Rheumatoid Arthritis: A growth opportunity for Roche

Karl Mahler, Head IR
IXIS RA Seminar, 11 April 2006
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Epidemiology of RA
Current and predicted prevalence

- Overall prevalence is 0.5–1.0 %
- Approximately 3 times more prevalent in woman than in men
- Incidence increases with age until approximately 75 years and decreases thereafter
**RA: Potential CHF 12 bn market by 2013**

*Biologics main driver*

![Sales to treat RA](chart)

- **2003:** 3,930
- **2008:** 8,466
- **2013:** 11,613

**Source:** Decision Resources March 2005, US/Top 5 EU/Japan; (1 USD=1.2737717 CHF)

**Majority patients still treated with DMARDs**

*Biologics account for majority sales*

**RA treated population in 2005**

- **Conventional DMARDs:** 86%
- **Biologics:** 14%

**RA sales in 2005**

- **Conventional DMARDs:** 90%
- **Biologics:** 10%

**Source:** IMS PADDs, Sales in LC CHF, Biologic sales estimate from US PDDA Verispan, Conventional DMARDs Sales in M1C0 (Spec Antirheum Agents), Estimated US/Top5 EU/Japan Patient Share from Decision Resources March 2005
Sales of biologics in RA
Strong sales growth also outside the US

RA 2004
Bio 4.97 CHF

RA 2005
Bio 6.68 CHF

2004 vs. 05 sales growth:
US ~29 %, Canada ~31 %, Top 5 EU ~41 %, Other ~68 %

Source: IMS PADDS, Sales 2005 in LC CHF; Sales in RA estimated with US PDDA Verispan

Increasingly competitive environment …
Opportunities remain for differentiated products
Roche in RA: A new therapeutic franchise

Urs Schleuniger
Business Director, Haematology and Autoimmune Diseases
IXIS RA Seminar, 11 April 2006

Rheumatoid Arthritis
A debilitating disease

• Affects about one per cent of population
• Progressive inflammation resulting in
  – Swollen and tender joints
  – Pain and fatigue
  – Disability
• Early Disease Progression:
  – Irreversible joint damage in 70% of patients within two years
  – 10% of patients stop working after one year
RA: Current treatment schedule

- 0.5 – 1% of population
- 90% of RA patients
- 60% of RA diagnosed patients
- 12% of RA diagnosed patients
- 30-40% inadequate response

RA patients → RA diagnosed → NSAID or Cox-2 → Non-MTX DMARDs

Methotrexate

Methotrexate + Other DMARD

Methotrexate + Biologics

DMARD: Disease Modifying Anti Rheumatic Drugs, NSAIDs: Non-Steroidal Anti Inflammatory Drugs

Assessment tools for RA

Commonly employed and validated tools include

<table>
<thead>
<tr>
<th>Disease activity</th>
<th>Radiology</th>
<th>Functional status</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACR response criteria</td>
<td>Sharp score</td>
<td>Health Assessment Questionnaire HAQ</td>
</tr>
<tr>
<td>EULAR response criteria</td>
<td>Larsen index</td>
<td></td>
</tr>
<tr>
<td>DAS Disease Activity Score</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

ACR: American College of Rheumatology
EULAR: European League against Rheumatism
**The Unmet Need**

*Major progress made but far from remission*

- 30 – 40 % of patients don’t have adequate control with current therapies
- 60 – 80 % of patients do not achieve **major** signs and symptoms control (ACR 70)
- No drug so far has gained regulatory approval for REMISSION

**Future challenge**

*Improvement in efficacy*

- ACR 70 is only achieved in ~20 % of patients with currently most effective therapies (MTX + biologics)
- The future - most patients on
  - Combination regimens
  - Individualized therapy
  - Intensive treatment in an early stage of the disease

ACR: American College of Rheumatology; HCQ: Hydroxychloroquine; SSZ: Sulfasalazine
MabThera/ Rituxan in Rheumatoid Arthritis

