## Vijoice® (alpelisib) – New formulation approval

- On April 24, 2024, the FDA approved Novartis' Vijoice (alpelisib) oral granules, for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy.
    - Vijoice was previously available as an oral tablet for this indication.
- This indication is approved under accelerated approval based on response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
- Warnings and precautions for Vijoice include severe hypersensitivity, severe cutaneous adverse reactions, hyperglycemia, pneumonitis, diarrhea or colitis, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 10%) with Vijoice use were diarrhea, stomatitis, and hyperglycemia.
- The recommended dosage of Vijoice in adult patients is 250 mg orally, once daily, administered as recommended until disease progression or unacceptable toxicity.
- The recommended initial dosage of Vijoice in pediatric patients is 50 mg orally, once daily, administered as recommended until disease progression or unacceptable toxicity.
    - A dose increase to 125 mg once daily can be considered in pediatric patients ≥ 6 years old for response optimization (clinical/radiological) after 24 weeks of treatment with Vijoice at 50 mg once daily. When a pediatric patient turns 18 years old, a gradual dose increase up to 250 mg can be considered.
    - Refer to the Vijoice drug label for complete dosing and administration recommendations.
- Novartis' launch plans for Vijoice oral granules are pending. Vijoice oral granules will be available as a 50 mg strength.