

THEAPIES FOR RHEUMATOID ARTHRITIS: TECHNOLOGIES AND GLOBAL MARKETS



PHM072A
July 2016

Geeta Ogra Bedi
Project Analyst

ISBN: 1-62296-332-6



BCC Research
49 Walnut Park, Building 2
Wellesley, MA 02481 USA
866-285-7215 (toll-free within the USA),
or (+1) 781-489-7301
www.bccresearch.com
information@bccresearch.com

TABLE OF CONTENTS

TOPIC	PAGE NO.
CHAPTER 1 INTRODUCTION	2
STUDY GOALS AND OBJECTIVES	2
REASONS FOR DOING THIS STUDY	3
INTENDED AUDIENCE	3
SCOPE OF REPORT	4
METHODOLOGY	4
INFORMATION SOURCES	4
ANALYST'S CREDENTIALS	4
RELATED BCC RESEARCH REPORTS	5
BCC RESEARCH WEBSITE	5
DISCLAIMER	5
CHAPTER 2 SUMMARY	7
<i>SUMMARY TABLE A GLOBAL MARKET FOR THERAPIES FOR RHEUMATOID ARTHRITIS, BY THERAPEUTIC CLASS, THROUGH 2020 (\$ MILLIONS)</i>	9
<i>SUMMARY FIGURE A GLOBAL MARKET FOR THERAPIES FOR RHEUMATOID ARTHRITIS BY THERAPEUTIC CLASS, 2014-2020 (\$ MILLIONS)</i>	9
<i>SUMMARY TABLE B GLOBAL MARKET FOR THERAPEUTIC PRODUCTS FOR RHEUMATOID ARTHRITIS BY REGION, THROUGH 2020 (\$ MILLIONS)</i>	10
<i>SUMMARY FIGURE B GLOBAL MARKET FOR THERAPEUTIC PRODUCTS FOR RHEUMATOID ARTHRITIS BY REGION, 2014-2020 (\$ MILLIONS)</i>	10
CHAPTER 3 DISEASE OVERVIEW	13
ETIOLOGY	13
PATHOPHYSIOLOGY	13
SYMPTOMS	15
<i>TABLE 1 COMMON SYMPTOMS OF RHEUMATOID ARTHRITIS</i>	15
PROGNOSIS	15
QUALITY OF LIFE	16
EPIDEMIOLOGY	16
DISEASE BACKGROUND	16
<i>TABLE 2 EPIDEMIOLOGICAL FORECAST FOR DIAGNOSED PREVALENT CASES OF RHEUMATOID ARTHRITIS, BY REGION, THROUGH 2020 (NO.)</i>	16
RISK FACTORS AND COMORBIDITIES	17
<i>TABLE 3 RISK FACTORS AND COMORBIDITIES FOR RHEUMATOID ARTHRITIS</i>	17
CHAPTER 4 DISEASE MANAGEMENT	19
DIAGNOSIS	19
1987 ACR RA DIAGNOSTIC CRITERIA	19
<i>TABLE 4 THE 1987 ACR DIAGNOSTIC CRITERIA FOR RA</i>	20
2010 ACR/EULAR RA DIAGNOSTIC CRITERIA	20
<i>TABLE 5 THE 2010 ACR/EULAR DIAGNOSTIC CRITERIA FOR RA</i>	21
TREATMENT OVERVIEW	21
<i>TABLE 6 TREATMENT GUIDELINES FOR RA</i>	22
ACR 2012 RECOMMENDATIONS FOR THE TREATMENT OF RA	24
<i>TABLE 7 THE ACR 2012 CRITERIA FOR RA REMISSION, AND LOW, MODERATE, AND HIGH DISEASE ACTIVITY</i>	25

