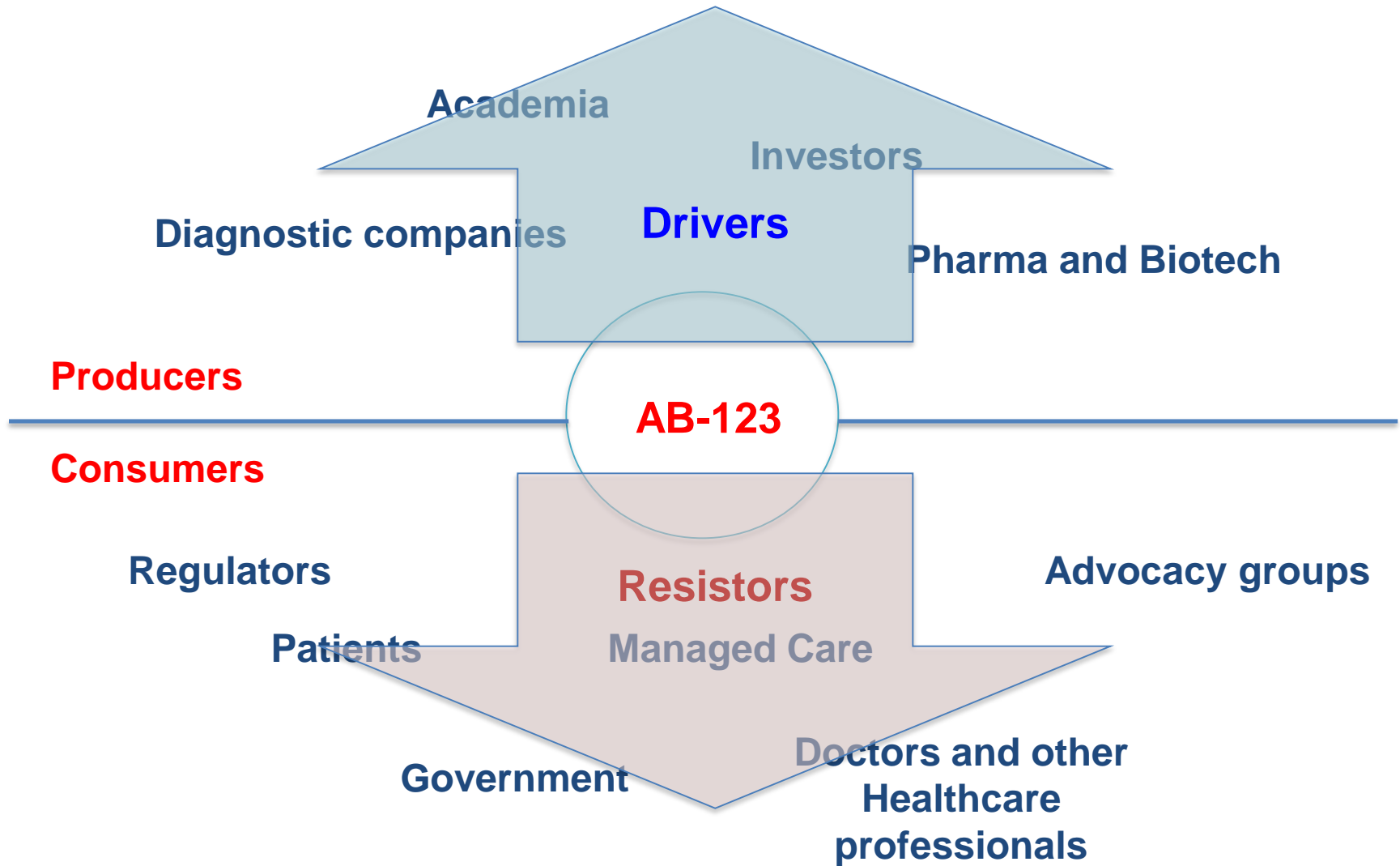
Health outcomes that matter to patients

Value in healthcare =

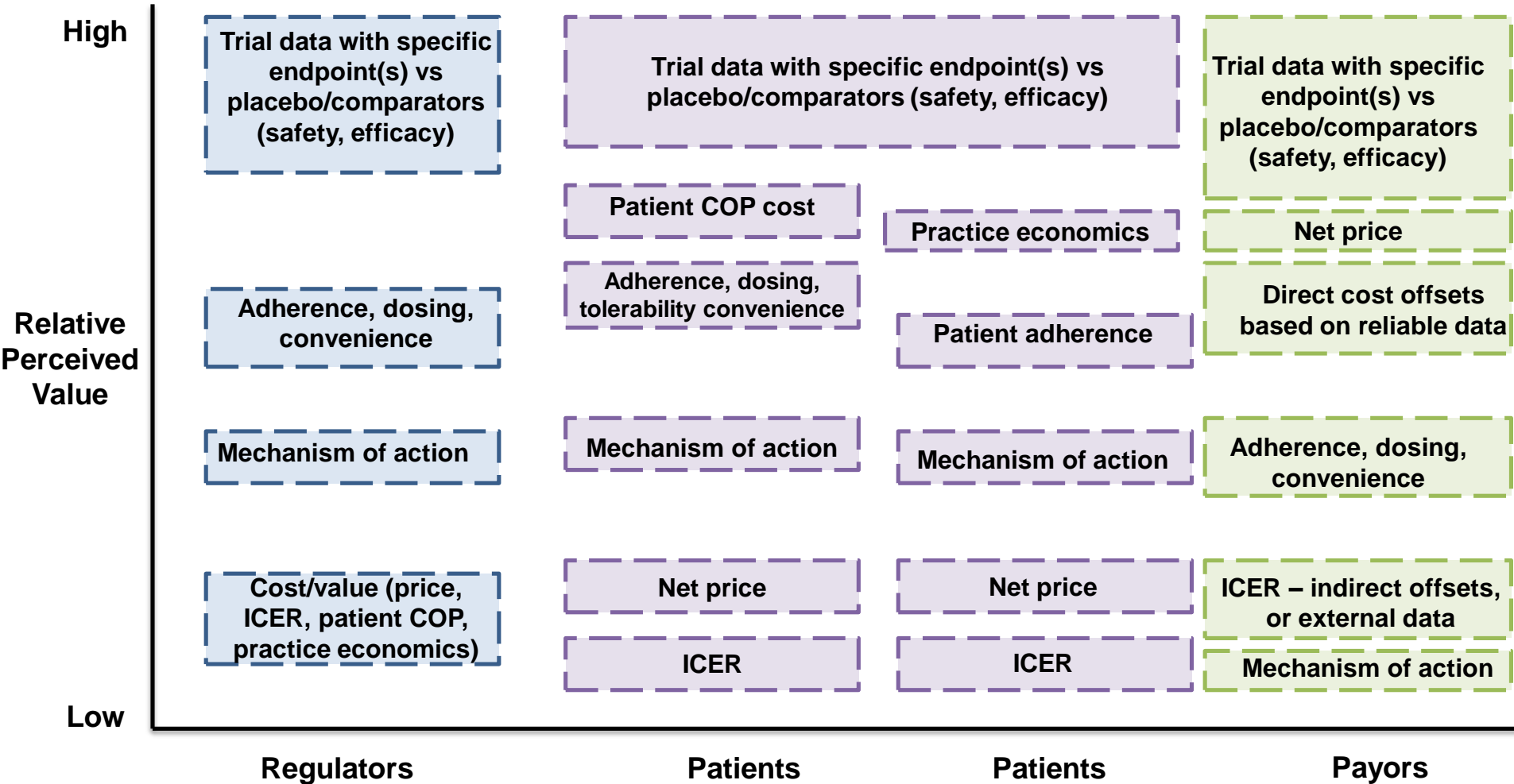
Cost of delivering those outcomes



