

# HUMIRA Commercial Update


Tim Walbert  
Divisional Vice President and General Manager  
Abbott Immunology Franchise

## Abbott Immunology

ESTABLISHING MARKET LEADERSHIP WITH HUMIRA



- HUMIRA success
  - From Knoll acquisition to launch
  - Launch update
- Investing for the future
  - Further advances in Rheumatoid arthritis
  - Psoriasis
  - Psoriatic arthritis
  - Ankylosing spondylitis
  - Crohn's disease
  - Juvenile RA



**NEW**  
**HUMIRA**  
(adalimumab)

## Delivering on the Promise of HUMIRA

SUPERIOR SCIENCE AND COMMERCIAL EXECUTION  
LEADING TO A BLOCKBUSTER



- World-class biologic science
  - Strong efficacy profile
  - Inhibits disease progression
  - Safe and well-tolerated
  - Best-in-class dosing and administration
- Superior execution leads to commercial success
  - Defined key success factors for Abbott Immunology and HUMIRA
  - Prelaunch activity designed to drive early success
  - Strong and experienced sales and marketing team

## Knoll Acquisition Assessment

CHALLENGES AT THE TIME OF ACQUISITION



- Third TNF antagonist to market
- Enbrel supply issues creating lack of confidence
- Limited Abbott relationships and presence in Immunology
- Little to no awareness of D2E7 (HUMIRA)
- Significant work to be done
  - Complete pivotal trials
  - File applications
  - Merge clinical organization
  - Build commercial franchise

## Developed Strategies for a Successful Launch

### MULTIFACETED APPROACH

- Accelerated clinical development program
  - Established Immunoscience Development Center (Parsippany, NJ)
  - Completed pivotal trials in RA
  - Submitted largest CBER application ever – approved in <9 months
- Established Abbott Immunology
  - Expanded talent base with significant category experience
  - Demonstrated Abbott's commitment to rheumatology
- Prepared the market for HUMIRA
  - Importance of early diagnosis and referral and early use of biologics
  - Developed and launched early access programs around the world

**Launch Strategy Translates Into Commercial Success**

## HUMIRA – Advancing RA Treatment

### THE NEXT-GENERATION TNF ANTAGONIST

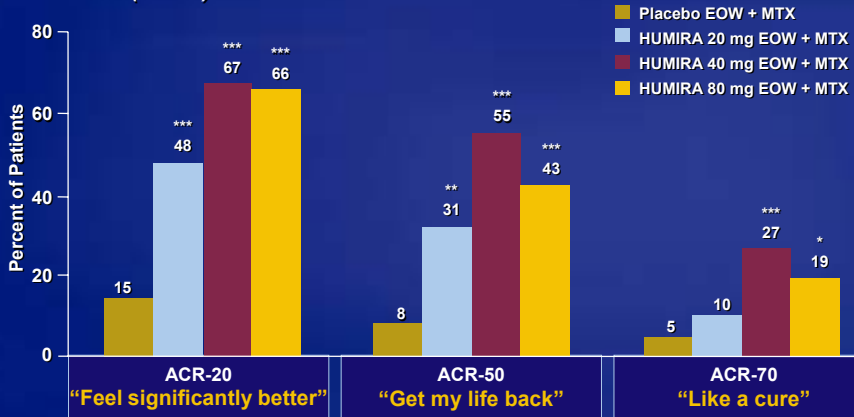
- First-in-class fully human anti-TNF monoclonal antibody
- Rapid and durable reduction in signs and symptoms
- Inhibits disease progression
- Convenient every-other-week dosing
- Easy to use prefilled syringe



# HUMIRA – Advancing RA Treatment

STRONG EFFICACY – RELIEVES SIGNS AND SYMPTOMS

## ARMADA (DE009)

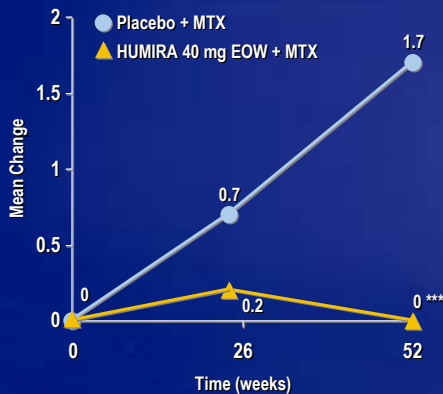


\* $P \leq 0.05$  vs. placebo; \*\* $P \leq 0.01$  vs. placebo; \*\*\* $P \leq 0.001$  vs. placebo  
Weinblatt ME, et al., *Arthritis Rheum.* 2003;48(1):35–45.

