

# Dealdoc

Marketing and distribution agreement for Kyprolis, Blincyto, Repatha, XGEVA, Vectibix and Prolia (updated)

Dr. Reddy's Laboratories Amgen

Aug 06 2015

# Marketing and distribution agreement for Kyprolis, Blincyto, Repatha, XGEVA, Vectibix and Prolia (updated)

Companies:	Dr. Reddy's Laboratories  Amgen
Announcement date:	Aug 06 2015
Amendment date:	Sep 16 2016
Deal value, US\$m:	n/d

- **Details**
- **Financials**
- **Termsheet**
- Press Release
- Filing Data
- Contract

#### **Details**

Announcement date: Aug 06 2015 Amendment date: Sep 16 2016 Bigpharma Industry sectors: Pharmaceutical

**Brand name:** Kyprolis, Blincyto, Repatha, XGEVA, Vectibix, Prolia

Compound name: Carfilzomib, Blinatumomab, Evolocumab

**Exclusivity:** Exclusive Asset type: Product Cardiovascular

Small molecules

Musculoskeletal » Osteoporosis Therapy areas:

Oncology

Oncology » Colorectal cancer

Distribution Deal components: Marketing Stages of development: Regulatory Geographic focus: Asia » India

**Financials** 

Deal value, US\$m: n/d

Technology types:

### **Termsheet**

September 2016

Dr. Reddy's Laboratories Ltd. announced that it has expanded its strategic collaboration with Amgen, one of the world's leading independent biotechnology companies, to market and distribute three of Amgen's medicines in India in the therapy areas of oncology and osteoporosis.

Under the terms of the collaboration, Dr. Reddy's will commercialise XGEVA® (denosumab), Vectibix® (panitumumab) and Prolia® (denosumab) in India.

XGEVA is a RANK ligand (RANKL) inhibitor and is approved in India for the prevention of skeletal related events in patients with advanced malignancies involving bone.

Vectibix is an epidermal growth factor receptor (EGFR) antagonist approved in India for the treatment of adult patients with wild-type KRAS metastatic colorectal cancer (m-CRC) as first line treatment as monotherapy following disease progression, in wild type RAS m-CRC as first-line combination with FOLFOX and in second line in combination with FOLFIRI after prior treatment with fluoropyrimidine-based chemotherapy (excluding irinotecan).

Prolia is a RANK ligand (RANKL) inhibitor approved in India for treatment of post-menopausal women with osteoporosis at high risk for fracture and also for treatment of increased bone mass in men with osteoporosis.

#### August 2015

Dr. Reddy's Laboratories has entered into a strategic collaboration with Amgen to market and distribute three Amgen medicines in India in the areas of oncology and cardiology.

Under the terms of the collaboration, Dr. Reddy's shall perform a full range of regulatory and commercial services to seek approval and launch Kyprolis (carfilzomib), BLINCYTO (blinatumomab) and Repatha (evolocumab) in India.

The collaboration leverages the capabilities of both companies, combining three of Amgen's innovative therapies with Dr. Reddy's deep understanding of patient and physician needs in India.

Dr Reddy's Laboratories has inked a pact with Amgen to market its three drugs used to treat heart diseases and cancer in India.

The Hyderabad-based firm said it has entered into a strategic collaboration with Amgen to market and distribute three Amgen medicines in India in oncology and cardiology.

Dr Reddy's shall undertake a full range of regulatory and commercial services to seek approval and launch the three drugs — Kyprolis, Blincyto and Repatha — in India.

#### **Press Release**

#### September 2016

HYDERABAD, India--(BUSINESS WIRE)--Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) today announced that it has expanded its strategic collaboration with Amgen, one of the world's leading independent biotechnology companies, to market and distribute three of Amgen's medicines in India in the therapy areas of oncology and osteoporosis. Under the terms of the collaboration, Dr. Reddy's will commercialise XGEVA® (denosumab), Vectibix® (panitumumab) and Prolia® (denosumab) in India.

"We are delighted to continue our relationship with Amgen as it strengthens our constant endeavor to enhance patients' access to novel treatment options across therapy areas. These medicines provide unique treatment options to physicians to address unmet medical need in the area of oncology and osteoporosis."

In 2015, Dr. Reddy's announced an initial strategic collaboration with Amgen to execute a full range of regulatory and commercial services to seek approval of and launch Amgen's Kyprolis® (carfilzomib), BLINCYTO® (blinatumomab) and Repatha<sup>TM</sup> (evolocumab) in India. The collaboration leverages the capabilities of both companies, combining Amgen's innovative therapies with Dr. Reddy's deep understanding of patient and physician needs in India.

M.V. Ramana, Executive Vice President and Head of Emerging markets and India Business, Dr. Reddy's Laboratories Limited, said, "We are delighted to continue our relationship with Amgen as it strengthens our constant endeavor to enhance patients' access to novel treatment options across therapy areas. These medicines provide unique treatment options to physicians to address unmet medical need in the area of oncology and osteoporosis."

Penny Wan, Amgen Vice President and General Manager, Japan Asia Pacific Region, said, "We are happy to strengthen our relationship with Dr. Reddy's. Amgen is committed to addressing unmet medical needs of patients in India, and we are pleased with the commitment Dr. Reddy's has demonstrated toward making our medicines available in India as quickly as possible."

XGEVA is a RANK ligand (RANKL) inhibitor and is approved in India for the prevention of skeletal related events in patients with advanced malignancies involving bone.