TOPIC	PAGE NO.
<i>TABLE 8 THE ACR/EULAR 2011 CRITERIA FOR RA REMISSION USED IN THE 2013 UPDATE TO THE EULAR RECOMMENDATIONS FOR RA MANAGEMENT</i>	26
<i>FIGURE 1 FLOWCHART FOR THE MANAGEMENT OF RA IN EARLY DISEASE, ACCORDING TO THE ACR2012 RECOMMENDATIONS</i>	26
<i>FIGURE 2 FLOWCHART FOR THE MANAGEMENT OF RA IN ESTABLISHED DISEASE, ACCORDING TO THE ACR2012 RECOMMENDATIONS</i>	26
2015 ACR GUIDELINE FOR THE TREATMENT OF RHEUMATOID ARTHRITIS	27
RECOMMENDATIONS FOR THE TREATMENT OF PATIENTS WITH EARLY RA	27
<i>TABLE 9 RECOMMENDATIONS FOR PATIENTS WITH SYMPTOMATIC EARLY RA</i>	28
<i>FIGURE 3 RECOMMENDATIONS FOR TREATMENT OF EARLY RA</i>	29
RECOMMENDATIONS FOR THE TREATMENT OF PATIENTS WITH ESTABLISHED RA	30
<i>TABLE 10 RECOMMENDATIONS FOR OPTIMAL FOLLOWUP LABORATORY MONITORING INTERVALS*</i>	32
RECOMMENDATIONS FOR LABORATORY MONITORING FOR DMARDS AND TB SCREENING IN PATIENTS RECEIVING BIOLOGICS OR TOFACITINIB	32
EULAR 2013 RECOMMENDATIONS FOR THE TREATMENT OF RA	33
<i>FIGURE 4 FLOWCHART FOR THE MANAGEMENT OF PATIENTS WITH RA, ACCORDING TO THE 2013 EULAR RECOMMENDATIONS</i>	34
<i>TABLE 11 MOSTMOST PRESCRIBED BIOLOGICS FOR THE TREATMENT OF RA (AFTER CSDMARDS), BY REGION</i>	35
<i>TABLE 12 MINOR THERAPEUTIC DRUG CLASSES USED TO TREAT RA</i>	36
CLINICAL PRACTICE	36
<i>TABLE 13 RA DIAGNOSIS PROFILE IN THE U.S.</i>	39
France	39
<i>TABLE 14 RA DIAGNOSIS PROFILE IN FRANCE</i>	40
Germany	40
<i>TABLE 15 RA DIAGNOSIS PROFILE IN GERMANY</i>	41
Italy	41
<i>TABLE 16 RA DIAGNOSIS PROFILE IN ITALY</i>	42
Spain	42
<i>TABLE 17 RA DIAGNOSIS PROFILE IN SPAIN</i>	43
U.K.	43
<i>TABLE 18 RA DIAGNOSIS PROFILE IN THE UK</i>	44
Japan	44
<i>TABLE 19 RA DIAGNOSIS PROFILE IN JAPAN</i>	45
Australia	45
<i>TABLE 20 RA DIAGNOSIS PROFILE IN AUSTRALIA</i>	46
China	46
<i>TABLE 21 RA DIAGNOSIS PROFILE IN CHINA</i>	47
India	47
<i>TABLE 22 RA DIAGNOSIS PROFILE IN INDIA</i>	48
<i>TABLE 23 LEADING DRUGS FOR TREATMENT OF RA</i>	49
BIOSIMILARS	49
<i>TABLE 24 GLOBAL MARKET FOR MAJOR BIOSIMILARS BY REGION AND TYPE, THROUGH 2020 (\$ MILLIONS)</i>	49
<i>TABLE 25 GLOBAL MARKET FOR ENBREL, BY REGION, THROUGH 2020 (\$ MILLIONS)</i>	50
<i>TABLE 26 GLOBAL MARKET FOR HUMIRA, BY REGION, THROUGH 2020 (\$ MILLIONS)</i>	51