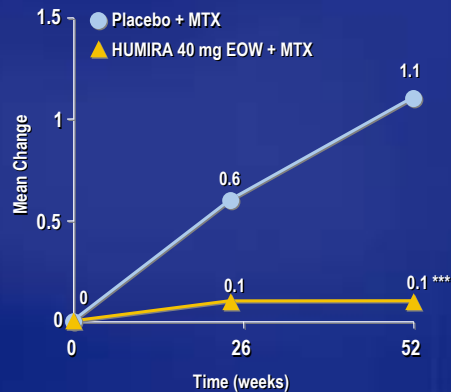
# HUMIRA – Advancing RA Treatment

STRONG EFFICACY – INHIBITS DISEASE PROGRESSION

## Joint Erosions



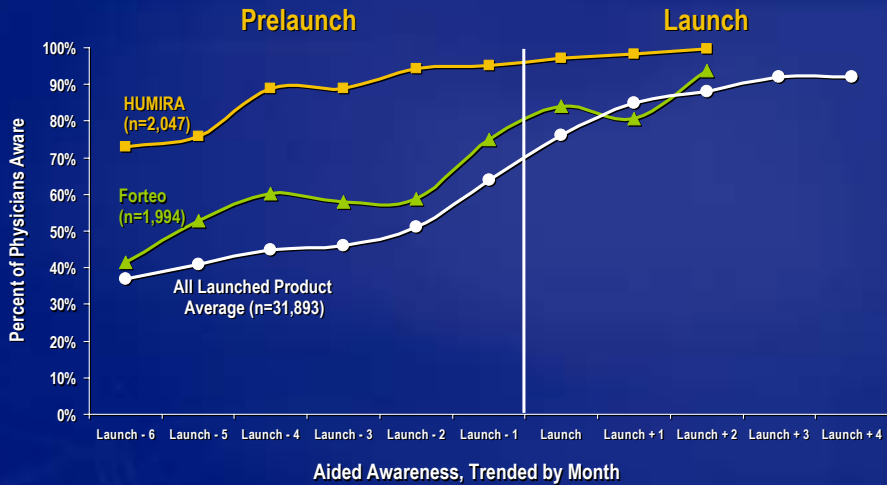
## Joint Space Narrowing



Source: ACR 2002 Abstract – New Orleans

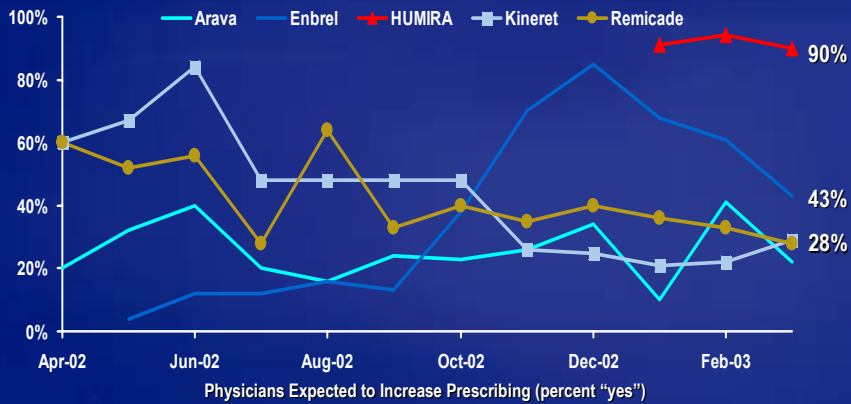
## Prelaunch Execution Lead to Fast Start

