

MARKET ASSESSMENT FOR THERAPEUTIC MONOCLONAL ANTIBODIES AND THEIR FORECAST TO 2023

Presentation Submitted to

The IIHMR University, Jaipur

by

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Introduction

What is Monoclonal Antibody?

Monoclonal antibodies are laboratory-produced molecules engineered to serve as substitute antibodies that can restore, enhance or mimic the immune system's attack on cancer cells. They are designed to bind to antigens that are generally more numerous on the surface of cancer cells than healthy cells.

Naming of Monoclonal Antibodies:

Monoclonal Antibodies are manufactured in 4 different ways and are named according to their ingredients:

- Murine: Made from mouse protein and treatment name ends with "omab".
- Chimeric: combination of some mice & people, and treatment named with "ximab".
- Humanized: formed by linking small portion of mice proteins with human-protein, and treatment named with "zumab".
- Human: completely human proteins, & treatment named with "umab".

Indian History of Monoclonal Antibodies:

In 2007, before biosimilars were approved in many countries, Dr. Reddy's Reditux (rituximab) for the treatment of lymphomas was the first Indian biosimilar to enter the market.

BIOMAb-EGFR[®] was India's first indigenously produced, innovative mAb. It is used to treat head and neck cancer. ALZUMAb[®], the first anti-CD6 monoclonal antibody for psoriasis, is another novel mAb developed by India's Biocon.

Who Approved the Biologics and Biosimilars?

Regulatory bodies liable for the approval of biosimilars in India are:

- The Department Of Biotechnology
- The Review Committee On Genetic Manipulation
- The Central Drugs Standard Control Organization

Global Market:

The global therapeutic monoclonal antibody market was valued at approximately US\$115.2 billion in 2018 and is expected to generate revenue of \$150 billion by the end of 2019 and \$300 billion by 2025. Market is expected to grow at a compound annual growth rate (CAGR) of 7.1%.

History:

The first FDA-approved therapeutic monoclonal antibody was a murine IgG2a CD3 specific transplant rejection drug, OKT3 (also called muromonab), in 1986.
In 1994.

RESEARCH METHODOLOGIES:

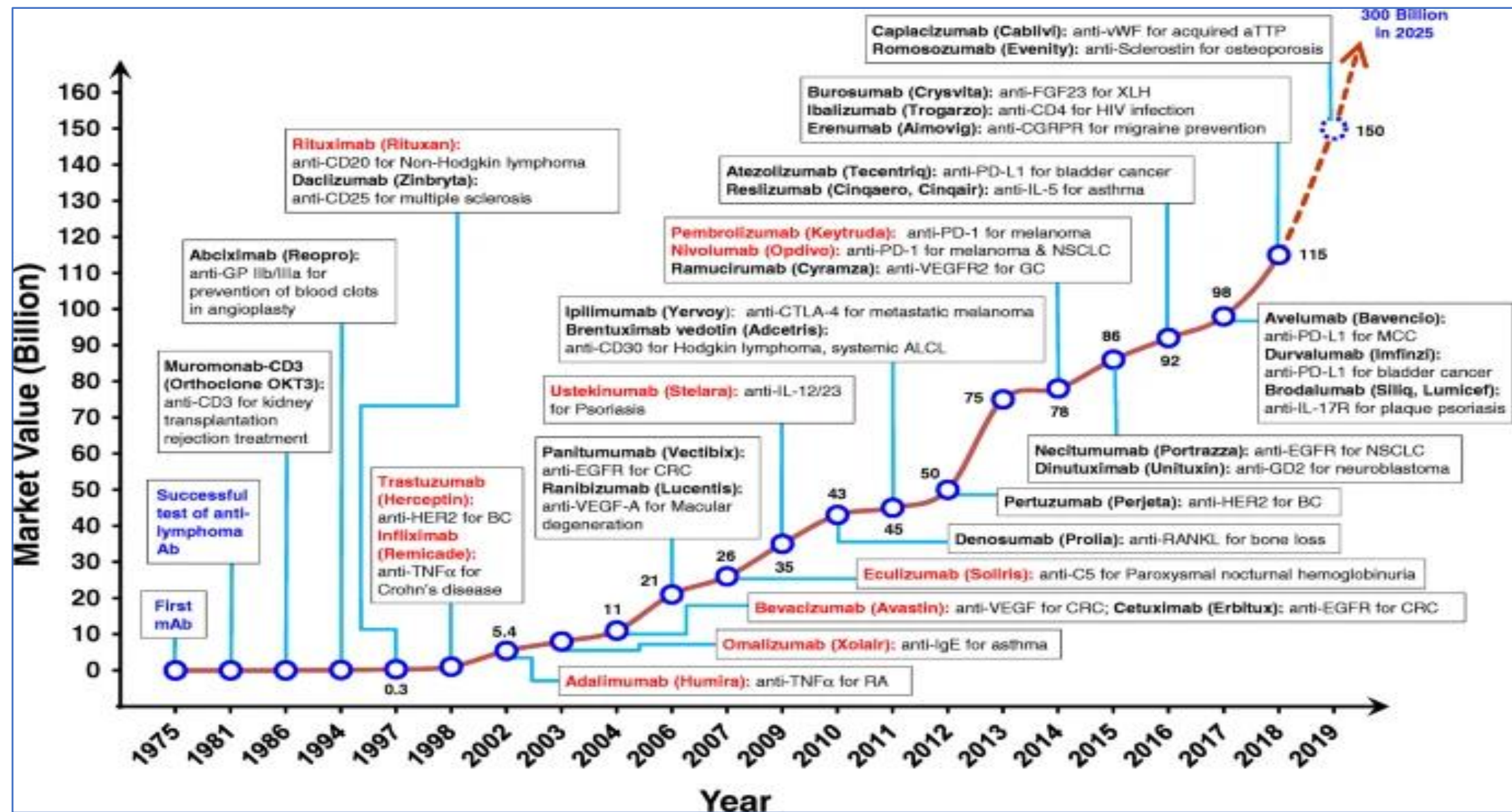
Sample area: The study was carried out with Therapeutic Monoclonal Antibodies at PharmaACE Analytics Pvt. Ltd., Pune, Maharashtra.

Sample design: It is an analytic study to evaluate and assess potential customers and the future market using a prediction model in the treatment of therapeutic monoclonal antibodies drugs and brands. The product was expected to have a market share, volume and revenue.

Study duration: The study was carried out for 3 months from 22 March 2021 to 19 June 2021.

Sample size: The entire Chapter 30 data and injectables domestic data was considered for estimation of volume and revenue of drug X. The year of the data is 2017 to 2020.