Actemra in Rheumatoid Arthritis

Potential roles of B Cells in the immunopathogenesis of RA

- Secretion of proinflammatory cytokines
- Antigen presentation
- T-cell activation
- Autoantibody production and self-perpetuation

Global MabThera/Rituximab development
A tri-company partnership

**Biogen Idec**
- Phase III in anti-TNF inadequate responders (IR)
- Reflex
- Globally filed
  - US: Aug ’05
  - EU: Sep ’05
  - Approval
    - US: March ’06

**Roche**
- Phase IIb
dancer
- SERENE, MIRROR, IMAGE
- Phase III in DMARD IR and MTX naïve patients
- Global filing 2007

**Genentech**

**REFLEX**
Study design in patients who failed anti-TNF therapy

- Anti-TNF inadequate responders (MTX for ≥ 3 m.) n = 500
- Placebo + MTX n=200
- **MabThera + MTX n=300**

*Primary endpoint*
- ACR20 at week 24

*Secondary endpoints*
- ACR50 and ACR70 at week 24
- DAS28 from baseline to week 24
- EULAR at week 24

A Randomised Evaluation of Long-term Efficacy of Rituximab in RA
REFLEX efficacy

ACR responses at 6 months (all patients)

Placebo + MTX (n=201) MabThera 2x1000mg + MTX (n=298)

51
27
12

MabThera significantly improves all ACR responses

ACR: American College of Rheumatology

REFLEX efficacy

ACR responses at 6 months

RF-positive RF-negative

Magnitude of response similar and independent of Rheumatoid Factor

ACR: American College of Rheumatology
**REFLEX efficacy**

*Change in DAS28 at 6 months (all patients)*

- **Placebo + MTX** (n=201)
  - Mean Change in DAS28: -0.34

- **MabThera 2x1000mg + MTX** (n=298)
  - Mean Change in DAS28: -1.83
  - Minimum clinically important difference: -1.8
  - p < 0.0001

**Impressive reduction in disease activity**

**REFLEX efficacy**

*Changes in SF-36 categories (all patients)*

- **Placebo + MTX** (n=201)
  - Physical Health: 20.3%
  - Mental Health: 37.8%

- **Rituximab 2x1000mg + MTX** (n=298)
  - Physical Health: 48%
  - Mental Health: 48%

**Substantial improvement in physical and mental health**
REFLEX efficacy
Radiographic endpoints at week 24

- Genant-Modified Total Sharp Score
- Total Joint Space Narrowing Score
- Total Erosion Score

**Placebo (N=177)**
- 0.6
- 0.2
- 0.4

**MabThera (N=268)**
- 1.2
- 0.5
- 0.8

*Statistically significant at the 0.05 level

24 Placebo and 30 rituximab patients were missing x-rays at week 24

Preliminary data suggest prevention of joint damage
1 year up-date EULAR June ’06

**Conclusions of 6-month primary analyses**

- MabThera is associated with highly significant and clinically meaningful improvement in all RA key outcome measures achieved after a single course of two MabThera administrations
- Significant efficacy irrespective of Rheumatoid Factor
- MabThera is well tolerated
- Preliminary data suggest prevention of structural damage
DANCER
Study design in RF-positive patients (n=360)

<table>
<thead>
<tr>
<th>Corticosteroid dose</th>
<th>Placebo</th>
<th>2 x 100mg i.v.</th>
<th>2 x 100mg i.v. and p.o.*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Placebo + MTX</td>
<td>A (n=40/20)</td>
<td>B (n=40)</td>
<td>C (n=40)</td>
</tr>
<tr>
<td>Rituximab 2 x 500mg + MTX</td>
<td>D (n=40)</td>
<td>E (n=40)</td>
<td>F (n=40)</td>
</tr>
<tr>
<td>Rituximab 2 x 1000mg + MTX</td>
<td>G (n=40/20)</td>
<td>H (n=40/20)</td>
<td>I (n=40/20)</td>
</tr>
</tbody>
</table>

