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FDA approves Uptravi tablets to treat adults with pulmonary arterial hypertension

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On December 21, the U.S. Food and Drug Administration approved Uptravi (selexipag) tablets to treat adults with pulmonary arterial hypertension (PAH), a chronic, progressive, and debilitating rare lung disease that can lead to death or the need for transplantation.

"Uptravi offers an additional treatment option for patients with pulmonary arterial hypertension," said Ellis Unger, M.D., director of the Office of Drug Evaluation I in the FDA's Center for Drug Evaluation and Research. "The FDA supports continued efforts to provide new treatment options for rare diseases."

PAH is high blood pressure that occurs in the arteries that connect the heart to the lungs. It causes the right side of the heart to work harder than normal, which can lead to limitations on exercise ability and shortness of breath, among other more serious complications.

Uptravi belongs to a class of drugs called oral IP prostacyclin receptor agonists. The drug acts by relaxing muscles in the walls of blood vessels to dilate (open) blood vessels and decrease the elevated pressure in the vessels supplying blood to the lungs.

Uptravi's safety and efficacy were established in a long-term clinical trial of 1,156 participants with PAH. Uptravi was shown to be effective in reducing hospitalization for PAH and reducing the risks of disease progression compared to placebo. Participants were exposed to Uptravi in this trial for a median duration of 1.4 years.

Common side effects observed in those treated with Uptravi in the trial include headache, diarrhea, jaw pain, nausea, muscle pain (myalgia), vomiting, pain in an extremity, and flushing.

Uptravi was granted orphan drug designation. [Orphan drug designation](#) provides incentives such as tax credits, user fee waivers, and eligibility for exclusivity to assist and encourage the development of drugs for rare diseases.

Uptravi is marketed by San Francisco-based Actelion Pharmaceuticals US, Inc.

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