TOPIC	PAGE NO.
<i>TABLE 27 GLOBAL MARKET FOR REMICADE (INFLIXIMAB), BY REGION, THROUGH 2020 (\$ MILLIONS)</i>	52
<i>TABLE 28 GLOBAL MARKET FOR ACTEMRA, BY REGION, THROUGH 2020 (\$ MILLIONS)</i>	53
<i>TABLE 29 GLOBAL MARKET FOR ORENCIA (ABATACEPT), BY REGION, THROUGH 2020 (\$ MILLIONS)</i>	54
<i>TABLE 30 GLOBAL MARKET FOR RITUXAN (MABTHERA), BY REGION, THROUGH 2020 (\$ MILLIONS)</i>	55
COMPETITIVE ASSESSMENT	56
OVERVIEW	56
CHAPTER 5 UNMET NEED AND OPPORTUNITY	58
UNMET NEED	58
GAP ANALYSIS	58
OPPORTUNITY	59
CHAPTER 6 PIPELINE ASSESSMENT	62
OVERVIEW	62
<i>TABLE 31 LIST OF RA THERAPIES IN CLINICAL TRIALS, BY PHASE</i>	62
<i>TABLE 32 LIST OF RA THERAPIES IN DEVELOPMENT, BY PHASE</i>	65
CHAPTER 7 PATENT ASSESSMENTS	67
<i>TABLE 33 LIST OF THERAPIES FOR RA IN THE MARKET, BY PATENT EXPIRY DATE</i>	67
<i>TABLE 34 LIST OF PATENTS ISSUED FOR RA THERAPIES</i>	67
<i>TABLE 35 LIST OF PATENT APPLICATIONS FOR RA THERAPIES</i>	73
CHAPTER 8 COMPANY PROFILES	82
AB SCIENCE	83
ABBOTT LABORATORIES	83
ABBVIE	83
AMGEN INC.	84
ASTELLAS	85
BAXALTA INC.	85
BRISTOL-MYERS SQUIBB	86
BOEHRINGER INGELHEIM	86
CELGENE CORP.	87
CELLTRION INC.	87
COHERUS BIOSCIENCES INC.	87
DAIICHI SANKYO CO. LTD.	88
EISAI	89
ELI LILLY	89
FUJIFILM KYOWA KIRIN BIOLOGICS CO. LTD.	90
GLAXOSMITHKLINE	91
INCYTE CORP.	92
JOHNSON & JOHNSON	92
KINETA INC.	93
MABTECH AB	93
MYCENAX BIOTECH INC.	93

TOPIC	PAGE NO.
NOVARTIS AG	94
ONO PHARMACEUTICAL CO. LTD.	95
PFIZER	95
ROCHE	96
SAMSUNG BIOLOGICS CO. LTD.	96
TAKEDA PHARMACEUTICALS	97
UCB GROUP/IMMUNOMEDICS	97
CHAPTER 9 DRIVERS AND BARRIERS	100
<i>TABLE 36 DRIVERS AND BARRIERS FOR RA THERAPIES</i>	100
DRIVER: LAUNCH OF NOVEL DRUGS, INCLUDING ORAL JAK INHIBITORS AND NOVEL BIOLOGICS FOR RA	100
DRIVER: EARLIER DIAGNOSIS AND TREATMENT	100
DRIVER: MARKET ENTRY OF BIOSIMILARS WILL BRING A THERAPY OPTION FOR THOSE WHO CANNOT AFFORD BRANDED BIOLOGICS	101
DRIVER: AGING POPULATION AND INCREASING PREVALENT CASES OF RA	101
BARRIER: EFFORTS TO REDUCE COSTS IN THE TREATMENT OF RA	101
BARRIER: LACK OF REGULATORY GUIDELINES FOR BIOSIMILARS WILL DELAY THEIR AVAILABILITY IN SOME REGIONS	102
BARRIER: ENTRY OF BIOSIMILARS WILL CREATE A LESS EXPENSIVE TREATMENT ALTERNATIVE	102

