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Professor Bruno Sepodes
Chair, Committee for Medicinal Products for Human Use
European Medicines Agency
Domenico Scarlattilaan 6
1083 HS Amsterdam
The Netherlands

06 April 2026

Subject: EMEA/H/C//006576
VIOKAT 25 mg, 75 mg, and 150 mg prolonged-release tablets
International non-proprietary name or common name: diazoxide choline

Dear Professor Sepodes,

I am writing on behalf of Soleno Therapeutics Europe Limited to formally notify the European Medicines Agency (EMA) and the Committee for Medicinal Products for Human Use (CHMP) of the applicant's decision to withdraw the application for centralised marketing authorisation for the above-referenced medicinal product. This application specifically concerned the treatment of adults and children aged 4 years and older with Prader-Willi syndrome (PWS) who experience hyperphagia. PWS is a rare, life-threatening genetic disorder characterised by pronounced hyperphagia and associated food-related behaviours. Currently, there are no approved therapies for hyperphagia in PWS within the European Union, highlighting a significant and urgent unmet medical need.

This decision to withdraw follows the preliminary assessment by the CHMP, which concluded that the evidence submitted based on multiple data sources and the comprehensive clinical development programme in this rare disease setting was not sufficient to support a positive benefit-risk determination. For the avoidance of doubt, this withdrawal does not affect any ongoing or planned clinical development activities in Europe or other jurisdictions, nor does it impact the compassionate use programme that facilitates earlier patient access based on the treating physician's informed clinical judgement in countries where this product is not yet approved.

The United States Food and Drug Administration has reached a different conclusion regarding the benefit-risk profile of this product, resulting in its approval for patients in the United States. This withdrawal is made without prejudice to that favourable assessment.

Soleno Therapeutics Europe Limited reserves all rights to engage with the European Medicines Agency and its advisory committees in future regulatory submissions for this product, with the intention of addressing the recognised unmet needs of PWS patients in the European Economic Area. In doing so, the

applicant will seek to further substantiate the clinically meaningful and statistically significant treatment-related effects observed, to support the establishment of safe and effective conditions of use for the product.

Thank you very much for your attention to this matter.

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