Ezallor™ (rosuvastatin) – New drug approval

- On December 19, 2019, the FDA approved Novo Nordisk's Fiasp (insulin aspart), to improve glycemic control in adult and pediatric patients with diabetes mellitus.
    - Fiasp was previously only approved in adult patients.
- The approval of Fiasp for the expanded indication was based on a 26-week, randomized, active controlled study in 777 pediatric patients with type 1 diabetes. Patients were randomized to blinded mealtime Fiasp, blinded mealtime NovoLog® (insulin aspart), or open-label postmeal Fiasp, all in combination with once daily Tresiba® (insulin degludec).
    - After 26 weeks of treatment, the treatment difference for change in HbA1c from baseline between mealtime Fiasp compared to mealtime NovoLog, and the treatment difference between postmeal Fiasp compared to mealtime NovoLog met the pre-specified non-inferiority margin (0.4%).
    - The estimated treatment difference vs. mealtime NovoLog was -0.17 (95% CI: -0.30, -0.03) for mealtime Fiasp and 0.13 (95% CI: -0.01, 0.26) for postmeal Fiasp.
- The recommended dose of Fiasp for all patients should be individualized and the dosage should be adjusted based on route of administration, individual's metabolic needs, blood glucose monitoring results and glycemic control goal.
- Refer to the Fiasp drug label for complete dosing and administration recommendations.