Primary endpoint
- ACR 20 response at week 24 for RF-positive patients

Patients
- stratified by region (US or non-US)
- failed at least one DMARD (other than MTX) but no more than 5 RF positive/RF negative

*770 mg total
ACR: American College of Rheumatology
Dose-ranging Assessment: International Clinical Evaluation of Rituximab in RA

DANCER efficacy
ACR responses at 6 months in RF-positive patients

ACR: American College of Rheumatology
### DANCER efficacy

**High-hurdle endpoints at 6 months in RF-positive patients**

![Graph showing efficacy endpoints](image)

- **ACR70**
- **EULAR Good Response**
- **EULAR Remission**
- **EULAR Low Disease**

- Placebo + MTX
- MabThera 2x500mg + MTX
- MabThera 2x1000mg + MTX

**High level of efficacy demonstrated with high dose of MabThera**

### DANCER efficacy

**ACR20 Logistic regression: Main effects model in RF-positive and RF-negative patients**

<table>
<thead>
<tr>
<th>Variable</th>
<th>DF</th>
<th>Wald Chi²</th>
<th>Pr &gt; Chi²</th>
</tr>
</thead>
<tbody>
<tr>
<td>MabThera</td>
<td>2</td>
<td>18.81</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Corticosteroids</td>
<td>2</td>
<td>2.85</td>
<td>0.241</td>
</tr>
<tr>
<td>Rheumatoid Factor</td>
<td>1</td>
<td>0.57</td>
<td>0.452</td>
</tr>
</tbody>
</table>

**Efficacy not dependent on glucocorticoid use and Rheumatoid Factor**

ACR: American College of Rheumatology; DF: Degrees of Freedom
DANCER safety
Most frequently reported AE’s in all patients

<table>
<thead>
<tr>
<th></th>
<th>Placebo + MTX (n=149)</th>
<th>MabThera 2 x 500mg + MTX (n=124)</th>
<th>MabThera 2 x 1000mg + MTX (n=192)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exacerbation of RA</td>
<td>19 (13%)</td>
<td>14 (11%)</td>
<td>21 (11%)</td>
</tr>
<tr>
<td>Headache</td>
<td>13 (9%)</td>
<td>8 (6%)</td>
<td>19 (10%)</td>
</tr>
<tr>
<td>Nausea</td>
<td>9 (6%)</td>
<td>10 (8%)</td>
<td>12 (6%)</td>
</tr>
<tr>
<td>URTI</td>
<td>8 (5%)</td>
<td>7 (6%)</td>
<td>10 (5%)</td>
</tr>
<tr>
<td>Arthralgia</td>
<td>5 (3%)</td>
<td>5 (4%)</td>
<td>11 (6%)</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>8 (5%)</td>
<td>7 (6%)</td>
<td>6 (3%)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>8 (5%)</td>
<td>5 (4%)</td>
<td>8 (4%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>4 (3%)</td>
<td>5 (4%)</td>
<td>12 (6%)</td>
</tr>
<tr>
<td>Rigors</td>
<td>3 (2%)</td>
<td>5 (4%)</td>
<td>13 (7%)</td>
</tr>
<tr>
<td>Dizziness</td>
<td>6 (4%)</td>
<td>4 (3%)</td>
<td>10 (5%)</td>
</tr>
</tbody>
</table>

URTI: Upper Respiratory Tract Infection

MabThera is well tolerated

DANCER
Conclusions from 6 months analyses

- MabThera is associated with highly significant and clinically meaningful improvement in all RA key outcome measures
  - Significant improvements in ACR response
  - Significant reductions in DAS
  - Clinically meaningful effects on EULAR responses, QOL, CRP, fatigue
- Both MabThera doses show significant efficacy, with the high dose showing greater high hurdle responses
- Efficacy not dependent on glucocorticoid use or Rheumatoid Factor
- Well tolerated
- Premedication with glucocorticoid administration reduces the frequency and severity of infusion reactions
- Slight increase in rate of infections
MabThera further courses