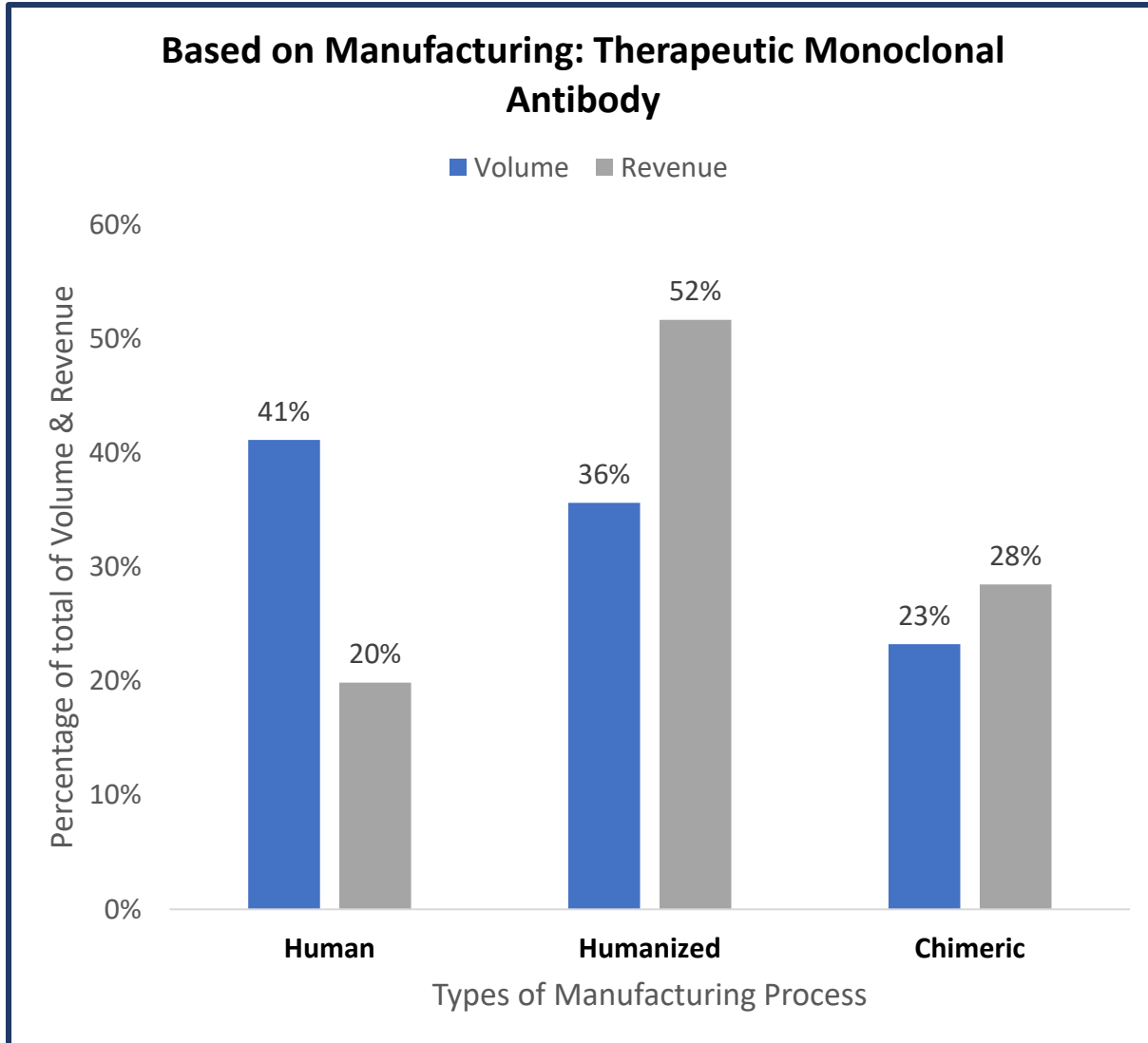
Data Collection Method: Primary data were received from the company.



History of Therapeutic Monoclonal Antibodies

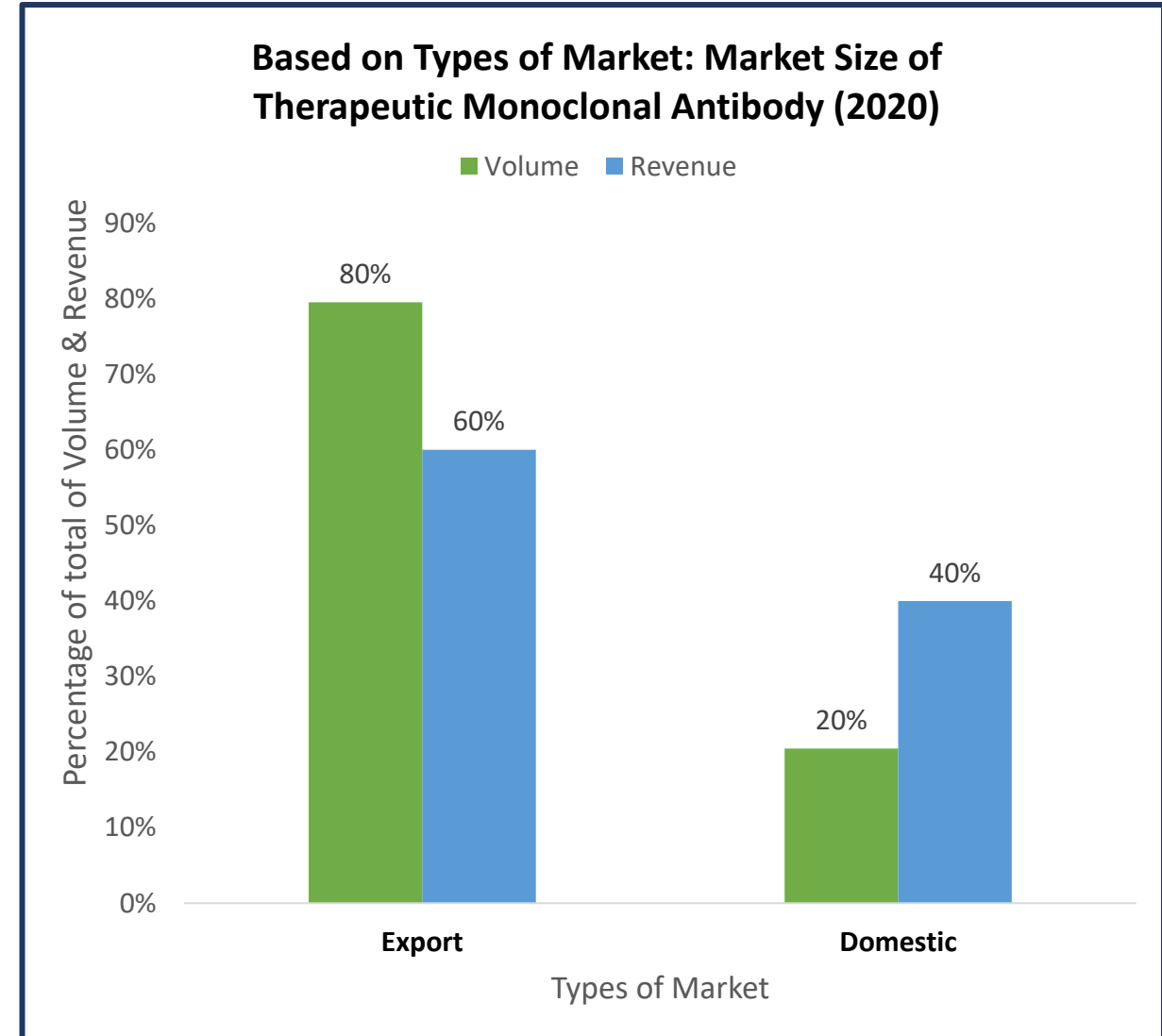
Market Size Based on Manufacturing of Therapeutic Monoclonal Antibody (2017-2020)

Most of the monoclonal antibody is manufactured by Human (41%), and the largest revenue obtained by Humanized(52%)



Market Size of Export & Domestic Market

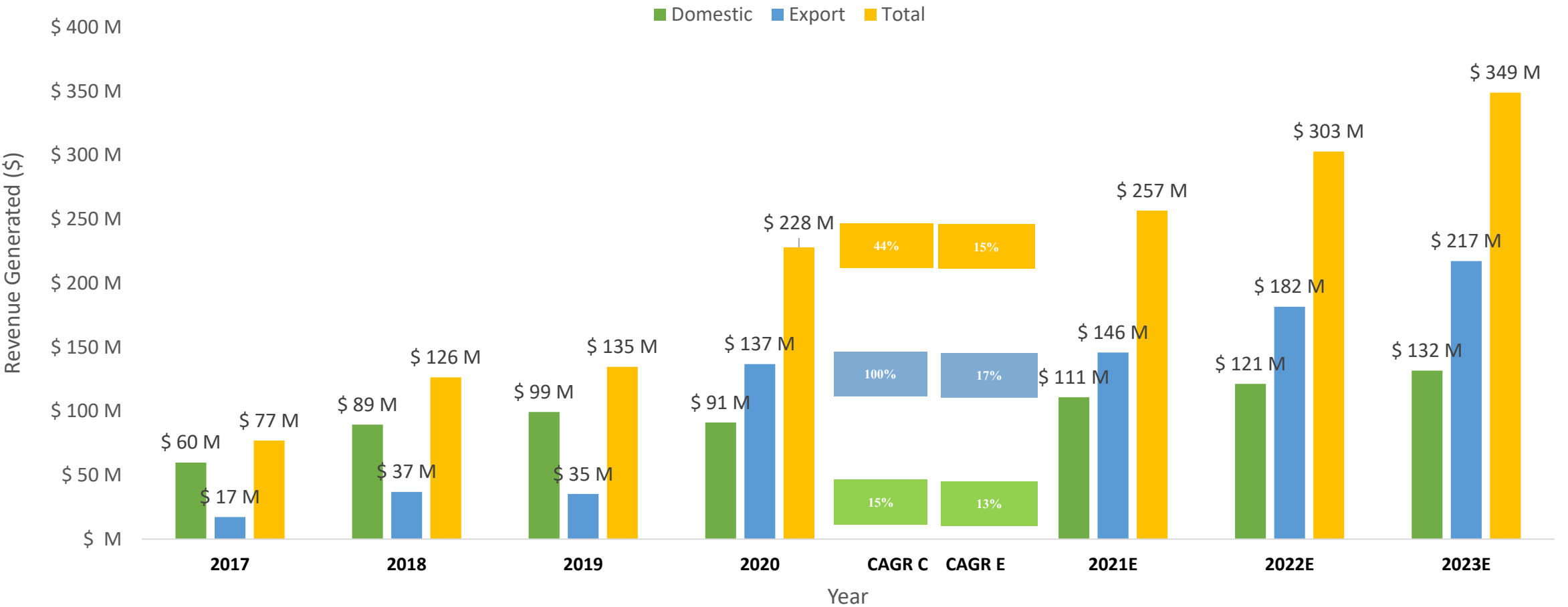
Volumes and market value generated by the export market is higher than the domestic market in the year 2020