Pricing environment: multiples stakeholders...



... with varying perspectives on value



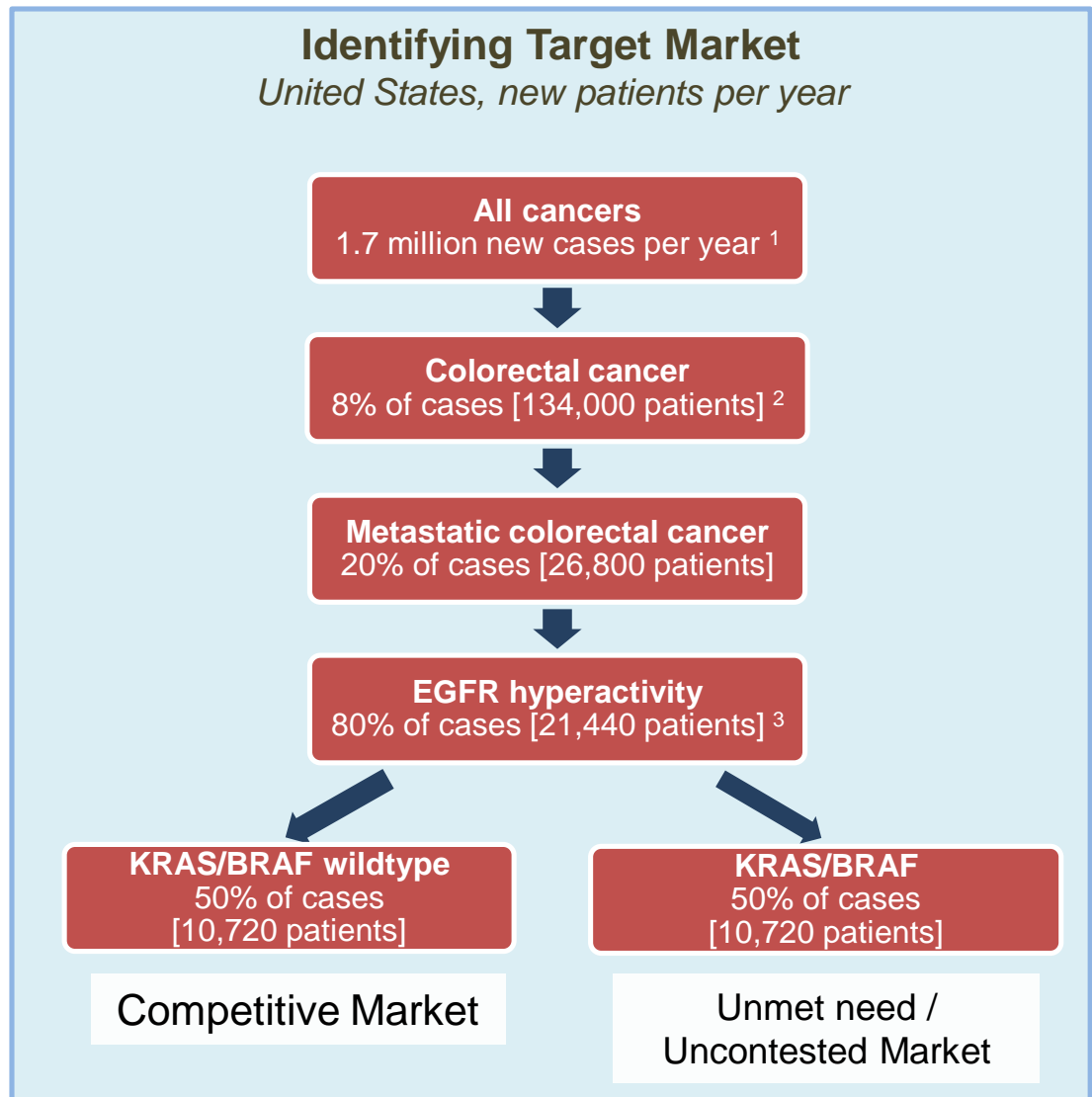
Market Opportunity (U.S.)

