Tasigna® (nilotinib) – Expanded indication

- On September 23, 2021, the FDA approved Novartis' Tasigna (nilotinib), for the treatment of pediatric patients greater than or equal to 1 year of age with chronic phase and accelerated phase Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy.
    - Tasigna was previously only approved in pediatric patients with chronic phase Ph+ CML with resistance or intolerance to prior TKI therapy.
- Tasigna is also approved for:
    - Treatment of adult and pediatric patients greater than or equal to 1 year of age with newly diagnosed Ph+ CML in chronic phase.
    - Treatment of adult patients with chronic phase and accelerated phase Ph+ CML resistant or intolerant to prior therapy that included imatinib.
- The approval of Tasigna for the expanded indication was based upon the final data report for study CAMN107A2203 in pediatric patients with Ph+ CML in chronic phase or accelerated phase resistant or intolerant to either imatinib or dasatinib.
- Tasigna carries a boxed warning for QT prolongation and sudden deaths.
- The recommended dosage of Tasigna for pediatric patients is 230 mg/m^2 orally twice daily, rounded to the nearest 50 mg dose (to a maximum single dose of 400 mg). If needed, the desired dose should be attained by combining different strengths of Tasigna capsules. Treatment should be continued as long as clinical benefit is observed or until unacceptable toxicity occurs.
    - Refer to the Tasigna drug label for dosing for all its other indications.