

## **Infacort<sup>®</sup> Update**

For young Congenital Adrenal Hyperplasia patients, especially neonates and infants, current hydrocortisone replacement therapy poses significant challenges especially at low doses of hydrocortisone where no licensed therapies exist for this age group. Diurnal (Cardiff, UK) is pleased to announce that the first patient has been enrolled in Europe onto a Phase 3 registration trial of its pediatric product Infacort<sup>®</sup>. Infacort<sup>®</sup> is an immediate-release, oral formulation of hydrocortisone which has been designed specifically for children. Infacort<sup>®</sup> is presented as taste-masked granules (or sprinkle) and allows flexible low dosing to children in units of 0.5mg, 1mg, 2mg and 5mg of hydrocortisone.

This work is supported by the European Commission through its 7th Framework Programme (HEALTH-FP7; Project No: 281654) under the TAIN project. TAIN involves European partners who along with Diurnal are leaders in drug development, neonatology and pediatric pharmacology. The European Medicines Agency has already approved a Pediatric Investigation Plan (EMA-001283-PIP01-12) for Infacort<sup>®</sup>, which sets out the regulatory pathway to market authorization in Europe. Diurnal is in discussions with the US Food and Drug Administration (FDA) to establish the pathway for market approval for Infacort<sup>®</sup> in the USA.