- 1.2AB people are currently living with the disease
- 134,000 new colorectal cancer cases/year
- Companion diagnostics increasingly becoming an industry standard
- Lung cancer – 80%
Glioblastoma – 50%
Head and neck – 80-100%

¹ National Cancer Institute. SEER Stat Fact Sheets: Cancer of Any Site. <http://seer.cancer.gov/statfacts/html/all.html>

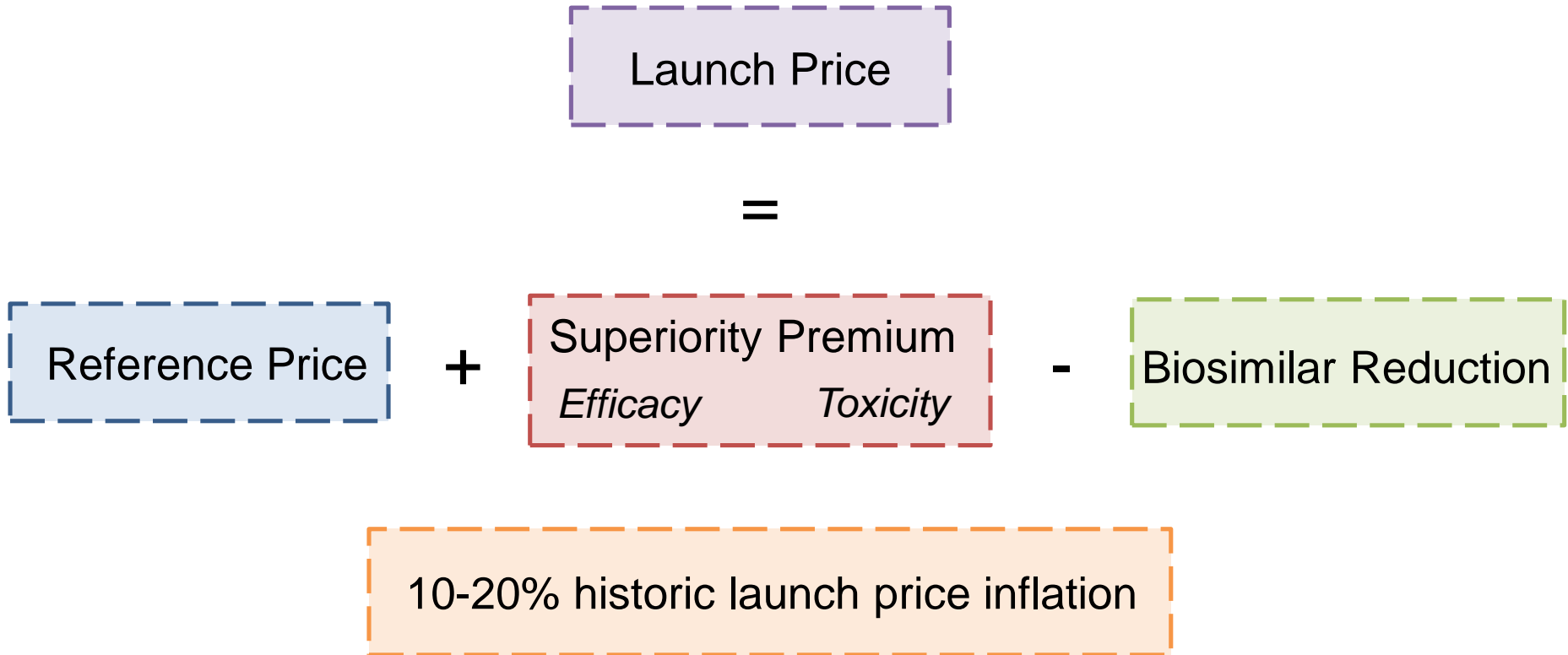
² National Cancer Institute. SEER Stat Fact Sheets: Colon and Rectum Cancer. <http://seer.cancer.gov/statfacts/html/colorect.html>

