Brand Name: MabThera / Rituxan
Generic: rituximab
Type: monoclonal antibody
Year Accepted/Phase: 1997

Mechanism:

Rituximab is a chimeric monoclonal antibody that targets the CD20 antigen on B-cells. Upon binding, it induces B-cell lysis through complement-dependent cytotoxicity (CDC), antibody-dependent cellular cytotoxicity (ADCC), and direct apoptosis.

Chemical Structure: N/A

Indication:

Rituxan is indicated for the treatment of various types of B-cell NHL, CLL, RA, granulomatosis with polyangiitis (GPA), and microscopic polyangiitis (MPA). It is used alone or in combination with chemotherapy or other agents.

Clinical trials:

Phase II Trial in Low-Grade Non-Hodgkin Lymphoma (NHL)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/9310469/
Purpose: Evaluate the efficacy and safety of rituximab in patients with relapsed or refractory low-grade NHL.
Dates: Results published in 1997.
Results: Rituximab showed a high overall response rate of 48% with minimal toxicity. This pivotal study demonstrated the potential of rituximab as a targeted therapy for B-cell lymphomas.
Impact: These results led to the FDA approval of Rituxan for relapsed or refractory, low-grade or follicular, CD20-positive B-cell NHL in November 1997.

GELA Study (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/11807147/
Purpose: Evaluate the addition of rituximab to CHOP chemotherapy (cyclophosphamide, doxorubicin, vincristine, and prednisone) in elderly patients with diffuse large B-cell lymphoma (DLBCL).
Dates: Results published in 2002.
Results: The combination of rituximab and CHOP (R-CHOP) significantly improved overall survival and progression-free survival compared to CHOP alone. The two-year overall survival rate was 70% for the R-CHOP group versus 57% for the CHOP group.
Impact: This study established R-CHOP as the standard of care for elderly patients with DLBCL, and expanded the use of Rituxan to this population.

CLL8 Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/20888994/
Purpose: Assess the efficacy and safety of rituximab in combination with fludarabine and cyclophosphamide (FCR) versus fludarabine and cyclophosphamide (FC) alone in patients with previously untreated chronic lymphocytic leukemia (CLL).
Dates: Results published in 2010.
Results: The addition of rituximab to FC significantly improved progression-free survival and overall survival. The median progression-free survival was 51.8 months for the FCR group compared to 32.8 months for the FC group. Overall survival at three years was 87.2% for the FCR group versus 82.5% for the FC group.
Impact: These findings led to the FDA approval of Rituxan for use in combination with FC for the treatment of previously untreated and relapsed/refractory CLL in February 2010.

REFLEX Trial (Phase III)
Pubmed: https://pubmed.ncbi.nlm.nih.gov/16947627/
Purpose: Evaluate the efficacy and safety of rituximab in patients with moderate-to-severe rheumatoid arthritis (RA) who had an inadequate response to one or more tumor necrosis factor (TNF) inhibitors.
Dates: Results published in 2006.
Results: Rituximab in combination with methotrexate significantly improved clinical outcomes compared to methotrexate alone. Patients receiving rituximab showed significant improvements in ACR20, ACR50, and ACR70 response rates, indicating reductions in RA symptoms.
Impact: The positive outcomes led to the FDA approval of Rituxan for the treatment of moderate-to-severe RA in combination with methotrexate in February 2006.