Study outline

• Patients received MabThera infusion with background MTX
• Second course was permitted at anytime post 24 weeks of initial treatment
  - required evidence of returning disease
• Protocol ongoing with continual accrual of patients from phase IIa and DANCER (cohort now > 250 patients)

MabThera — ACR Efficacy

Repeat courses provide improved ACR efficacy over the first treatment course
Proportion of adverse events by treatment course

<table>
<thead>
<tr>
<th>AEs</th>
<th>Placebo</th>
<th>First</th>
<th>Second</th>
<th>Third</th>
<th>Fourth</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Any</td>
<td>86 (88%)</td>
<td>911 (88%)</td>
<td>404 (71%)</td>
<td>121 (63%)</td>
<td>22 (55%)</td>
</tr>
<tr>
<td>Serious</td>
<td>23 (22%)</td>
<td>161 (15%)</td>
<td>60 (11%)</td>
<td>11 (6%)</td>
<td>3 (8%)</td>
</tr>
</tbody>
</table>

No evidence for additional safety signals with repeat courses

MabThera further courses

Conclusions

- Repeated courses of MabThera are further improving signs and symptoms control and are well tolerated
- No long term safety signal identified to date
- Time course of DAS-CRP and RF would suggest a 2nd course is required for a large part of the patients before the 12 months mark after the 1st infusion

DAS: Disease Activity Score; CRP: C Reactive Protein; RF: Rheumatoid Factor
MabThera/ Rituxan in Rheumatoid Arthritis

Actemra in Rheumatoid Arthritis

IL-6: A new target in the treatment of RA

- Hepatocytes
  - Production of acute phase proteins (CRP) and hepcidin
- Induction of auto-antibodies, RF
- Hyper γ-globulinemia
- B cells
- T cell activation
- Induction of adhesion molecules
- Maturation of megakaryocytes
- Thrombocytosis
- Activation of osteoclasts
- Bone resorption
- Differentiation of monocytes to macrophages

After Yoshizaki et al. 1988
Actemra: Phase II efficacy

ACR scores improved in mono- and combination therapy in different populations

Japanese study (162 pts, 12 wks)

- Placebo: 11.3%
- 4mg/kg: 26.4%
- 8mg/kg: 40.4%
- MTX: 16.4%
- 4mg/kg + MTX: 41%
- 8mg/kg + MTX: 37%

EU study (Charisma) (359 pts, 16 wks)

- Placebo: 2%
- 4mg/kg: 29%
- 8mg/kg: 28%
- MTX: 26%
- 4mg/kg + MTX: 37%
- 8mg/kg + MTX: 37%

* Statistically different from placebo  ** Statistically different from MTX

Actemra: Phase II efficacy (Charisma)
Effects on DAS 28

- Baseline: 6.75
- Week 4: 6.55
- Week 8: 6.39
- Week 12: 6.43
- Week 16: 6.47


***p < 0.001; **p < 0.05 vs. MTX

Fast onset of action
**Actemra: Phase II safety (Charisma)**

**Liver enzymes profile**

- Elevations of liver enzymes (mainly ALT)
  - Mild, transient and reversible
  - No evidence of clinical hepatitis in any patients with ALT elevations
- Periodicity of elevations
  - Coincides with frequency of Tocilizumab administration (monthly infusions), especially at beginning of treatment
- The liver appears to adapt over time
  - Linked to mechanism of action of the drug

<table>
<thead>
<tr>
<th># of patients</th>
<th>Patients with ALT &gt; 2.5 ULN</th>
<th>Patients withdrawn due to ALT changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actemra mono</td>
<td>159</td>
<td>3 (2 %)</td>
</tr>
<tr>
<td>Actemra + MTX</td>
<td>151</td>
<td>17 (11 %)</td>
</tr>
<tr>
<td>MTX</td>
<td>49</td>
<td>0</td>
</tr>
</tbody>
</table>