³ Yarom, N., Jonker, D., *The Role of the Epidermal Growth Factor Receptor in the Mechanism and Treatment of Colorectal Cancer*, *Discovery Medicine*, 2011



Launch Price Rationale

AB-123 + Multivide

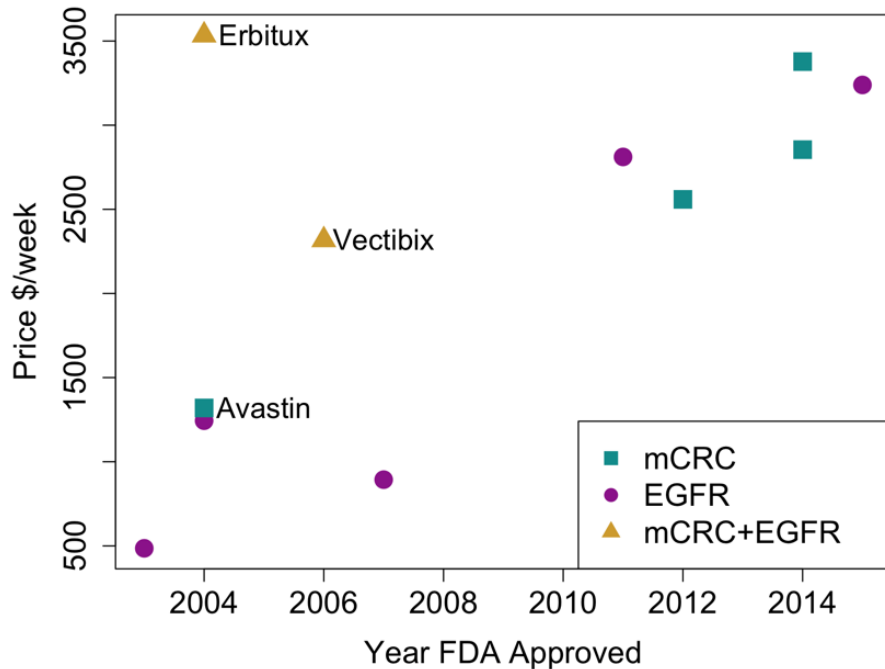


Ref: Howard et al., 2015 JEP

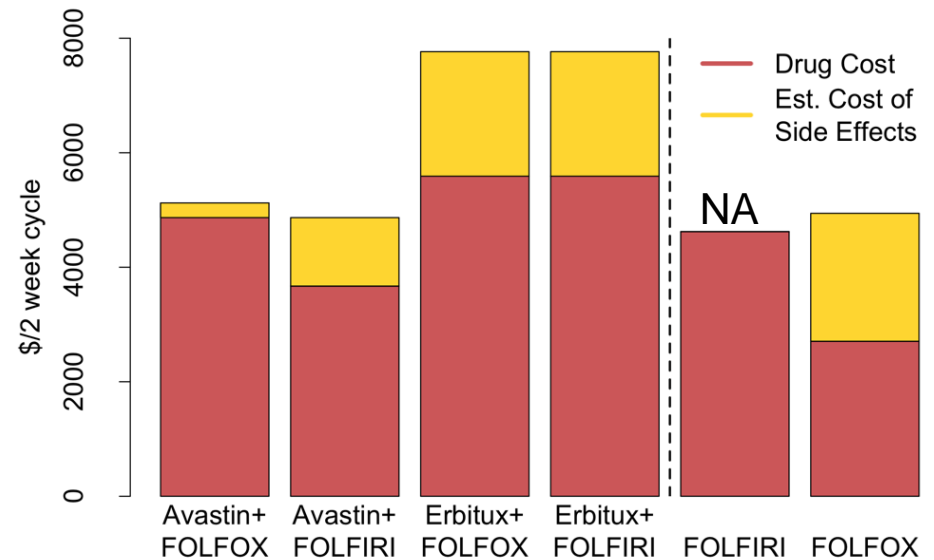
Launch Price Rationale – Reference Price

Cost of treatment based on direct competitors

Price of mCRC & EGFR inhibitor drugs
(Adjusted for Inflation)



Total Cost of 1 Line Treatment
(Adjusted for Inflation)



Ref: (left) Memorial Sloan Kettering Cancer Center (2015)

