

GSK's Nucala is the first biologic approved in the US for eosinophilic asthma

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Nucala is the first biologic approved in the US for six to 11-year-old children with severe eosinophilic asthma



GlaxoSmithKline has announced that the US Food and Drug Administration (FDA) has approved Nucala (mepolizumab) for use in children as young as six years old who are living with severe eosinophilic asthma. Nucala is the only targeted biologic to be approved for the condition in the six to 11-year age group in the US.

Dr Hal Barron, Chief Scientific Officer and President, R&D, GSK, said: "Children with severe eosinophilic asthma currently have limited treatment choices available to them. We believe this important new indication for Nucala is a significant development for these children and their families."

Tonya Winders, CEO and President, Allergy and Asthma Network, noted: "As a mother of children who suffer from asthma, I know first-hand the huge impact it has on a family, from the constant worry about your child being hospitalised, to practical issues like arranging time off work to care for them. Having Nucala approved as the first biologic for treating severe eosinophilic asthma in this young age group represents a significant step forward for the asthma community."

The FDA approval is supported by an open-label study, conducted in children aged six to 11 years and suffering from severe eosinophilic asthma, that investigated Nucala's pharmacokinetics, pharmacodynamics and long-term safety. Evidence from adequate and well-controlled trials in adults and adolescents also supported approval in this age group. The 52-week long-term phase of the study showed that the safety profile in paediatric patients aged six to 11 years was similar to the known safety profile in patients aged 12 years and older.

Dr Daniel Jackson, MD, Department of Pediatrics, University of Wisconsin, added: "Severe eosinophilic asthma in children is a complicated condition that can be extremely challenging to treat. Nucala has made a difference for many adults and adolescents living with severe asthma. This approval is an important development, giving physicians like me a much-needed option to consider for our paediatric patients."

Nucala (100mg dose subcutaneous injection) was first approved in 2015 as an add-on maintenance treatment for patients with severe eosinophilic asthma aged 12 years and older. This approval (40mg dose subcutaneous injection) extends the

current indication in the US for Nucala to patients aged six to 11 years.

Nucala has been approved for use as an add-on treatment for severe eosinophilic asthma in patients aged six years and older in the EU since August 2018.