Vectibix is an epidermal growth factor receptor (EGFR) antagonist approved in India for the treatment of adult patients with wild-type KRAS metastatic colorectal cancer (m-CRC) as first line treatment as monotherapy following disease progression, in wild type RAS m-CRC as first-line combination with FOLFOX and in second line in combination with FOLFIRI after prior treatment with fluoropyrimidine-based chemotherapy (excluding irinotecan).

Prolia is a RANK ligand (RANKL) inhibitor approved in India for treatment of post-menopausal women with osteoporosis at high risk for fracture and also for treatment of increased bone mass in men with osteoporosis. Often referred to as the "silent epidemic," osteoporosis is a global

problem that is increasing in significance as the population of the world both increases and ages. The World Health Organization (WHO) has recently identified osteoporosis as a priority health issue along with other major non-communicable diseases.

About Dr. Reddy's: Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses – Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, India, Russia & CIS countries, and Europe. For more information, log on to: www.drreddys.com

#### August 2015

Dr. Reddy's Announces Strategic Collaboration with Amgen in India Dr. Reddy's to Market and Distribute Amgen's Repatha™ (evolocumab), Kyprolis® (carfilzomib) and BLINCYTO® (blinatumomab) in India upon Approval

HYDERABAD, India--(BUSINESS WIRE)--Dr. Reddy's Laboratories Ltd. (NYSE: RDY) today announced that it has entered into a strategic collaboration with Amgen − one of the world's leading independent biotechnology companies − to market and distribute three Amgen medicines in India in the areas of oncology and cardiology. Under the terms of the collaboration, Dr. Reddy's shall perform a full range of regulatory and commercial services to seek approval and launch Kyprolis® (carfilzomib), BLINCYTO® (blinatumomab) and Repatha<sup>™</sup> (evolocumab) in India. The collaboration leverages the capabilities of both companies, combining three of Amgen's innovative therapies with Dr. Reddy's deep understanding of patient and physician needs in India.

Dr. Reddy's Executive Vice President and Head of India Business & Global Business Development Alok Sonig stated, "We are excited about our strategic collaboration with an innovation powerhouse like Amgen and look forward to making their innovative medicines accessible to Indian patients. Addressing significant unmet needs of patients in oncology and cardiovascular are key areas in India and, therefore, a priority for us at Dr. Reddy's. We believe that good health can't wait and that this is an important milestone for us in our journey as we improve patient care."

"We are pleased to be joining forces with Dr. Reddy's Laboratories in order to make Amgen's innovative medicines available to patients in India," said Penny Wan, Amgen vice president and general manager, Japan Asia Pacific Region. "Dr. Reddy's has significant experience serving oncology and cardiovascular patients in India and shares Amgen's interest in delivering new treatment options to seriously ill patients."

Kyprolis® was approved by the U.S. Food and Drug Administration in July 2015, in combination with lenalidomide and dexamethasone, for the treatment of patients with relapsed multiple myeloma who have received one to three prior lines of therapy. Kyprolis® is also indicated under FDA accelerated approval as a single agent for the treatment of patients with multiple myeloma who have received at least two prior therapies including bortezomib and an immunomodulatory agent and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified. A form of blood cancer that arises from plasma cells, multiple myeloma usually grows in bone marrow, the soft, tissue found inside most bones where normal blood cells are produced.

BLINCYTO® is an example of immunotherapy, a treatment that uses certain parts of a person's immune system to fight diseases such as cancer. BLINCYTO® is the first approved bispecific CD19-directed CD3 T-cell engager. It engages the body's T-cells, a type of white blood cell or lymphocyte, to destroy leukemia cells. It was approved by the U.S. FDA in 2014, to treat patients with Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (B-cell ALL), an uncommon form of ALL. This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification of clinical benefit in subsequent trials.

In July, this year, the European Commission (EC) granted marketing authorisation for Repatha<sup>™</sup>, the first proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor to be approved in the world, for the treatment of patients with uncontrolled cholesterol despite taking maximum doses of statins or who cannot take statins, who require additional intensive low-density lipoprotein cholesterol (LDL-C) reduction. Elevated LDL-C or "bad" cholesterol is an abnormality of cholesterol and/or fats in the blood and is recognized as a major risk factor for cardiovascular disease.

### About Dr. Reddy's:

Dr. Reddy's Laboratories Ltd. (NYSE: RDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastro-intestinal, cardiovascular, diabetology, oncology, pain management and anti-infectives. Dr. Reddy's operates in markets across the globe. Our major markets include – USA, Russia & CIS, Venezuela and India. For more information, log on to: www.drreddys.com

### August 2015

Dr. Reddy's Laboratories Ltd. (RDY) Grabs Deal to Market Three Amgen (AMGN) Drugs in India

NEW DELHI: Dr Reddy's Laboratories on Thursday said it has inked a pact with US-based biotechnology firm Amgen to market its three drugs used to treat heart diseases and cancer in India.

The Hyderabad-based firm said it has entered into a strategic collaboration with Amgen to market and distribute three Amgen medicines in India in oncology and cardiology, Dr Reddy's Laboratories said in a statement.

Under the terms of the collaboration, Dr Reddy's shall undertake a full range of regulatory and commercial services to seek approval and launch the three drugs — Kyprolis, Blincyto and Repatha — in India.

## **Filing Data**

Not available.

### Contract

Not available.