The Market Value of Therapeutic Monoclonal Antibodies are Estimated to Reach \$ 349 Million in 2023

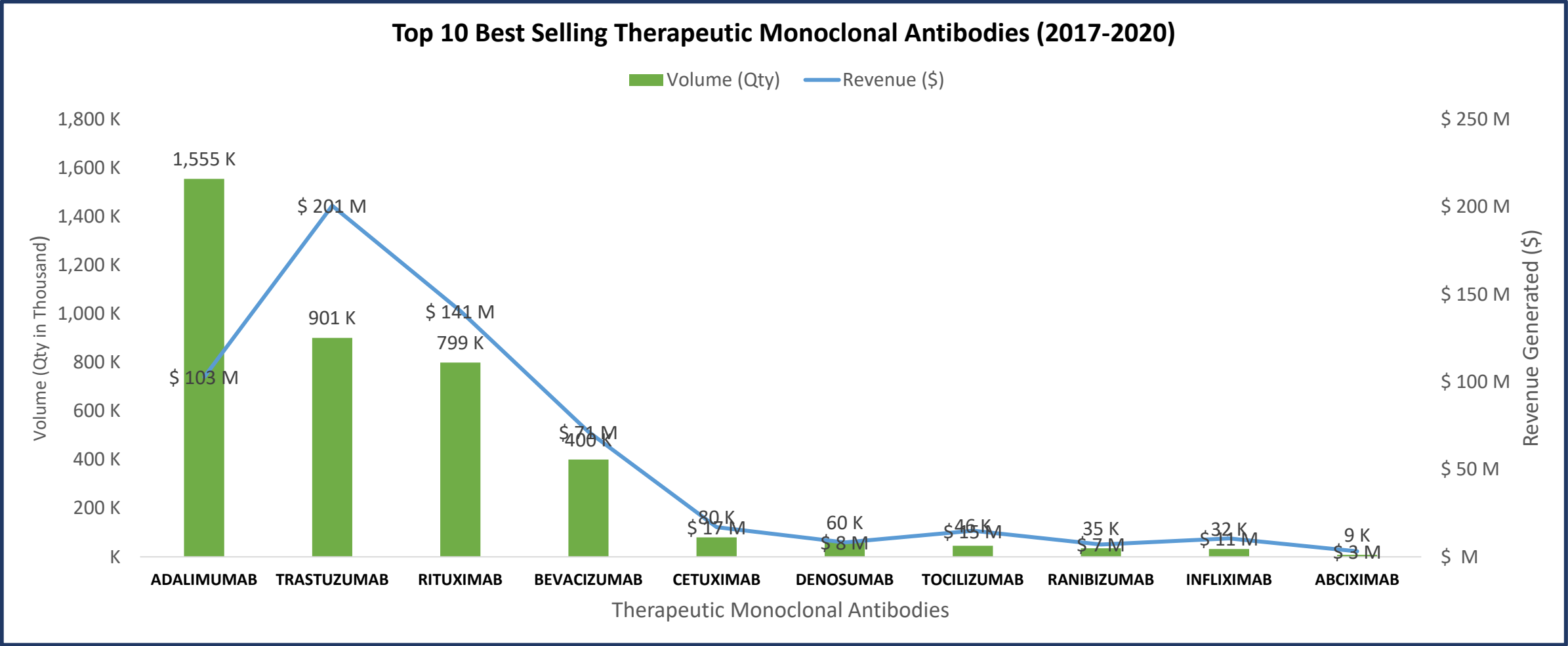
From 2017 to 2020, India's therapeutic monoclonal antibody market grew at a rate of 44%, where the domestic market grew at a rate of 15%, and export market grew at a rate of 100%.

Therapeutic Monoclonal Antibodies Market Size: Market Value (2017-2023)



Best Selling Top 10 Therapeutic Monoclonal Antibodies from Year 2017 to 2020

The market volume of Adalimumab is highest where the unit price is lower, and the revenues generated by Trastuzumab is higher. Top 5 MABs are Adalimumab, Trastuzumab, Rituximab, Bevacizumab, Cetuximab, & Denosumab.

