Website address:
https://www.gesundheitsindustrie-bw.de/en/article/press-release/liver-cell-infusion-performed-for-first-time-in-the-united-states-on-child-with-life-threatening-dis

Healthcare industry BW

Liver cell infusion performed for first time in the United States on child with life-threatening disorder

The liver cell infusion developed by the Weinheim-based biotechnology company Cytonet GmbH & Co. KG has been granted orphan drug status in the USA. The first American child suffering from urea cycle disorder (UCD) was treated with Cytonet's liver cell infusion in a clinical trial that began in autumn 2010.

On 14th February 2011, Cytonet received an orphan drug designation from the American Food and Drug Administration (FDA) enabling it to use its liver cell infusion (human heterologous liver cells; HHLivC) for the treatment of children with urea cycle disorders. Cytonet is currently carrying out the SELICA (Safety and Efficacy of Liver Cell Application) clinical trial programme in the USA and Germany. The Phase II clinical trials are designed to evaluate the safety and efficacy of liver cell therapy in children with innate and life-threatening urea cycle disorders.

Based on interim results gained in an ongoing clinical trial into newborns with urea cycle disorders in Germany, Cytonet received the approval from the FDA in 2010 to carry out the clinical trial SELICA III in the USA. As part of this trial, the first American child has been treated with Cytonet's liver cell infusion without displaying complications. Cytonet's liver cell therapy now holds orphan drug status in Germany and the USA, which makes it easier for the company to gain marketing approval in these states.

Press release

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