Voxzogo® (vosoritide) – Expanded indication

- On October 20, 2023, BioMarin announced the FDA approval of Voxzogo (vosoritide), to increase linear growth in pediatric patients with achondroplasia with open epiphyses.
    - Voxzogo was previously approved for this indication in patients 5 years of age and older. This expanded indication now includes children of all ages with open growth plates.
    - This indication is approved under accelerated approval based on an improvement in annualized growth velocity. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trial(s).

- The use of Voxzogo for pediatric patients is supported by evidence from an adequate and well-controlled study in 121 pediatric patients aged 5 to 15 years with achondroplasia, pharmacokinetic data in pediatric patients aged 4.5 months to 15 years, and additional safety data in pediatric patients aged 4.4 months to < 5 years.

- The recommended dosage of Voxzogo is based on the patient's actual body weight. Voxzogo is administered by subcutaneous injection once daily. Refer to the Voxzogo drug label for complete dosing information.