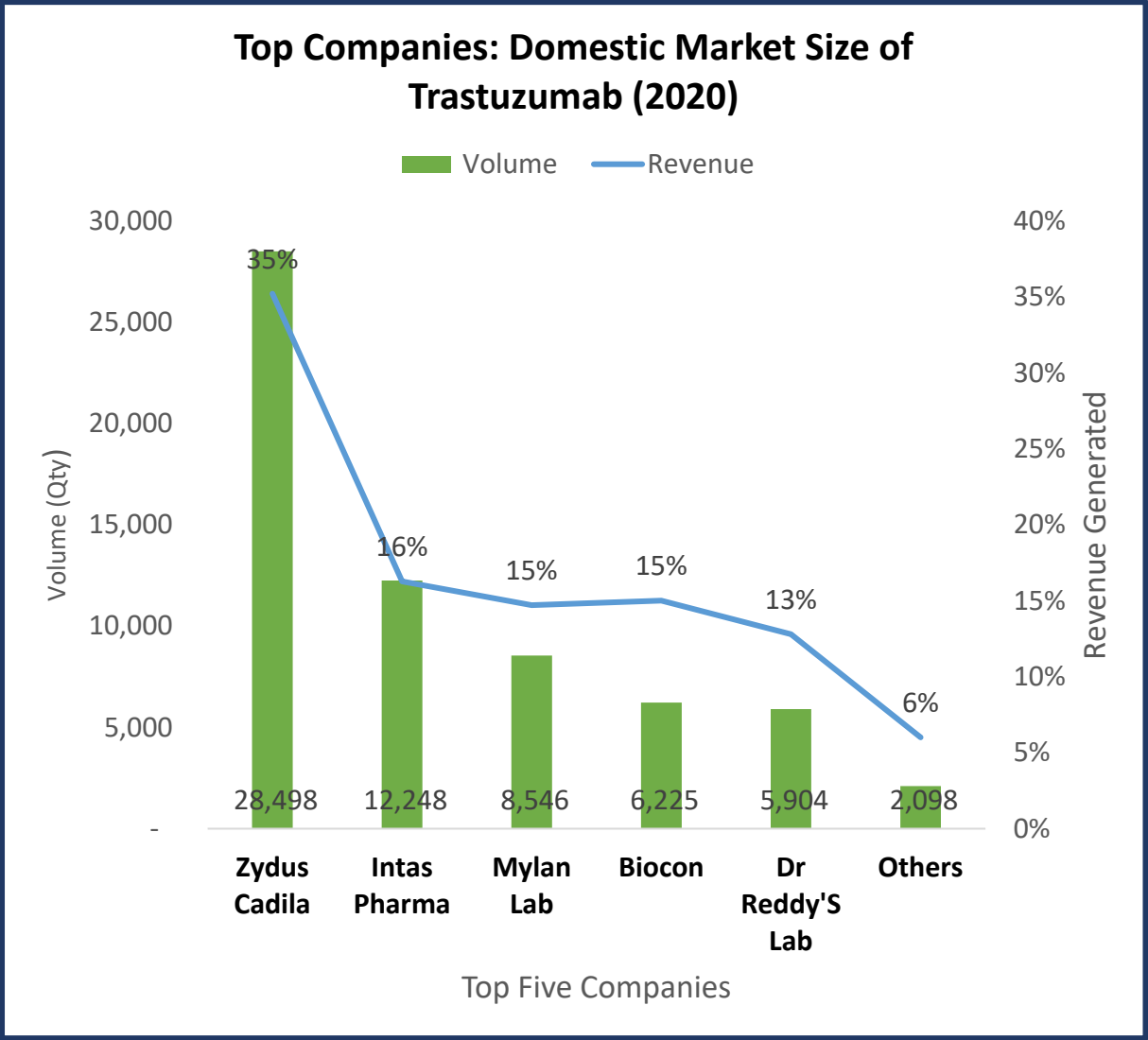


Information of Best Selling Therapeutic Monoclonal Antibody

Molecule	First Brand	Indications	Global Market	First Biosimilar (IND)
Adalimumab Target: TNF Blocker	Brand Name: HUMIRA FDA Approval: 2002 Company: Abbvie	Treat many inflammatory conditions in adults, such as ulcerative colitis, rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, plaque psoriasis, and hidradenitis suppurativa.(1)	The title of best-selling drug in the world to AbbVie Inc.'s Humira. In 2020 Humira pulled in \$19.83 billion in revenue for a year-over-year increase of 3.5%.(2)	Year: 2014 Company: Cadila Healthcare Brand Name: Exemptia
Trastuzumab Target: HER2/neu antagonist	Brand Name: HERCEPTIN FDA Approval: 1998 Company: Roche/Genentech	Treatment of HER2 overexpressing breast cancer and treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.(3)	The global Herceptin biosimilar market size is estimated to be valued at US\$ 1.3 billion in 2020 and is expected to exhibit a CAGR of 24.5 % over the forecast period (2020-2027).(4)	Year: 2014 Company: Mylan Inc Brand Name: Hertraz
Rituximab Target: CD20-directed cytolytic antibody	Brand Name: RITUXAN FDA Approval: 1997 Company: Roche/Genentech	Treatment of patients with Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, Rheumatoid Arthritis in combination with methotrexate in adult patients with moderately-to severely-active RA who have inadequate response to one or more TNF antagonist therapies.(5)	Rituxan hit \$6.54 billion in sales in 2019, putting it second behind colorectal cancer therapy. Rituxan's sales could plummet to just \$1.84 billion in 2026 due to biosimilars.(6)	Year: 2013 Company: Dr Reddy's Brand Name: Reditux
Bevacizumab Target: Vascular endothelial growth factor-specific angiogenesis inhibitor	Brand Name: AVASTIN FDA Approval: 2004 Company: Roche/Genentech	Treatment of Metastatic colorectal cancer, with intravenous 5-fluorouracil-based chemotherapy for first- or second-line treatment, Non-squamous non-small cell lung cancer, with carboplatin and paclitaxel for first line treatment of unresectable, locally advanced, recurrent or metastatic disease, Metastatic breast cancer, with paclitaxel for treatment of patients who have not received chemotherapy for metastatic HER2-negative breast cancer, & Glioblastoma.(7)	Avastin picked up \$7.12 billion in sales in 2019. Bevacizumab Market Opportunity: > USD 12 Billion by 2025.(8)	Year: 2016 Company: Reliance Life Sciences Brand Name: Bevacirel
Denosumab Target: RANK ligand inhibitor	Brand Name: XGEVA/PROLIA FDA Approval: 2010 Company: Amgen	Prevention of skeletal-related events in patients with bone metastases from solid tumors, treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.(9)	In 2020 (1 st Qtr.) Prolia (denosumab) sales were \$654 million, up 10%, lifted by higher unit demand. Xgeva (denosumab) sales were \$481 million, up 2%, driven by higher unit demand.(10)	Year: 2018 Company: Dr Reddy's Brand Name: Prolia/Xgeva

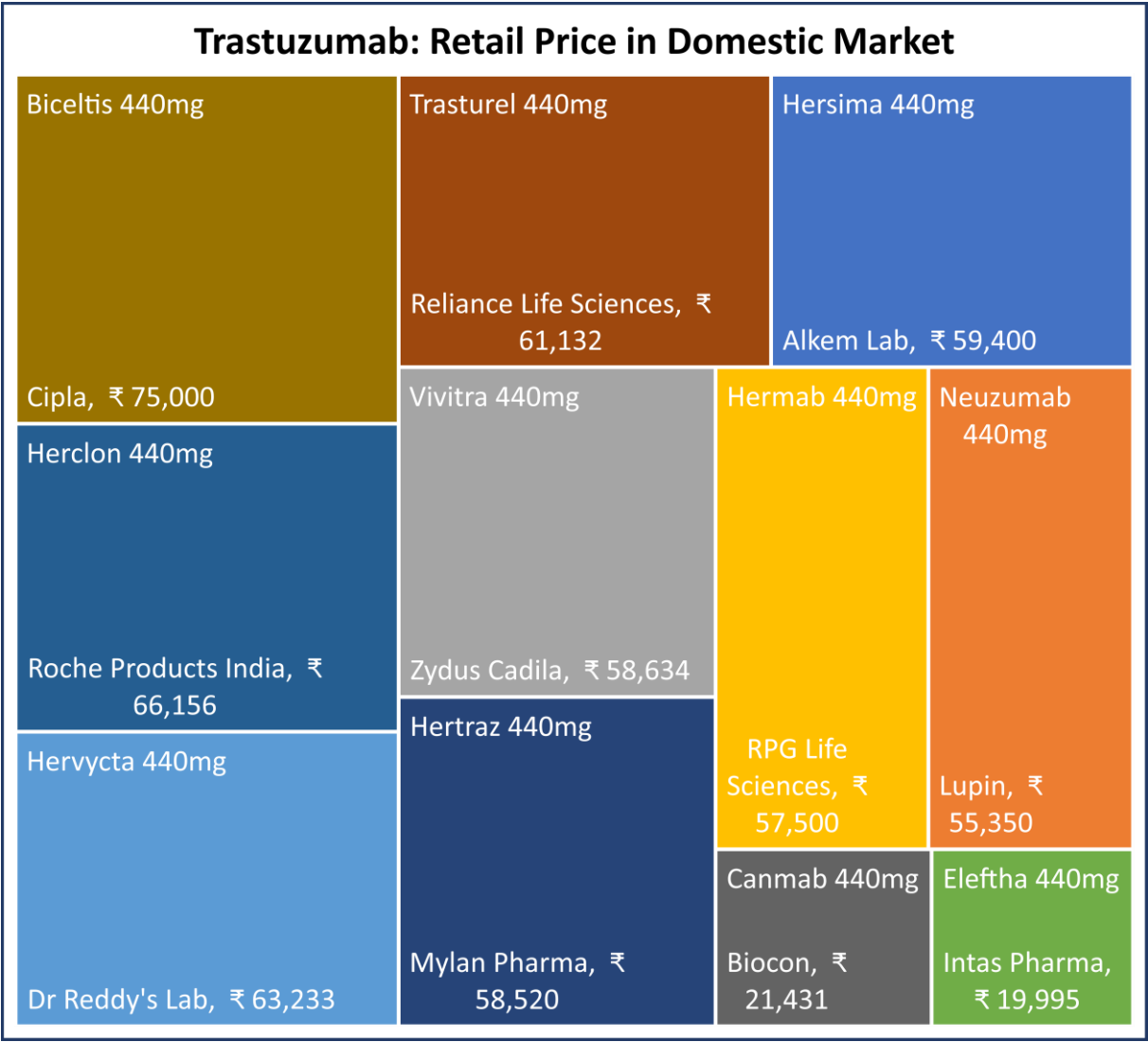
Top Five Players in the Domestic Market for Trastuzumab in Year 2020

Volume of Zydus Cadila is 28,498, and the revenue generated from it is 35% from the overall Trastuzumab's Market.