LIST OF TABLES

TABLE HEADING	PAGE NO.
SUMMARY TABLE A GLOBAL MARKET FOR THERAPIES FOR RHEUMATOID ARTHRITIS, BY THERAPEUTIC CLASS, THROUGH 2020 (\$ MILLIONS)	9
SUMMARY TABLE B GLOBAL MARKET FOR THERAPEUTIC PRODUCTS FOR RHEUMATOID ARTHRITIS BY REGION, THROUGH 2020 (\$ MILLIONS)	10
TABLE 1 COMMON SYMPTOMS OF RHEUMATOID ARTHRITIS	15
TABLE 2 EPIDEMIOLOGICAL FORECAST FOR DIAGNOSED PREVALENT CASES OF RHEUMATOID ARTHRITIS, BY REGION, THROUGH 2020 (NO.)	16
TABLE 3 RISK FACTORS AND COMORBIDITIES FOR RHEUMATOID ARTHRITIS	17
TABLE 4 THE 1987 ACR DIAGNOSTIC CRITERIA FOR RA	20
TABLE 5 THE 2010 ACR/EULAR DIAGNOSTIC CRITERIA FOR RA	21
TABLE 6 TREATMENT GUIDELINES FOR RA	22
TABLE 7 THE ACR 2012 CRITERIA FOR RA REMISSION, AND LOW, MODERATE, AND HIGH DISEASE ACTIVITY	25
TABLE 8 THE ACR/EULAR 2011 CRITERIA FOR RA REMISSION USED IN THE 2013 UPDATE TO THE EULAR RECOMMENDATIONS FOR RA MANAGEMENT	26
TABLE 9 RECOMMENDATIONS FOR PATIENTS WITH SYMPTOMATIC EARLY RA	28
TABLE 10 RECOMMENDATIONS FOR OPTIMAL FOLLOWUP LABORATORY MONITORING INTERVALS*	32
TABLE 11 MOSTMOST PRESCRIBED BIOLOGICS FOR THE TREATMENT OF RA (AFTER CSDMARDS), BY REGION	35
TABLE 12 MINOR THERAPEUTIC DRUG CLASSES USED TO TREAT RA	36
TABLE 13 RA DIAGNOSIS PROFILE IN THE U.S.	39
TABLE 14 RA DIAGNOSIS PROFILE IN FRANCE	40
TABLE 15 RA DIAGNOSIS PROFILE IN GERMANY	41
TABLE 16 RA DIAGNOSIS PROFILE IN ITALY	42
TABLE 17 RA DIAGNOSIS PROFILE IN SPAIN	43
TABLE 18 RA DIAGNOSIS PROFILE IN THE UK	44
TABLE 19 RA DIAGNOSIS PROFILE IN JAPAN	45
TABLE 20 RA DIAGNOSIS PROFILE IN AUSTRALIA	46
TABLE 21 RA DIAGNOSIS PROFILE IN CHINA	47
TABLE 22 RA DIAGNOSIS PROFILE IN INDIA	48
TABLE 23 LEADING DRUGS FOR TREATMENT OF RA	49
TABLE 24 GLOBAL MARKET FOR MAJOR BIOSIMILARS BY REGION AND TYPE, THROUGH 2020 (\$ MILLIONS)	49
TABLE 25 GLOBAL MARKET FOR ENBREL, BY REGION, THROUGH 2020 (\$ MILLIONS)	50
TABLE 26 GLOBAL MARKET FOR HUMIRA, BY REGION, THROUGH 2020 (\$ MILLIONS)	51
TABLE 27 GLOBAL MARKET FOR REMICADE (INFLIXIMAB), BY REGION, THROUGH 2020 (\$ MILLIONS)	52
TABLE 28 GLOBAL MARKET FOR ACTEMRA, BY REGION, THROUGH 2020 (\$ MILLIONS)	53
TABLE 29 GLOBAL MARKET FOR ORENCIA (ABATACEPT), BY REGION, THROUGH 2020 (\$ MILLIONS)	54
TABLE 30 GLOBAL MARKET FOR RITUXAN (MABTHERA), BY REGION, THROUGH 2020 (\$ MILLIONS)	55
TABLE 31 LIST OF RA THERAPIES IN CLINICAL TRIALS, BY PHASE	62
TABLE 32 LIST OF RA THERAPIES IN DEVELOPMENT, BY PHASE	65
TABLE 33 LIST OF THERAPIES FOR RA IN THE MARKET, BY PATENT EXPIRY DATE	67
TABLE 34 LIST OF PATENTS ISSUED FOR RA THERAPIES	67
TABLE 35 LIST OF PATENT APPLICATIONS FOR RA THERAPIES	73
TABLE 36 DRIVERS AND BARRIERS FOR RA THERAPIES	100

LIST OF FIGURES

FIGURE TITLE	PAGE NO.
SUMMARY FIGURE A GLOBAL MARKET FOR THERAPIES FOR RHEUMATOID ARTHRITIS BY THERAPEUTIC CLASS, 2014-2020 (\$ MILLIONS)	9
SUMMARY FIGURE B GLOBAL MARKET FOR THERAPEUTIC PRODUCTS FOR RHEUMATOID ARTHRITIS BY REGION, 2014-2020 (\$ MILLIONS)	10
FIGURE 1 FLOWCHART FOR THE MANAGEMENT OF RA IN EARLY DISEASE, ACCORDING TO THE ACR2012 RECOMMENDATIONS	26
FIGURE 2 FLOWCHART FOR THE MANAGEMENT OF RA IN ESTABLISHED DISEASE, ACCORDING TO THE ACR2012 RECOMMENDATIONS	26
FIGURE 3 RECOMMENDATIONS FOR TREATMENT OF EARLY RA	29
FIGURE 4 FLOWCHART FOR THE MANAGEMENT OF PATIENTS WITH RA, ACCORDING TO THE 2013 EULAR RECOMMENDATIONS	34