STRONG AWARENESS OF HUMIRA AT LAUNCH



## Positive Market Research

90% OF PHYSICIANS EXPECT TO INCREASE PRESCRIBING HUMIRA

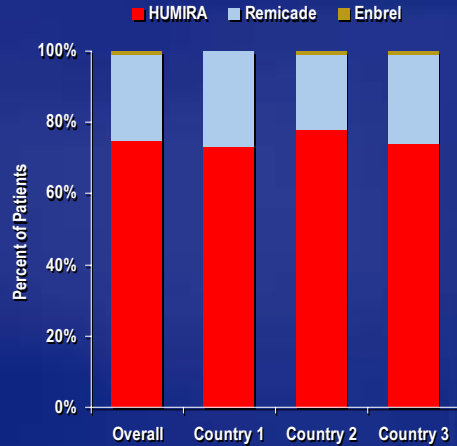


- Enbrel has declined significantly following the launch of HUMIRA
- Remicade also continues to decline

## 75% of RA Patients Prefer HUMIRA's Pre-filled Syringe

### HUMIRA – PREFERRED DOSING AND ADMINISTRATION

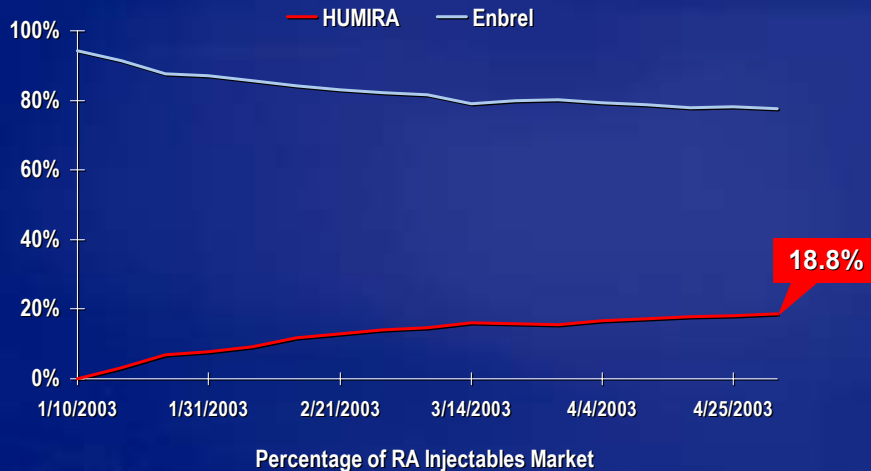
- Enbrel: Reconstitution and preparation poorly received by 63 percent of patients
  - Comments: **“Too complicated”**
- Enbrel: Dosing interval was an issue with 37 percent of patients
  - Comments: **“Too frequently administered”**
- Remicade: <25 percent of patients prefer I.V. administration



Base: 300 patients (100 per country)

## HUMIRA Weekly NRx

### RAPID PRESCRIPTION SHARE GROWTH



## HUMIRA Script Strength

SUBCUTANEOUS TNF ANTAGONIST MARKET – APRIL RX DATA

	<b>HUMIRA</b>	<b>Enbrel</b>
April NRx	5,508	24,961
<i>% Change from March</i>	<b>11.5%</b>	<b>-0.7%</b>
Market Share	17.3%	78.6%
April TRx	9,710	70,634
<i>% Change from March</i>	<b>35.0%</b>	<b>3.0%</b>
Market Share	11.6%	84.2%