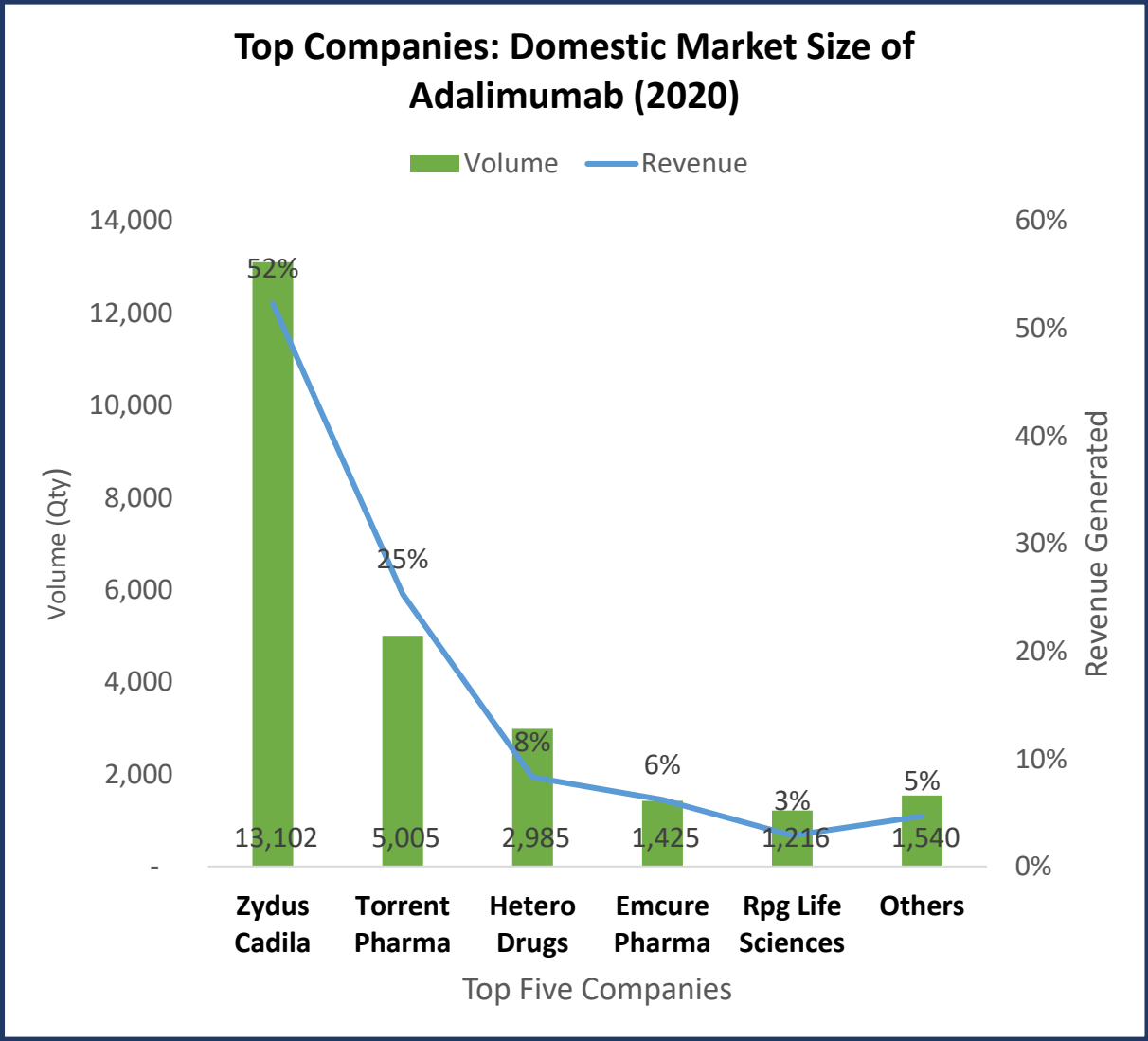
Trastuzumab Different Brands Available in Domestic Market

The overall price range of all brands of Trastuzumab in the domestic market is between Rs 75,000 to Rs 19,995.



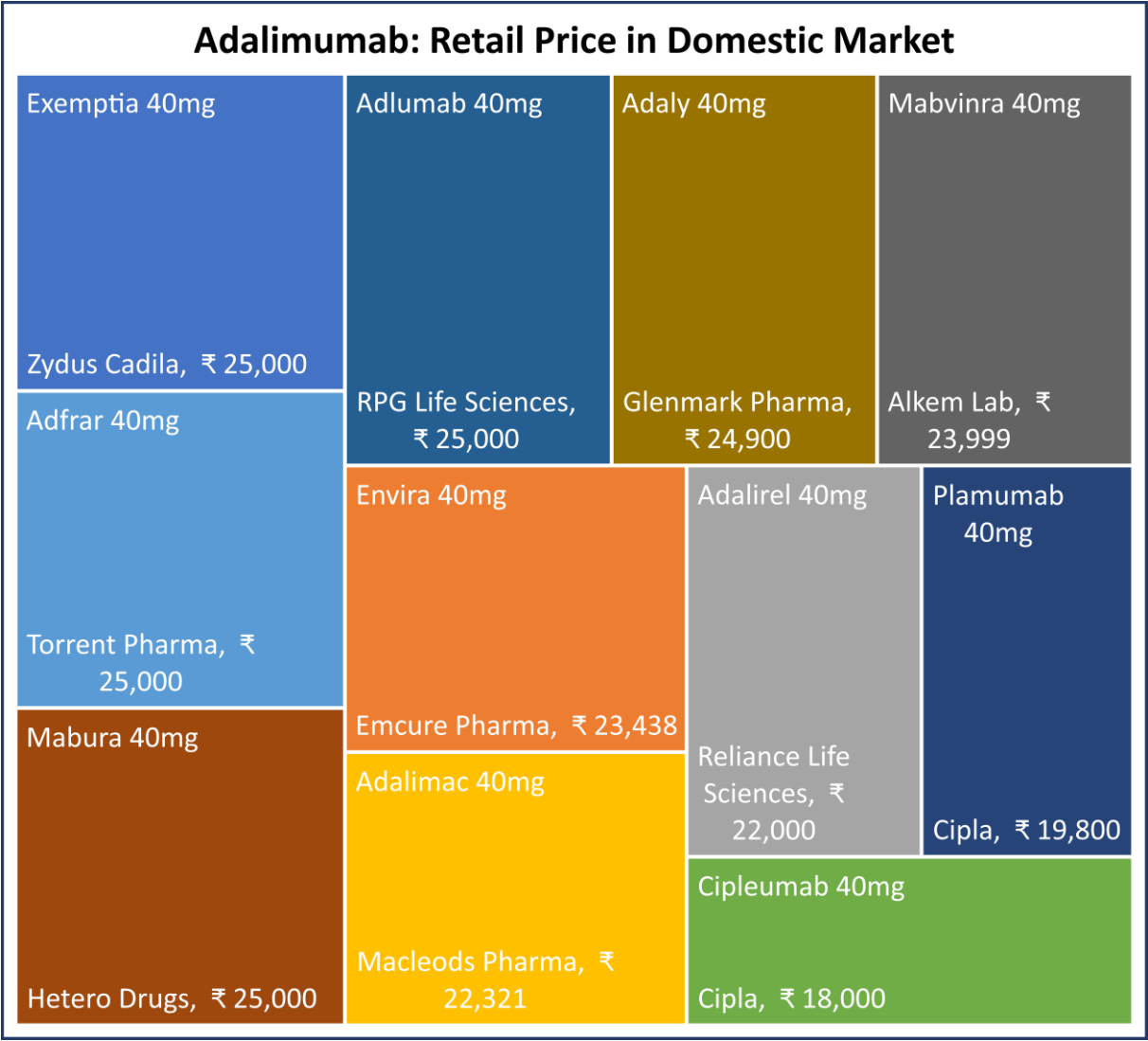
Top Five Players in the Domestic Market for Adalimumab in Year 2020

