

**Brand Name:** Winrevair

**Generic:** sotatercept

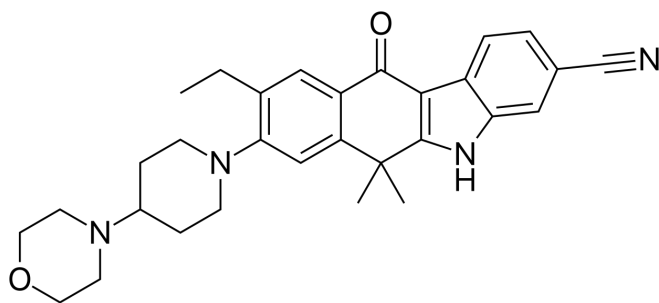
**Type:** protein

**Year Accepted/Phase:** N/A

### **Mechanism:**

Sotatercept is a fusion protein that acts as a ligand trap for members of the TGF- $\beta$  superfamily, particularly activins and growth differentiation factors (GDFs). By binding these ligands, sotatercept inhibits their interaction with cell surface receptors, thereby reducing pro-proliferative and pro-inflammatory signaling pathways. This results in decreased vascular remodeling and reduced pulmonary arterial pressure.

### **Chemical Structure:**



### **Indication:**

Sotatercept is being investigated primarily for the treatment of pulmonary arterial hypertension (PAH).

## Clinical trials:

### **PULSAR Trial (Phase II)**

**Pubmed:** <https://pubmed.ncbi.nlm.nih.gov/33789009/>

**Purpose:** Evaluate the efficacy and safety of sotatercept in patients with pulmonary arterial hypertension (PAH).

**Dates:** Conducted from 2018 to 2020.

**Results:** The PULSAR trial demonstrated that sotatercept significantly improved pulmonary vascular resistance (PVR) and six-minute walk distance (6MWD) compared to placebo. Patients receiving sotatercept showed improvements in exercise capacity and hemodynamic parameters, indicating a positive impact on PAH progression.

**Impact:** The promising results from the PULSAR trial led to further investigation of sotatercept in larger Phase III trials to confirm its efficacy and safety in a broader patient population.

### **STELLAR Trial (Phase III)**

**Pubmed:** <https://pubmed.ncbi.nlm.nih.gov/36877098/>

**Purpose:** Assess the long-term efficacy and safety of sotatercept in patients with pulmonary arterial hypertension (PAH).

**Dates:** Initiated in 2020, with ongoing data collection and analysis expected to extend into 2024.

**Results:** Interim results from the STELLAR trial have shown consistent improvements in exercise capacity and hemodynamic parameters, corroborating the findings from the Phase II PULSAR trial. The trial aims to provide comprehensive data on the long-term benefits and potential risks of sotatercept in PAH management.

**Impact:** The ongoing STELLAR trial is expected to provide the necessary data for regulatory approval and establish sotatercept as a potential new treatment option for patients with PAH.