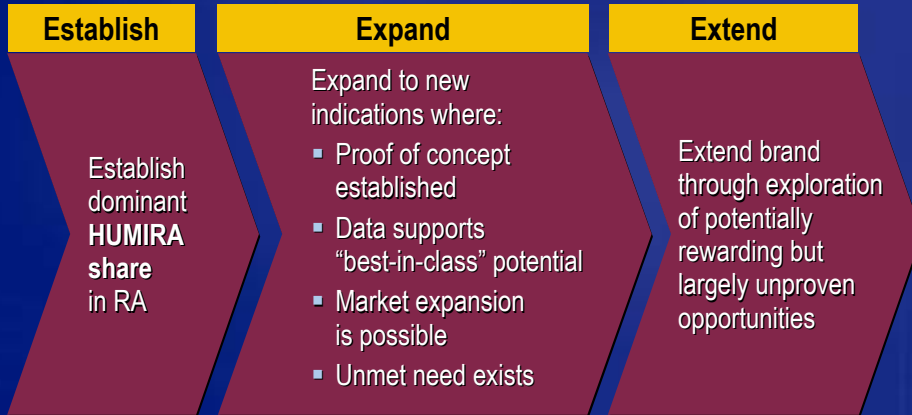
## Regulatory Update

EUROPE LAUNCH IMMINENT

- Submitted dossiers in 32 countries
- Positive opinion received from EMEA
  - European approval expected within 90 days
  - Largest markets are included in initial launch wave (2H03)
- Early access programs are exceeding expectations
- We will not be capacity constrained

# Realizing the Potential of HUMIRA

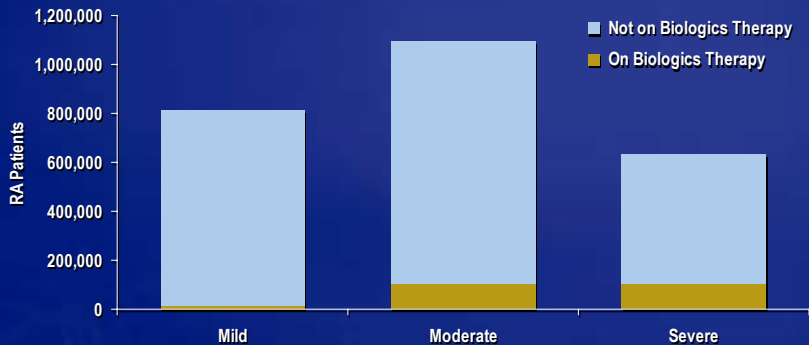
## LONG-TERM STRATEGY



# Treatment Evolution Expands HUMIRA Potential

## NEED FOR EARLY TREATMENT WITH BIOLOGIC DMARDS

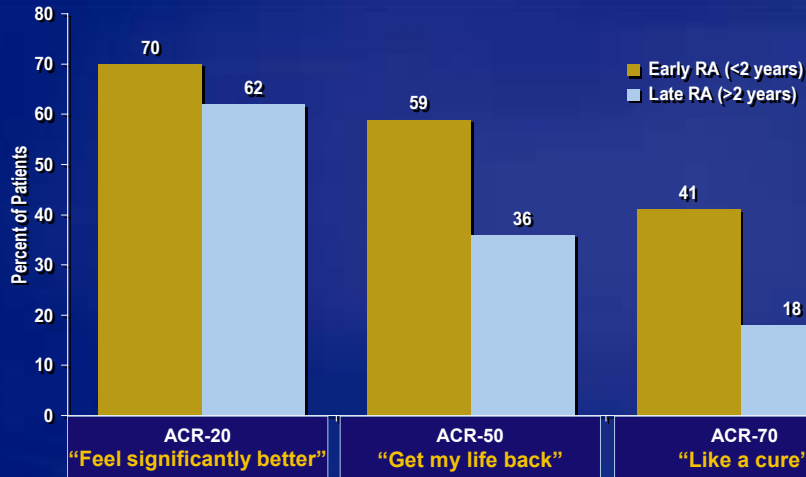
- Increased penetration of biologics into RA (>25 percent by 2005)
- Expansion into early RA as physicians appreciate need to halt disease progression early





## Potential for Market Expansion

HUMIRA DATA IN EARLY RA – SIGNIFICANT RESPONSE



Source: EULAR 2003 Abstract - Lisbon

## Expansion of HUMIRA in Large, Growing Markets

TREMENDOUS COMMERCIAL POTENTIAL

**HUMIRA**

RA, JRA, Early RA



Total biologic market (2010):  
**>\$9 billion**

Crohn's Disease



Total biologic market (2010):  
**>\$1 billion**

Psoriatic Arthritis



Total biologic market (2010):  
**~\$1.5 billion**

Psoriasis



Total biologic market (2010):  
**>\$2 billion**

Ankylosing Spondylitis



Total biologic market  
**~\$1 billion**

Delivery Advancements



Autoimmune disorders and novel applications

Other Diseases



Autoimmune disorders and novel applications

**>\$14 Billion Market Opportunity**

## Expanding HUMIRA Potential

### PROMISING FOLLOW-ON INDICATIONS

#### ■ Trial initiation and status

##### 2002

Crohn's Disease (Phase II/III)

JRA (Phase III)



##### 2003

Psoriasis (Phase II)

Psoriatic Arthritis (Phase III)

Ankylosing Spondylitis (Phase III)



## Expanding HUMIRA Potential

### PROJECTED FILING DATES

##### 2003 – 2004

Physical Function (U.S.)