Volume of Zydus Cadila is 13,102, and the revenue generated from it is 52% from the overall Adalimumab's Market



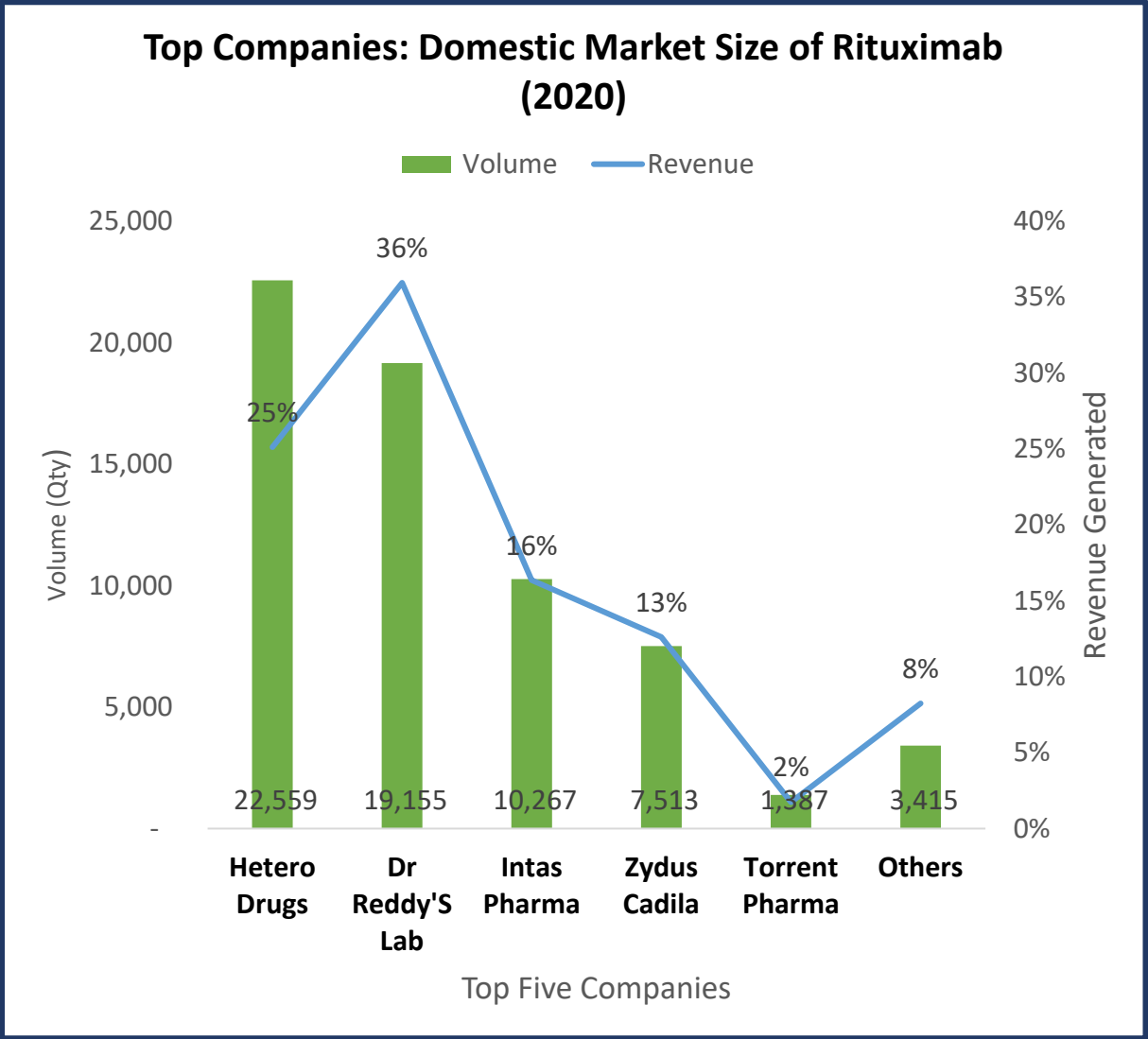
Adalimumab Different Brands Available in Domestic Market

The overall price range of all brands of Adalimumab in the domestic market is between Rs 25,000 to Rs 18,000.



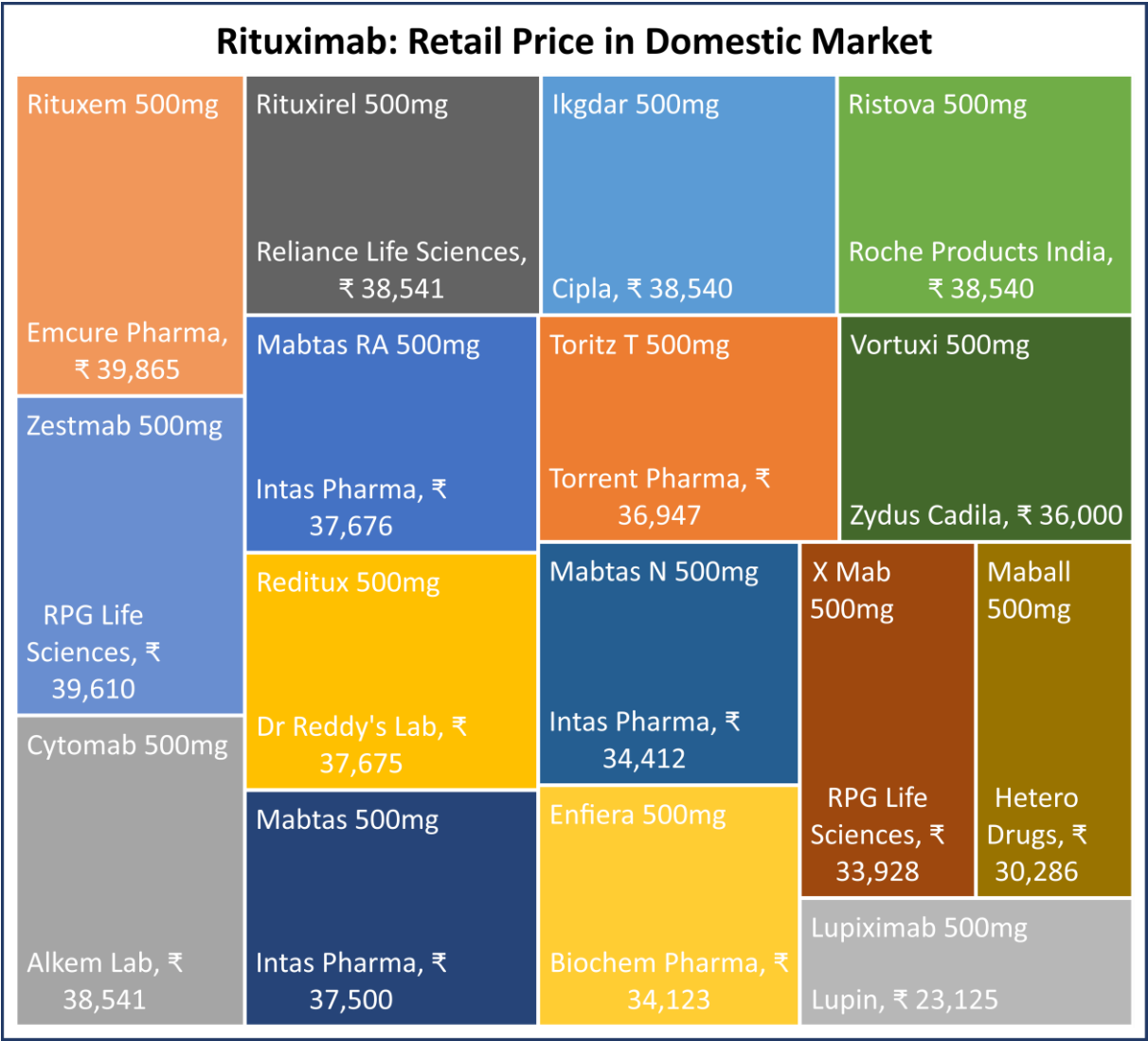
Top Five Players in the Domestic Market for Rituximab in Year 2020

Volume of Hetero Drugs is 22,559, and the revenue generated from it is 25% from the overall Rituximab's Market



