

Brand Name: Valcyte

Generic: valganciclovir

Type: monoclonal antibody

Year Accepted/Phase: 2001

Mechanism:

Valganciclovir is a prodrug of ganciclovir, which inhibits viral DNA replication by interfering with viral DNA polymerase.

Chemical Structure: N/A

Indication:

Valcyte is indicated for the treatment of CMV retinitis in patients with AIDS and for the prevention of CMV disease in transplant recipients at high risk.

Clinical trials:

Phase III Trials for CMV Retinitis

Pubmed: <https://pubmed.ncbi.nlm.nih.gov/11948271/>

Purpose: Evaluate the efficacy and safety of valganciclovir in treating CMV retinitis in patients with AIDS.

Dates: Conducted in the late 1990s and early 2000s.

Results: The Phase III trials demonstrated that valganciclovir was as effective as intravenous ganciclovir, the standard treatment at the time, in treating CMV retinitis. It also offered the convenience of oral administration.

Impact: These trials led to the approval of valganciclovir for the treatment of CMV retinitis, providing a more convenient and effective treatment option for patients with AIDS.

Phase III Trials for CMV Prophylaxis in Transplant Recipients

Pubmed: <https://pubmed.ncbi.nlm.nih.gov/15888055/>

Purpose: Evaluate the efficacy and safety of valganciclovir in preventing CMV disease in transplant recipients.

Dates: Conducted in the early 2000s.

Results: The Phase III trials showed that valganciclovir was effective in preventing CMV disease in transplant recipients. It reduced the incidence of CMV disease compared to placebo or other antiviral medications.

Impact: These trials supported the approval of valganciclovir for the prevention of CMV disease in transplant recipients, helping to reduce the risk of this serious complication following transplantation.