Early RA (U.S.)

X-ray Claim (E.U.)

##### 2005 – 2006

Psoriasis

Psoriatic Arthritis

Ankylosing Spondylitis

JRA

Crohn's Disease

**>\$1 billion opportunity for HUMIRA  
on top of blockbuster sales in RA**

# Psoriasis Could Be the Next Large Opportunity

## TREMENDOUS COMMERCIAL POTENTIAL

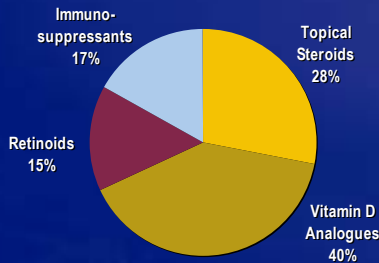
Current psoriasis market is underdeveloped

- Lack of innovative therapies
- Generics mask potential
- Relative low penetration of therapies

Total current psoriasis patients

- U.S.: ~4.2 million
- E.U.: ~5.7 million

### Current Psoriasis Treatments



# Psoriasis Could Be the Next Large Opportunity

## TREMENDOUS COMMERCIAL POTENTIAL

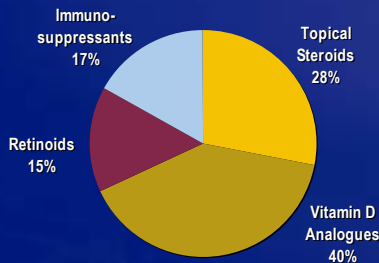
Current psoriasis market is underdeveloped

- Lack of innovative therapies
- Generics mask potential
- Relative low penetration of therapies

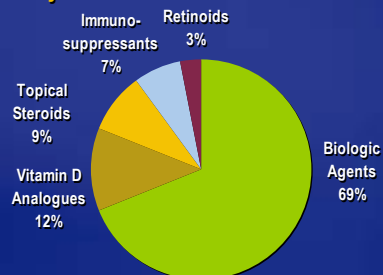
Total current psoriasis patients

- U.S.: ~4.2 million
- E.U.: ~5.7 million

### Current Psoriasis Treatments



### Projected Psoriasis Treatments – 2010



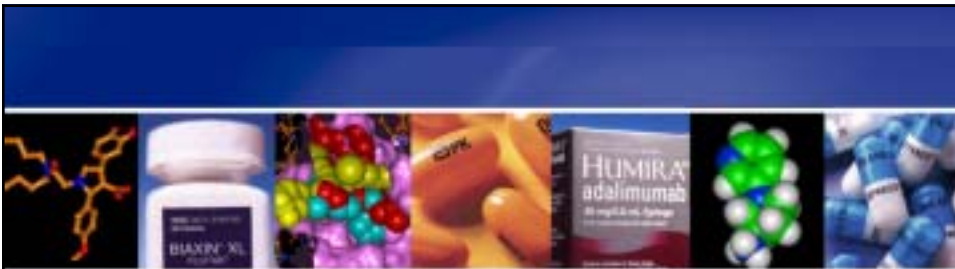
Market Projected to Exceed \$2 Billion

## Abbott Immunology

### ESTABLISHING MARKET LEADERSHIP

- Immunology is poised for rapid advances
- Abbott has invested wisely to benefit from significant market expansion
- Broad, diverse and balanced pipeline provides a steady stream of opportunity
- Proven track record of commercial success with HUMIRA

**NEW**  
**HUMIRA**  
(adalimumab)



## HUMIRA Commercial Update

Tim Walbert

Divisional Vice President and General Manager  
Abbott Immunology Franchise