## Aurlumyn™ (iloprost) – New orphan drug approval

- On February 14, 2024, the FDA announced the approval of Eicos Sciences' Aurlumyn (iloprost), for the treatment of severe frostbite in adults to reduce the risk of digit amputations.
    - Effectiveness was established in young, healthy adults who suffered frostbite at high altitudes.
- Frostbite can occur in several stages, ranging from mild frostbite that does not require medical intervention and does not cause permanent skin damage, to severe frostbite when both the skin and underlying tissue are frozen and blood flow is stopped, sometimes requiring amputation.
- Aurlumyn is a vasodilator and prevents blood from clotting. It is the first FDA approved treatment for severe frostbite.
- The efficacy of iloprost was derived from a published open-label, randomized controlled study in 47 patients with severe frostbite. At enrollment, all eligible patients were treated with rapid rewarming of areas with frostbite, aspirin 250 mg intravenous (IV), and buflomedil 400 mg IV and then randomized to Groups A, B or C. All patients continued to receive aspirin 250 mg IV daily up to 8 days. In addition, Group A received buflomedil 400 mg IV for up to 8 days, Group B received iloprost IV for 6 hours daily for up to 8 days, and Group C received recombinant tissue plasminogen activator IV on day 1 and iloprost IV for 6 hours daily for up to 8 days. The primary endpoint was the presence of an anomaly (absence of uptake) in the bone phase of technetium 99m scan performed 7 days after initial clinical presentation of frostbite (BS2 bone scintigraphy anomaly) in at least one finger/toe affected by severe frostbite.
    - On day 7, the presence of BS2 bone scintigraphy anomaly was observed in 60% (9/15), 0% (0/16) and 19% (3/16) of the patients in Groups A, B, and C, respectively.
    - Compared to Group A, the presence of bone scintigraphy anomaly was significantly lower in Group B ($p < 0.001$) and Group C ($p < 0.03$), favoring iloprost.
- A warnings and precaution for Aurlumyn was hypotension.
- The most common adverse reactions with Aurlumyn use were headache, flushing, palpitations/tachycardia, nausea, vomiting, dizziness, and hypotension.
- Aurlumyn is administered as a continuous IV infusion over 6 hours each day for up to a maximum of 8 consecutive days.
    - The initial infusion should be started on day 1 at a rate of 0.5 ng/kg/minute and increased in increments of 0.5 ng/kg/minute every 30 minutes according to tolerability up to 2 ng/kg/minute. Dosage is based on actual patient body weight (kg).
    - Dose titration steps should be repeated on day 2 and day 3. From day 4 onward, the infusion should be started at the highest tolerated dose from the previous day, and the rate should be adjusted as needed, based on tolerability.
- Eicos Sciences' launch plans for Aurlumyn are pending. Aurlumyn will be available as a 100 mcg/mL single dose vial.