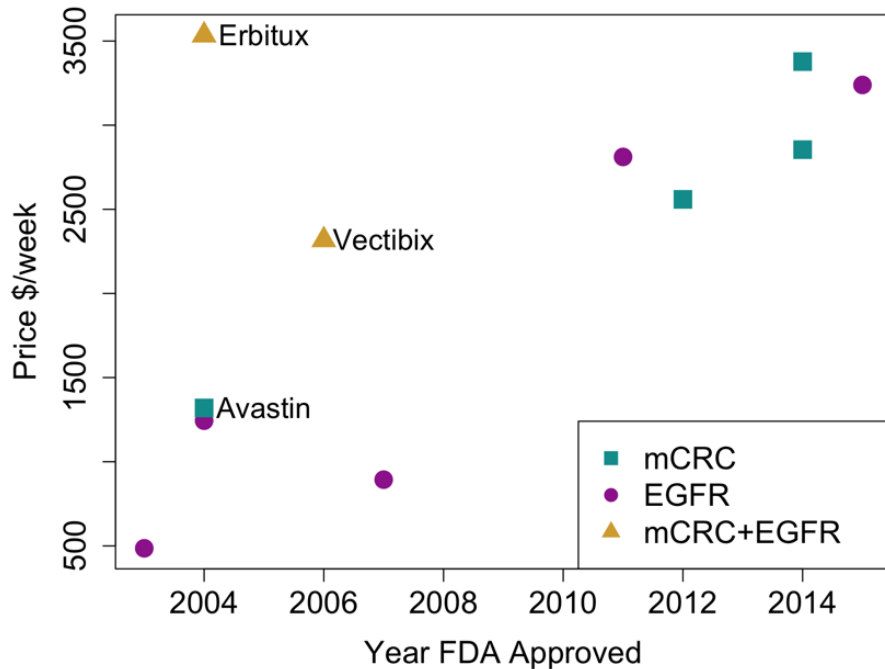
(right) Nelson et al. (2011), Chustecka (2008), ASCO (2015) National Bureau of Economic Research (2009)



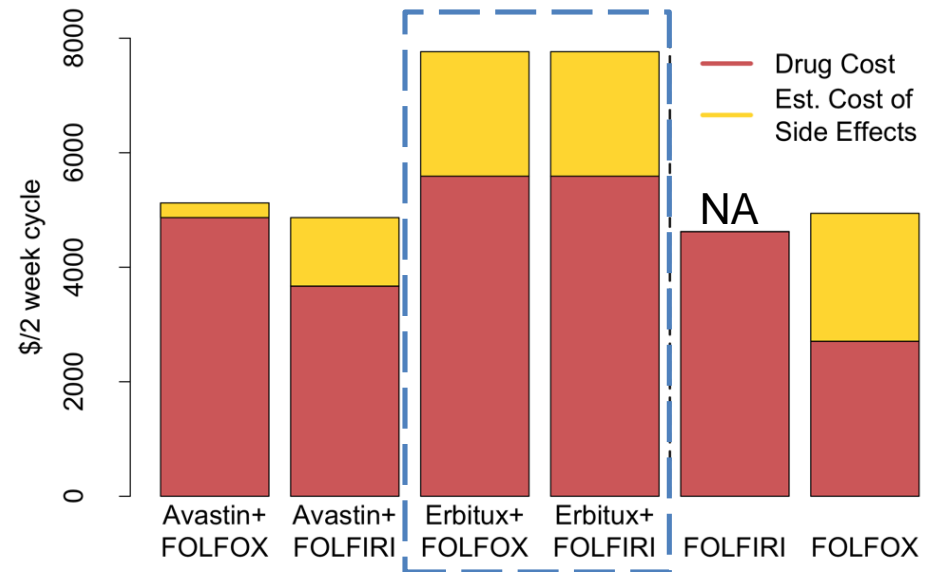
Launch Price Rationale – Reference Price

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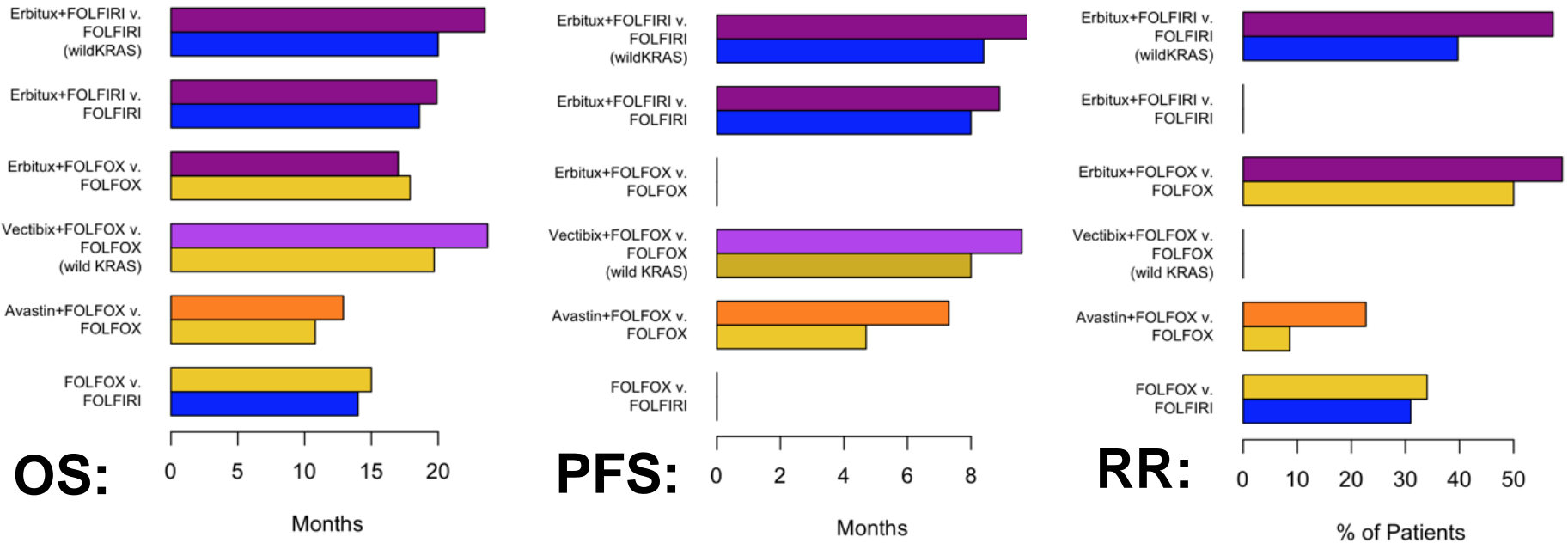