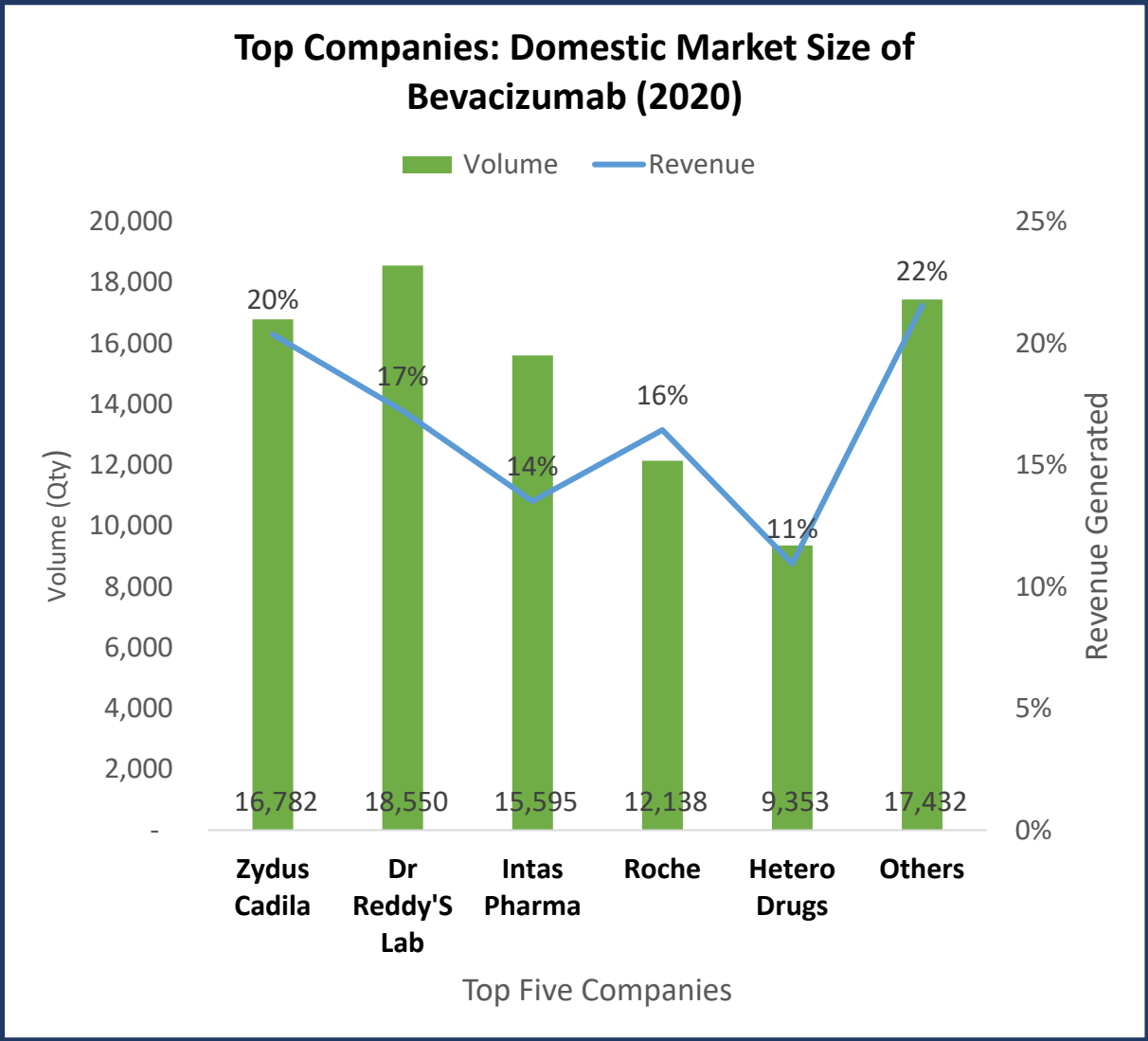
Rituximab Different Brands Available in Domestic Market

The overall price range of all brands of Rituximab in the domestic market is between Rs 39,865 to Rs 23,125.



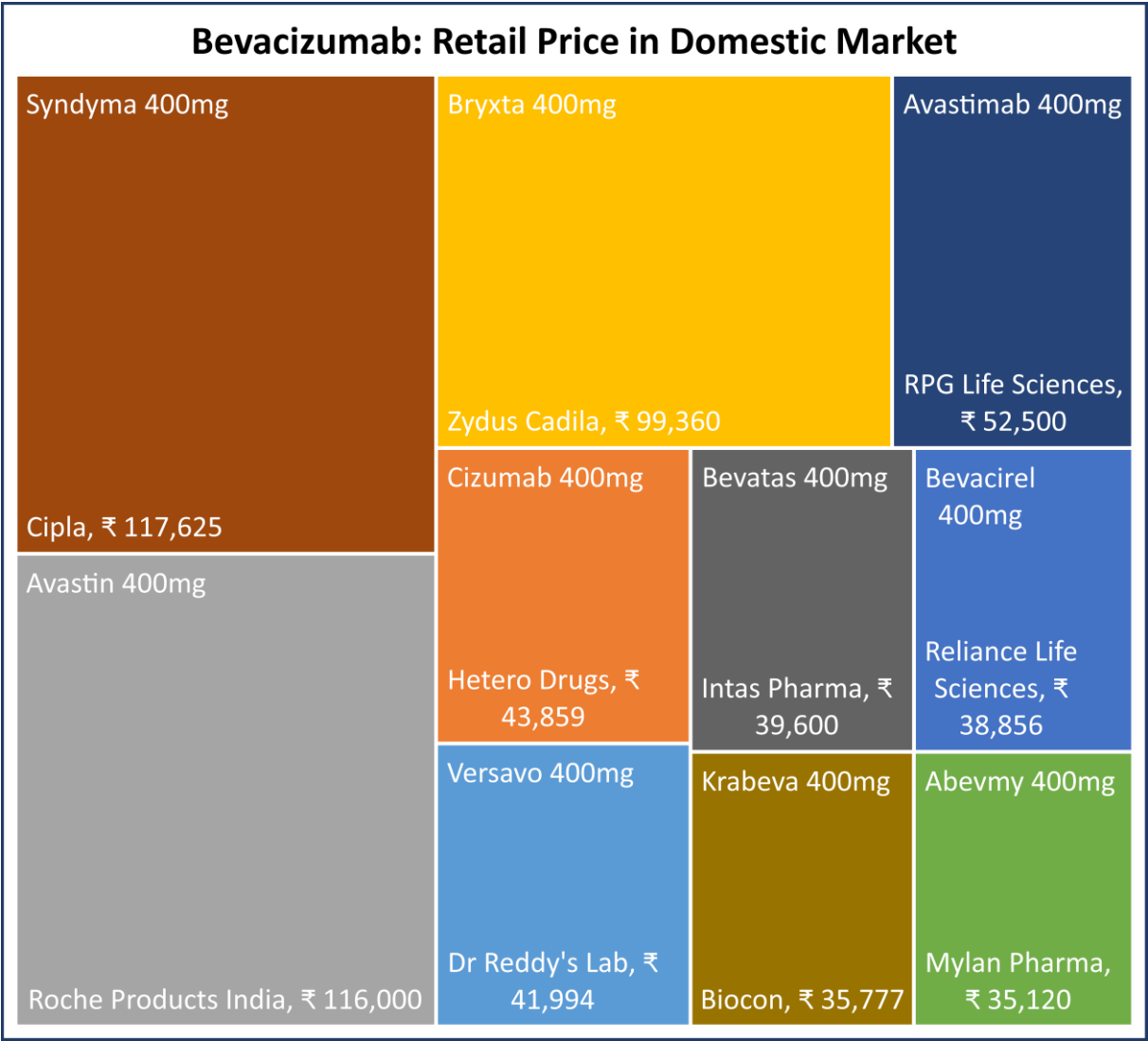
Top Five Players in the Domestic Market for Bevacizumab in Year 2020

Volume of Zydus Cadila is 16,782, and the revenue generated from it is 20% from the overall Bevacizumab's Market



