

FDA approves Opsumit to treat pulmonary arterial hypertension

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The U.S. Food and Drug Administration today approved Opsumit (macitentan), a new drug to treat adults with pulmonary arterial hypertension (PAH), a chronic, progressive and debilitating disease that can lead to death or the need for lung transplantation.

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. Opsumit belongs to a class of drugs called endothelin receptor blockers, which act to relax the pulmonary arteries, decreasing blood pressure in the lungs.

Opsumit's safety and effectiveness were established in a long-term clinical trial where 742 participants were randomly assigned to take Opsumit or placebo. The average treatment duration was about two years. In the study, Opsumit was effective in delaying disease progression, a finding that included a decline in exercise ability, worsening symptoms of PAH or need for additional PAH medication.

Similar to other members of its drug class, Opsumit carries a Boxed Warning alerting patients and health care professionals that the drug should not be used in pregnant women because it can harm the developing fetus. Female patients can receive the drug only through the Opsumit Risk Evaluation and Mitigation Strategy (REMS) Program. This restricted-distribution program requires prescribers to be certified by enrolling in the program; all female patients to be enrolled in the program and comply with applicable pregnancy testing and contraception requirements before initiating treatment; and pharmacies to be certified and to dispense Opsumit only to patients who are authorized to receive it.

Common side effects observed in those treated with Opsumit include low red blood cell count (anemia), common cold-like symptoms (nasopharyngitis), sore throat, bronchitis, headache, flu and urinary tract infection.

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

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ATTEND EVENTS

08-11 SEP	Fierce Pharma Week Philadelphia, PA
10 SEP	Fierce Pharma Marketing Awards Gala National Constitution Center
07-09 OCT	Fierce Biotech Week Boston, MA