Erbitux + FOLFOX/FOLFIRI =
\$5500 per 2 week cycle

Launch Price Rationale – Superiority Premium

Efficacy of competitors

Phase 3 Clinical Trials of Direct Competitors



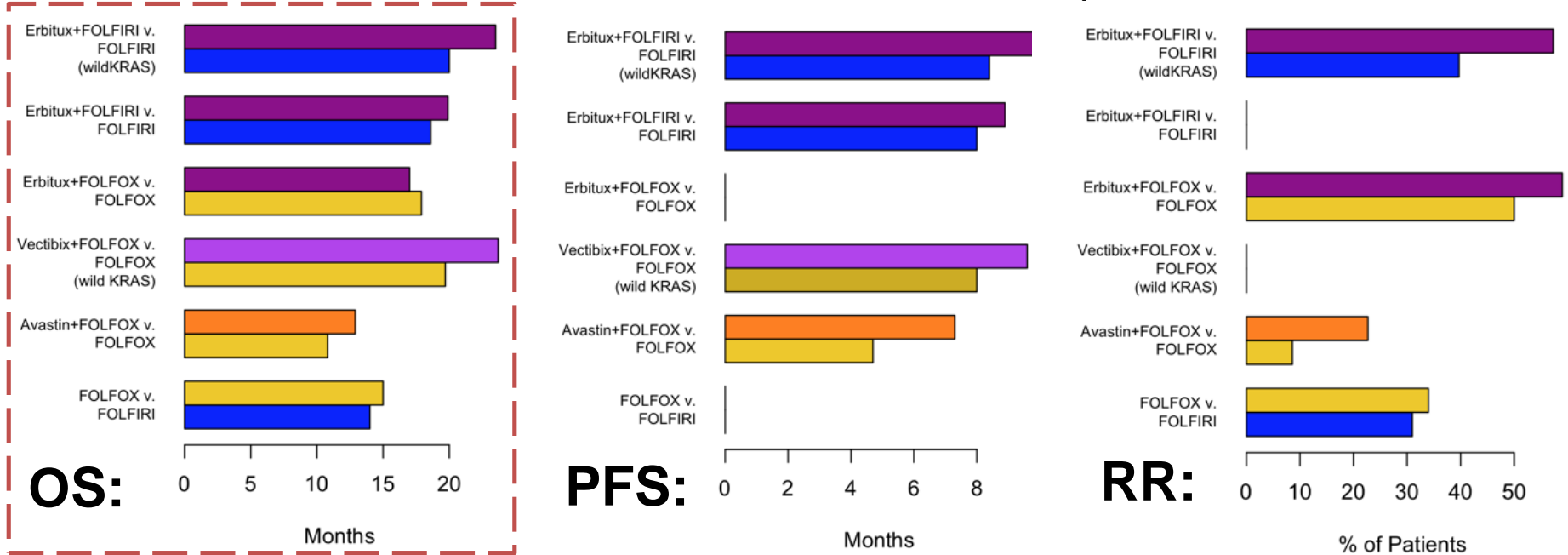
Ref: Phase 3 clinical trial data (Gustavsson et al. 2015)

A Review of the Evolution of Systemic Chemotherapy in the Management of Colorectal Cancer

Launch Price Rationale – Superiority Premium

Efficacy of competitors

Phase 3 Clinical Trials of Direct Competitors



- AB-123 +Multivide in 1L treatment extends life by 30%
 - 4-7 additional months for OS
- Physicians value extension of OS of 2-4 months at \$70,000 per year
 (4-7 additional months) ~ + \$2700 to \$3800 per 2 week cycle

Launch Price Rationale – Superiority Premium

Grade 3-4 Toxicities

	Ab Pain	Diarrhea	Nausea	Vomiting	Neutropenia
Erbix+FOLFIRI	<10%	16%	<10%	NA	31%
Avastin+FOLFIRI	8%	34%	1%	1%	21%
Avastin+FOLFOX	8%	23%	8%	9%	12%
Onivyde	NA	13%	8%	11%	17%
FOLFOX	6%	15%	4%	6%	39%
FOLFIRI	5%	24%	12%	8%	40%