ALT: Alanin Aminotransferase

**Actemra: Phase II safety (Charisma)**

**Lipid profile**

- Mild non-fasting elevations of total cholesterol, HDL cholesterol and triglycerides, with no change in atherogenic index
- Lipid elevations reported in patients with RA successfully treated with DMARDs
- No clear temporal association with ALT increases
- Temporally related to CRP levels

CRP: C Reactive protein  ALT: Alanin Aminotransferase
Actemra: Japanese PJD phase III trial

Study design

Primary endpoints
- Sharp score at week 52
- ACR response

ACR: American College of Rheumatology

Japanese phase III efficacy

Impressive ACR responses in monotherapy at week 52

Actemra significantly improves ACR responses

ACR: American College of Rheumatology
Japanese phase III efficacy

*Actemra can prevent joint damage*

![Bar chart showing radiographic progression with Actemra](chart.png)

- **Total Sharp Score (TSS):**
  - Actemra 8 mg/kg: 6.12, p < 0.001
  - DMARDs control: 2.30
- **Joint Space Narrowing (JSN):**
  - Actemra 8 mg/kg: 2.91, p < 0.05
  - DMARDs control: 1.45
- **Erosion Score (ES):**
  - Actemra 8 mg/kg: 3.21, p < 0.001
  - DMARDs control: 0.85

Significantly less radiographic progression with Actemra

TSS: Total Sharp Score; JSN: Joint Space Narrowing; ES: Erosion Score

---

Japanese phase III safety

*Preliminary results*

- **Treatment–emergent AEs:** 96 % in Actemra vs. 87 % in DMARDs group
- **Treatment–emergent SAEs:** 19 % in Actemra vs. 13 % in DMARDs group
- The most frequently reported infectious event was nasopharyngitis
- Mild, transient increases in LFTs were observed in both groups
- Lipid increases were mainly reported in the Actemra group:
  - Mean total cholesterol levels became stable (217 ± 39.3 mg/dl)
  - At around the normal upper limit

LFT: Liver Function Test
Japanese phase III
Conclusions

• IL-6 is an important pro-inflammatory cytokine in the pathogenesis of RA

• Blocking the IL-6 receptor with Actemra leads to significant improvement in signs and symptoms and reduce the progression of joint damage

• Adverse events are within expectations

• First trial showing superiority of Actemra compared to conventional DMARDs in preventing joint damage

Roche RA portfolio summary
### MabThera phase III program in DMARD failures

**Three trials to start end 2005/ early 2006**

<table>
<thead>
<tr>
<th>Trial</th>
<th>Treatment</th>
<th>Sample Size</th>
<th>Endpoints</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MTX-IR SERENE</strong></td>
<td>MTX + placebo vs. MTX + MabThera 1g vs. MTX + MabThera 2g</td>
<td>495</td>
<td>Reduction in signs and symptoms</td>
</tr>
<tr>
<td><strong>MTX active comparator (X-ray study) IMAGE</strong></td>
<td>MTX vs. MTX + MabThera 1g vs. MTX + MabThera 2g</td>
<td>852</td>
<td>Reduction in signs and symptoms</td>
</tr>
<tr>
<td></td>
<td><strong>MTX-IR Dose Escalation MIRROR</strong></td>
<td>Rituximab 1g retx 1g vs. Rituximab 1g retx 2g vs. Rituximab 2g no retx</td>
<td>375</td>
</tr>
</tbody>
</table>

