Panzyga® (immune globulin intravenous, human - ifas) – New indication

- On February 12, 2021, Pfizer announced the FDA approval of Panzyga (immune globulin intravenous, human - ifas), for the treatment of adults with chronic inflammatory demyelinating polyneuropathy (CIDP) to improve neuromuscular disability and impairment.

- Panzyga is also approved for primary humoral immunodeficiency and chronic immune thrombocytopenia.

- CIDP is a rare disorder of the peripheral nerves characterized by gradually increasing symmetrical motor and sensory loss and weakness associated with loss of deep tendon reflexes. Most individuals will require long term treatment; nearly a third of CIDP patients will progress to wheelchair dependence if left untreated.

- The approval of Panzyga for the new indication was based on a double-blind, randomized, study of 142 adult patients with CIDP. Efficacy was based on the proportion of responders in the 1.0 g/kg Panzyga arm at week 24 relative to baseline (week 0). A responder was defined as a subject with a decrease of at least 1 point in the adjusted 10-point Inflammatory Neuropathy Cause and Treatment (INCAT) disability score.

    - The proportion of responders in the 1.0 g/kg arm was 79.71% (95% CI: 68.8, 87.5).
    - Efficacy was supported by the proportion of responders in the 2.0 g/kg dose arm in the adjusted INCAT disability score.

- Panzyga carries a boxed warning for thrombosis, renal dysfunction, and acute renal failure.

- The most common adverse reactions (> 5%) with Panzyga use were headache, fever, dermatitis, and increased blood pressure.

- The recommended loading dose of Panzyga for the treatment of CIDP is 2 g/kg (20 mL/kg) via intravenous infusion, divided into 2 daily doses of 1 g/kg (10 mL/kg) given on 2 consecutive days. The maintenance dose is 1 to 2 g/kg (10 to 20 mL/kg) every 3 weeks divided in 2 doses given over 2 consecutive days.

- Refer to the Panzyga drug label for dosing for its other indications.