We estimate about 2/3 of toxicities of direct competitors:
 +(1/3)\$2500 = \$830 per 2 week cycle

Ref: Phase 3 clinical trial data

Launch Price Rationale – Superiority Premium

Other Unique Benefits:

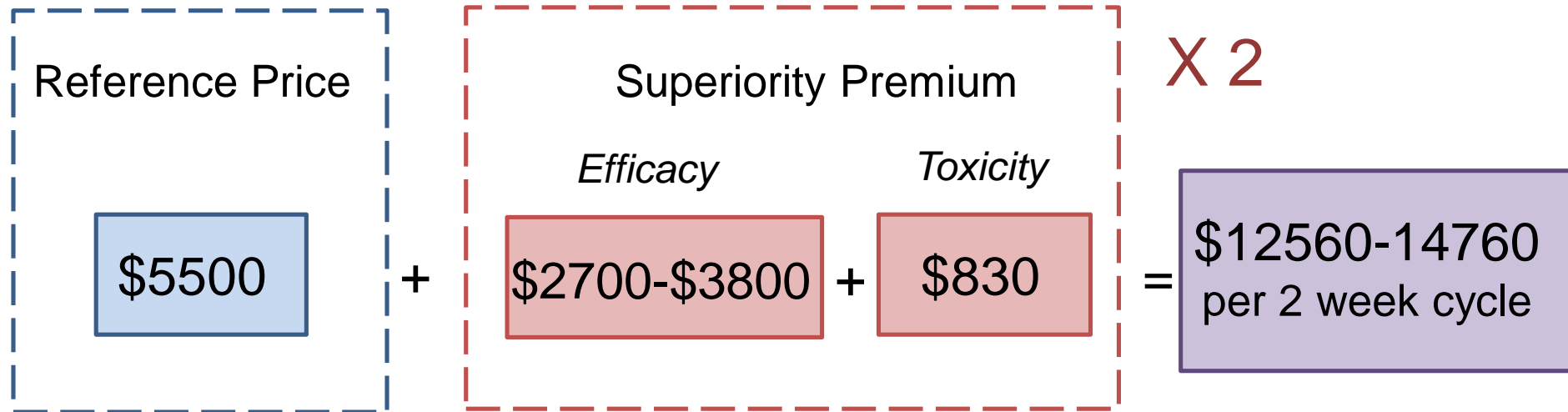
- AB-123 completely blocks EGFR & mutated EGFR
- AB-123 + Multivide does not produce neural toxicity
- Enhanced iABune effector function
- Synergy with MEKi allows for treatment of KRAS & BRAF mutations (50% of Patients with mCRC – significant unmet medical need)

Launch Price Rational – Superiority Premium

Other Unique Benefits:

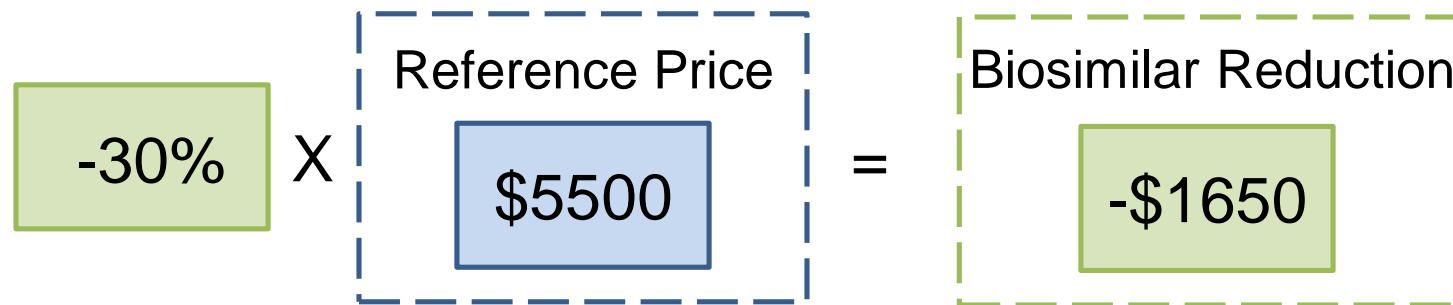
- AB-123 completely blocks EGFR & mutated EGFR
- AB-123 + Multivide does not give patients neural toxicity
- Enhanced iABune effector function
- Synergy with MEKi allows for treatment of KRAS & BRAF mutations

AB-123 + Multivide:



Launch Price Rationale – Biosimilar Reduction

- In 2018 a biosimilar of cetuximab (Erbitux) will be released
- Predict decrease in ~30% of price of cetuximab



- Multitude unique characteristics (superiority premium) will not be affected by biosimilars of cetuximab

Ref: Rand(2014), Amgen (2015)

Launch Price Rationale

AB-123 + Multivide

\$10900 to \$13000
Per 2 week cycle

=

$$\boxed{\$5500} + \boxed{\begin{array}{l} \$2700 \text{ to } \$3800 \\ \$830 \end{array}} \times 2 - \boxed{\$1650}$$

AB-123

\$5400 to \$7600
Per 2 week cycle

Post-launch pricing (Years 2-3)

Value is not fully understood at launch

- Patient population in trials different from reality – limits observable amount of clinical benefit

AB-123: price adjustment when empirical “value” in wider population, earlier stages of the disease, or adjuvant settings becomes more apparent.

