Brand Name: Tamiflu **Generic:** oseltamivir **Type:** small molecule

Year Accepted/Phase: 1995

Mechanism:

Oseltamivir is a neuraminidase inhibitor that prevents the release of new viral particles from infected cells, thereby limiting the spread of the virus within the body.

Chemical Structure:

Indication:

Tamiflu is indicated for the treatment of acute, uncomplicated influenza A and B in patients who have been symptomatic for no more than 48 hours. It is also indicated for the prophylaxis of influenza A and B in patients one year and older.

Clinical trials:

WV15671 Trial (Phase III)

Pubmed: https://pubmed.ncbi.nlm.nih.gov/24811411/

Purpose: Evaluate the efficacy and safety of oseltamivir in the treatment of acute

influenza in otherwise healthy adults. **Dates:** Conducted from 1997 to 1998.

Results: The WV15671 trial showed that oseltamivir significantly reduced the duration of flu symptoms by approximately 1.3 days compared to placebo. It also decreased the severity of symptoms and the incidence of secondary complications.

Impact: This trial was pivotal for the FDA approval of oseltamivir for the treatment of acute influenza in adults in October 1999.

WV15730 Trial (Phase III)

Purpose: Evaluate the efficacy and safety of oseltamivir in the treatment of acute influenza in elderly and high-risk patients.

Dates: Conducted from 1998 to 1999.

Results: The WV15730 trial demonstrated that oseltamivir reduced the duration of flu symptoms and the severity of illness in elderly and high-risk patients, including those with chronic cardiac or respiratory conditions.

Impact: Supported the use of oseltamivir in high-risk populations, leading to its expanded indication.

WV15812 Trial (Phase III)

Purpose: Assess the efficacy of oseltamivir in the treatment of influenza in pediatric patients (1 to 12 years old).

Dates: Conducted from 1999 to 2000.

Results: The WV15812 trial showed that oseltamivir significantly reduced the duration of flu symptoms in children by 1.5 days compared to placebo and decreased the incidence of acute otitis media as a complication.

Impact: Led to the FDA approval of oseltamivir for the treatment of influenza in pediatric patients aged 1 year and older in December 2000.

WV16193 Trial (Phase III)

Purpose: Evaluate the efficacy and safety of oseltamivir for the prophylaxis of influenza in adults.

Dates: Conducted from 1998 to 1999.

Results: The WV16193 trial demonstrated that oseltamivir was effective in preventing influenza infection in adults who had been exposed to the virus, reducing the incidence of flu by over 70% compared to placebo.

Impact: Supported the FDA approval of oseltamivir for the prophylaxis of influenza in adults in November 2000.

WV15759 Trial (Phase III)

Purpose: Assess the efficacy of oseltamivir for the prophylaxis of influenza in household contacts of influenza-infected patients.

Dates: Conducted from 1999 to 2000.

Results: The WV15759 trial showed that oseltamivir significantly reduced the transmission of influenza within households, decreasing the incidence of flu by over 80% among household contacts.

Impact: Provided evidence for the use of oseltamivir in preventing the spread of influenza within households, reinforcing its approval for prophylactic use.