2016 Harvard vs. MIT Case Competition

Harvard Team 6
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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

$5400 to $7600
Per 2 week cycle

= Reference Price

+ Superiority Premium
  Efficacy  Toxicity

- Biosimilar Reduction

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

Cost of delivering those outcomes

Value in healthcare =

Existing Drivers

Features – what it is
Molecule
Mechanism of Action

Benefits – what it does
Efficacy
Safety

Evolving Drivers

Features – what it is
Molecule
Mechanism of Action

Benefits – what it does
Efficacy
Safety

Value – why it matters
Cost effectiveness
Quality of Life
Convenience
Pricing environment: multiples stakeholders…
… with varying perspectives on value

- **High Relative Perceived Value**
  - **Regulators**:
    - Trial data with specific endpoint(s) vs placebo/comparators (safety, efficacy)
    - Adherence, dosing, convenience
    - Mechanism of action
    - Cost/value (price, ICER, patient COP, practice economics)
    - ICER
  - **Patients**:
    - Patient COP cost
    - Adherence, dosing, tolerability convenience
    - Mechanism of action
    - Net price
  - **Payors**:
    - Trial data with specific endpoint(s) vs placebo/comparators (safety, efficacy)
    - Practice economics
    - Patient adherence
    - Direct cost offsets based on reliable data

- **Low Relative Perceived Value**
  - **Regulators**:
  - **Patients**:
  - **Payors**:
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%

Identifying Target Market
United States, new patients per year

- All cancers
  1.7 million new cases per year
- Colorectal cancer
  8% of cases [134,000 patients]
- Metastatic colorectal cancer
  20% of cases [26,800 patients]
- EGFR hyperactivity
  80% of cases [21,440 patients]

KrAS/BRAF wildtype
50% of cases [10,720 patients]

KrAS/BRAF
50% of cases [10,720 patients]

Competitive Market

Unmet need / Uncontested Market

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 + Multivariate

Launch Price = Reference Price + Superiority Premium - Biosimilar Reduction

Superiority Premium = Efficacy - Toxicity

10-20% historic launch price inflation

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)
Launch Price Rationale – Reference Price

Cost of treatment based on direct competitors

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

- Erbitux
- Vectibix
- Avastin

Year FDA Approved:
- 2004
- 2006
- 2008
- 2010
- 2012
- 2014

Price $/week:
- 500
- 1500
- 2500
- 3500

Total Cost of 1 Line Treatment (Adjusted for Inflation)

- Avastin + FOLFOX
- Avastin + FOLFIRI
- Erbitux + FOLFOX
- Erbitux + FOLFIRI
- FOLFIRI
- FOLFOX

Drug Cost
Est. Cost of Side Effects

Erbitux + FOLFOX/FOLFIRI = $5500 per 2 week cycle
Launch Price Rationale – Superiority Premium

Efficacy of competitors
Phase 3 Clinical Trials of Direct Competitors

<table>
<thead>
<tr>
<th>OS:</th>
<th>PFS:</th>
<th>RR:</th>
</tr>
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<tr>
<td>0 5 10 15 20</td>
<td>0 2 4 6 8</td>
<td>0 10 20 30 40 50</td>
</tr>
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Months

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

<table>
<thead>
<tr>
<th></th>
<th>Ab Pain</th>
<th>Diarrhea</th>
<th>Nausea</th>
<th>Vomiting</th>
<th>Neutropenia</th>
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<tbody>
<tr>
<td>Erbitux+FOLFIRI</td>
<td>&lt;10%</td>
<td>16%</td>
<td>&lt;10%</td>
<td>NA</td>
<td>31%</td>
</tr>
<tr>
<td>Avastin+FOLFIRI</td>
<td>8%</td>
<td>34%</td>
<td>1%</td>
<td>1%</td>
<td>21%</td>
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<tr>
<td>Avastin+FOLFOX</td>
<td>8%</td>
<td>23%</td>
<td>8%</td>
<td>9%</td>
<td>12%</td>
</tr>
<tr>
<td>Onivyde</td>
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<td>13%</td>
<td>8%</td>
<td>11%</td>
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<tr>
<td>FOLFOX</td>
<td>6%</td>
<td>15%</td>
<td>4%</td>
<td>6%</td>
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<tr>
<td>FOLFIRI</td>
<td>5%</td>
<td>24%</td>
<td>12%</td>
<td>8%</td>
<td>40%</td>
</tr>
</tbody>
</table>

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:

Reference Price

$5500

Superiority Premium

Efficacy

$2700-$3800

Toxicity

$830

$12560-14760 per 2 week cycle

X 2
Launch Price Rationale – Biosimilar Reduction

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

\[ \text{Reference Price} \times -30\% = \text{Biosimilar Reduction} \]

\[ \text{Reference Price} = $5500 \]

\[ \text{Biosimilar Reduction} = -$1650 \]

• Multivide unique characteristics (superiority premium) will not be affected by biosimilars of cetuximab

Launch Price Rationale

AB-123 + Multivide

$10900 to $13000
Per 2 week cycle

= 

$5500 + $2700 to $3800
$830 × 2

$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

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

$5400 to $7600 Per 2 week cycle = Reference Price + Superiority Premium Efficacy - Toxicty - Biosimilar Reduction

Years 2 and 3

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

2. Center for Health & Policy Outcomes (2015), Memorial Sloan Kettering Cancer Center, *Price & Value of Cancer Drug*
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*
8. Assessing an Improving Value in Cancer Care (2009) Chapter 6: *Value in Oncology Practice: Oncologist and Health Insurer*