- Complex regulatory path over life-cycle

~ 5% yearly increase in inflation-adjusted monthly price post-launch
additional approvals often associated with price increases:
supplemental FDA approval - ~10% increase in monthly price

AB-123: price adjustment upon standalone approval (2 years post-launch?)
Must consider pricing of competition in new settings

Ref: Bennette et al. (2016), Rand (2014), Amgen (2015)

Data to Be Gathered at Time of Launch

**Clinical proof focus
(Evidence-based medicine)**



**Treatment “value” focus
(Value-based medicine)**

“Value” dossier (MUST be included in trial design):

Clinical evidence

Surrogate outcomes: HR, PFS, RR, Symptom palliation, Time Off Treatment
Long-term outcomes: OS
Comparative effectiveness

Economic evidence

Cost effectiveness (incremental cost-effectiveness ratios (ICERs))

Humanistic evidence

Safety

Patient reported outcomes: QoL, convenience, impact on activities of daily living, ability to achieve personal and professional goals

Risks and Mitigating strategies

- What surrogate endpoints reliably approximate the definitive clinical endpoints?
- Are the data on outcomes robust enough?
- Marked difference in cancer-trial populations versus cancer-patient populations
- Total costs obtained in clinical trials may not be the same in real world
- Are we using correct comparators?
- Changes in regulatory and reimbursement environment
- Effect of biosimilar and new competition

Mitigating strategies (under- and overpricing)

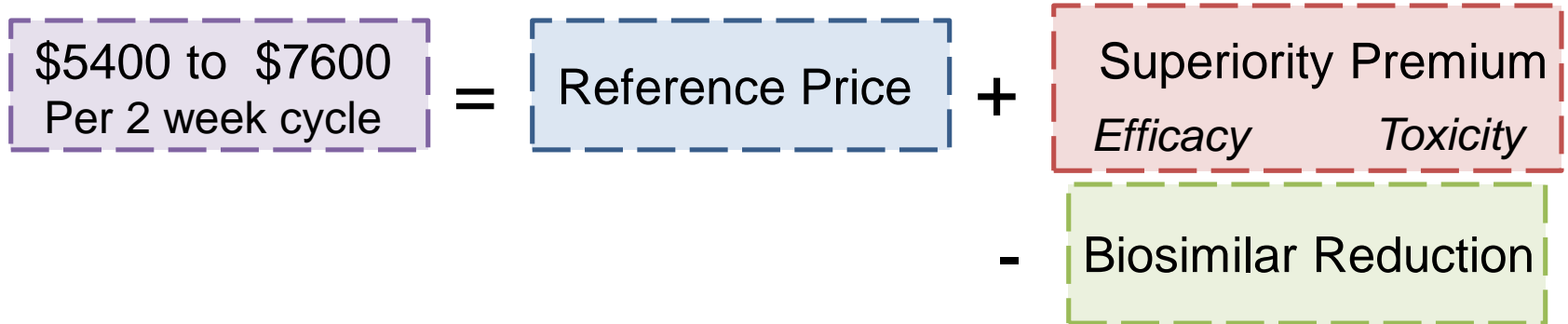
Post-marketing research on “true” value
Market performance assessment
Pharmacovigilance



Dynamic pricing
Risk Sharing Agreements (RSAs)
Patient assistance programs and
expenditure caps

3 year Pricing strategy (AB-123)

Year 1



Years 2 and 3

- Natural inflation
- Adjust based on true clinical performance
- Any additional FDA approvals

References

1. Howard et al. (2015), Journal of Economic Perspectives, *Pricing in the Market for Anticancer Drugs*
2. Center for Health & Policy Outcomes (2015), Memorial Sloan Kettering Cancer Center, *Price & Value of Cancer Drug*
3. Nelson et al. (2011), Journal of Medical Economics, *A comparison of mortality and costs associated with FOLFOX versus FOLFIRI in stage IV colorectal cancer*
4. Chustecka (2008), Medscape Medical News, *Cost of Treating Colorectal Cancer has Skyrocketed*
5. ASCO (2015) , *Cost of Cancer Drugs Should Be Part of Treatment Decisions*
6. Lucarelli & Nicholson (2009), National Bureau of Economic Research, *A Quality Adjusted Price Index for Colorectal Cancer Drugs*
7. Gustavsson (2015) et al. , Clinical Colorectal Cancer, *A Review of the Evolution of Systemic Chemotherapy in the Management of Colorectal Cancer*
8. Assessing an Improving Value in Cancer Care (2009) Chapter 6: *Value in Oncology Practice: Oncologist and Health Insurer*
9. Rand (2014) Rand Corporation , *The Cost Savings Potential of Biosimilar Drugs in the United States*
10. Amgen (2015) Amgen, *Trends in Biosimilars Report*