**EU Filing 2007**

IR: Inadequate Responders

### Actemra phase III program in Roche territories

**Five trials ongoing**

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Sample Size</th>
<th>Patient population</th>
<th>Endpoints</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actemra 4 mg + MTX, Tocilizumab 8mg + MTX, MTX</td>
<td>630</td>
<td>MTX partial responders</td>
<td>ACR 20 response at Wk 24</td>
</tr>
<tr>
<td>Actemra 4 mg + MTX, Actemra 8 mg + MTX, MTX</td>
<td>1'170</td>
<td>MTX partial responders</td>
<td>ACR 20 at Wk 24, Sharp Score at Wk 52, Sharp Score at Wk 104, Physical function at Wk 104</td>
</tr>
<tr>
<td>Actemra 8 mg + DMARDs, DMARDs</td>
<td>1'200</td>
<td>DMARD partial responders</td>
<td>ACR 20 response at Wk 24</td>
</tr>
<tr>
<td>Actemra 4 mg + MTX, Actemra 8 mg + MTX, MTX</td>
<td>570</td>
<td>Anti-TNFα failures</td>
<td>ACR 20 response at Wk24</td>
</tr>
<tr>
<td>Actemra 8 mg + MTX</td>
<td>550</td>
<td>MTX naive</td>
<td>ACR 20 response at Wk 24</td>
</tr>
</tbody>
</table>

**Filing 2007**
Summary of Roche RA Phase III Biologics

<table>
<thead>
<tr>
<th>Description</th>
<th>MabThera/ Rituxan</th>
<th>Actemra/ Tocilizumab</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target</td>
<td>CD20 on B cells</td>
<td>Humanized anti-IL-6 receptor</td>
</tr>
<tr>
<td>Mechanism</td>
<td>B cell reduction</td>
<td>Inhibition of IL-6 signaling</td>
</tr>
<tr>
<td>Dose Regimen</td>
<td>IV days 1 &amp; 15 Q 6-12 mo</td>
<td>IV every 4 weeks</td>
</tr>
<tr>
<td>Treatment Strategy</td>
<td>Combo MTX</td>
<td>Mono &amp; Combo MTX and other DMARDs</td>
</tr>
<tr>
<td>Target Population</td>
<td>Anti-TNF failures; General RA patients</td>
<td>General RA patients, including anti-TNF failures</td>
</tr>
<tr>
<td>Efficacy</td>
<td>ACR20/50/70; EULAR response supports joint protection</td>
<td>ACR20/50/70; EULAR response joint protection shown</td>
</tr>
<tr>
<td>Safety</td>
<td>Manageable infusion reactions; Slight increase infections</td>
<td>Manageable infusion reactions; Chol, LFT, CBC changes; Slight increase infections</td>
</tr>
</tbody>
</table>

Roche RA portfolio

- Oral DMARDs
  - R1295
- Improved Biologics
  - R1503
  - R1594
  - MabThera
  - Actemra

Diversified and exciting

- Roche is well-positioned to enter RA market with biologics and small molecules
- Secondary indications/ claims extension offer relatively low risk/ low investment way to leverage our emerging RA portfolio
2006: Roche in Rheumatoid Arthritis
The first products in the autoimmune franchise

**RA**

- Oral DMARDs
  - Phase I: R1503 (RA)
  - Phase II: R1295 (RA)
  - Phase III: R1594 (RA)

- Improved Biologics
  - Phase I: R1295 (RA)
  - Phase II: R1594 (RA)
  - Phase III: MabThera (RA DMARD)

**AI diseases**

- Phase I:
  - IBD: R1541 (IBD)
  - RA: R1295 (RA)
  - AI: R3421 (AI)
  - BR3-FC (RA): GNE

- Phase II:
  - RA DMARD: MabThera (RA DMARD)
  - RA: MabThera (RA DMARD)
  - AI: Actemra (sJIA)
  - LN: CellCept (LN)

- Phase III:
  - Filed/Approved:
    - MabThera (RA DMARD)
    - Actemra (RA)
    - CellCept (LN)
    - MabThera (PPMS)
    - MabThera (ANCA av)
    - MabThera (SLE)
    - MabThera (RA TNF)

**Oral DMARDs**

- Improved Biologics

**Actemra**

**MabThera**