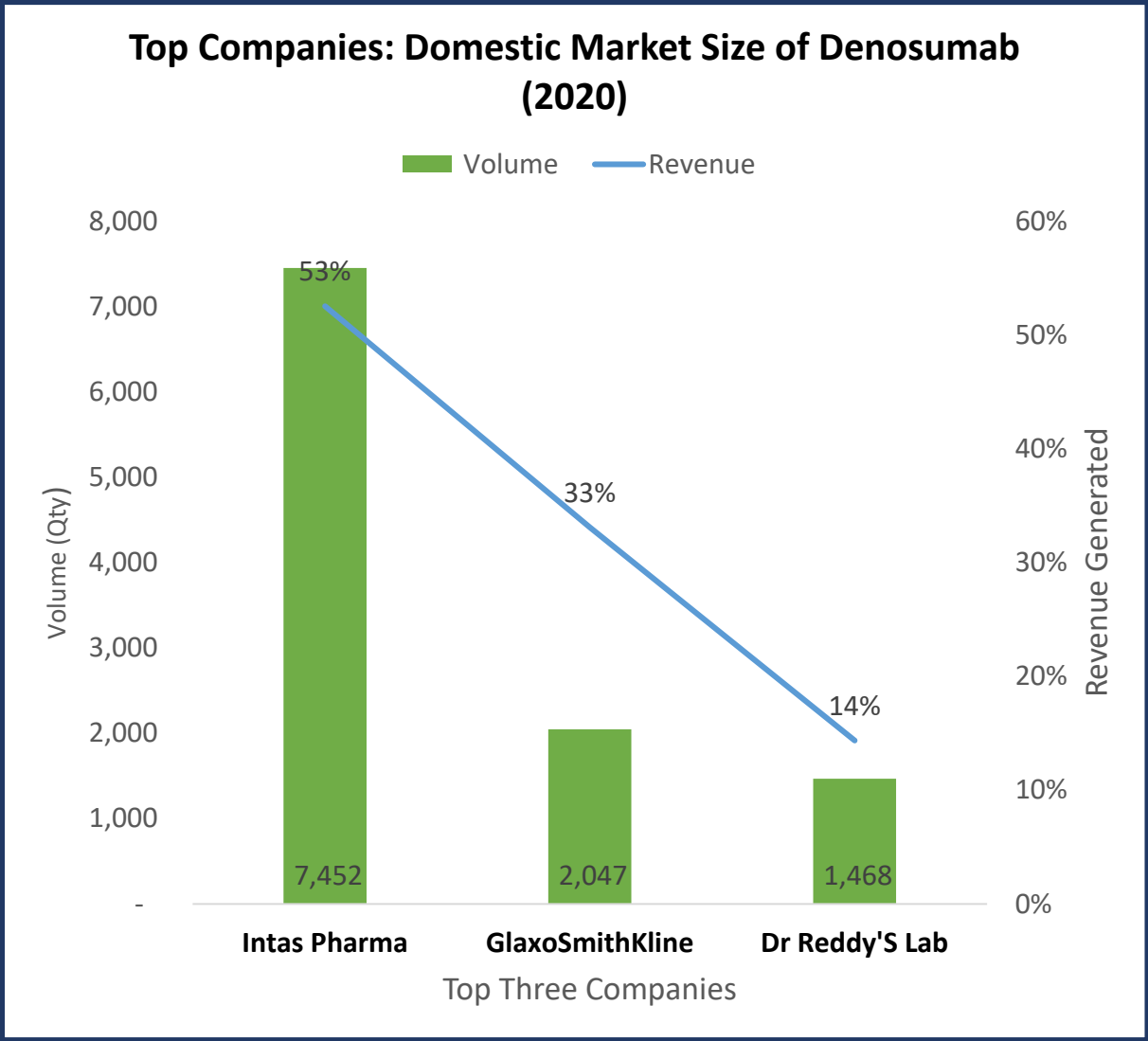
Bevacizumab Different Brands Available in Domestic Market

The overall price range of all brands of Bevacizumab in the domestic market is between Rs 1,16,000 to Rs 35,120.



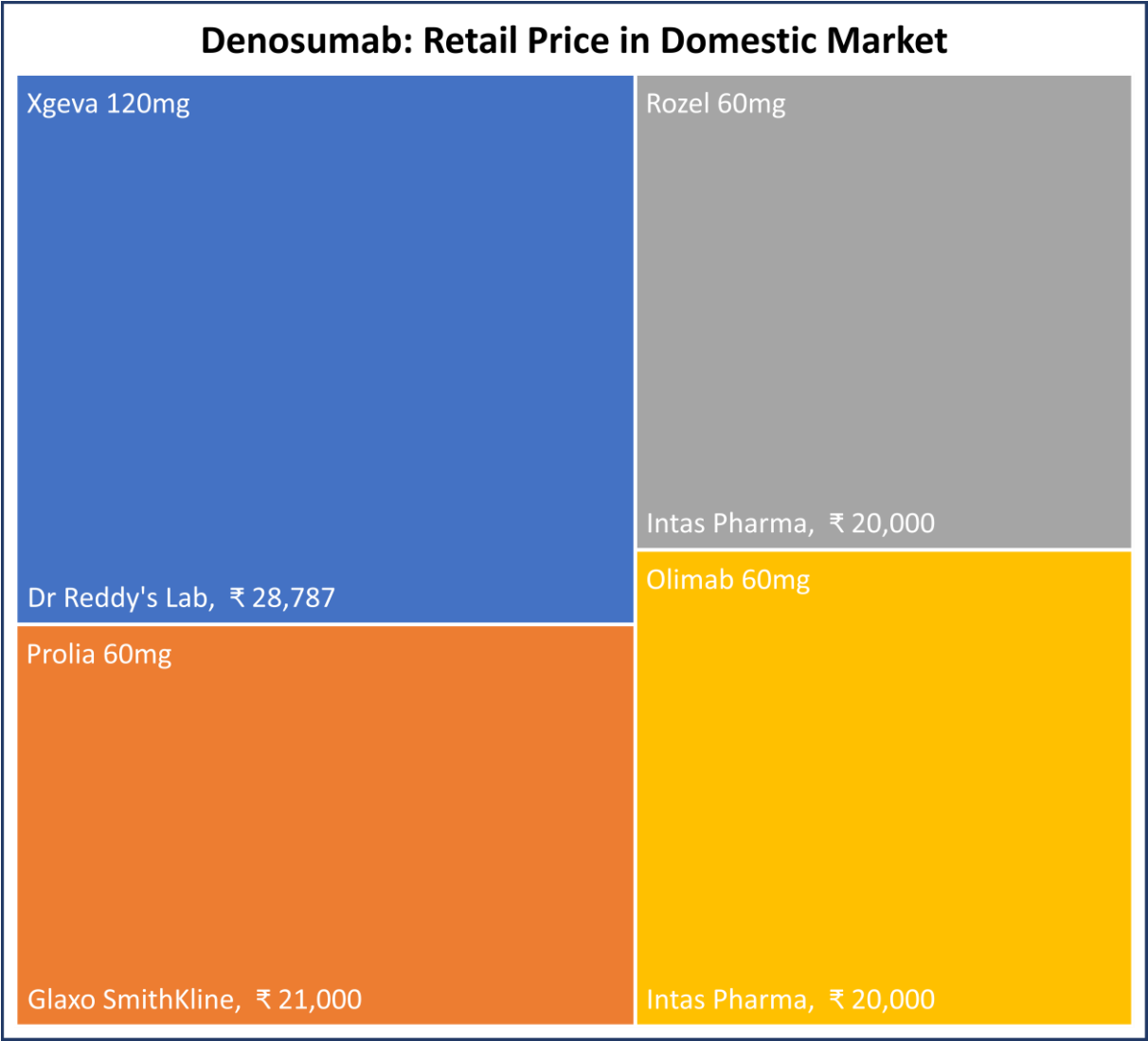
Top Players in the Domestic Market for Denosumab in Year 2020

Volume of Intas Pharma is 7,452, and the revenue generated from it is 53% from the overall Denosumab's Market



Denosumab Different Brands Available in Domestic Market

The overall price range of all brands of Denosumab in the domestic market is between Rs 28,787 to Rs 20,000.





Thank You