European Commission approves the only immunotherapy for high-risk neuroblastoma, bringing hope to thousands of children affected by a rare and devastating form of cancer

HEMEL HEMPSTEAD, England – 9th May 2017 EUSA Pharma today announced that the European Commission (EC) has approved the antibody ch14.18/CHO, dinutuximab beta, for the treatment of high-risk neuroblastoma in patients aged 12 months and above.[1] Today's announcement makes dinutixumab beta the only approved immunotherapy in Europe for high risk neuroblastoma and an important tool in the fight against the condition.

Neuroblastoma, is the second most common solid tumour in childhood, following brain tumours[2], and predominantly affects children under five years old[3]. Every year in Europe, around 1,200 children are diagnosed with neuroblastoma[4], a rare cancer arising from neural crest cells, which are involved in the foetal development of the nervous system and other tissues.[2] Because neuroblastoma can spread very quickly, almost half of children are initially diagnosed at an advanced stage of their disease and are recognised as 'high-risk' and with a poor prognosis. Approval of dinutuximab beta brings new hope to these 'high-risk' children who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and stem cell transplantation, as well as those with history of relapsed or refractory neuroblastoma, with or without residual disease.[1]

"Today's announcement is a leap forward for the children and families affected by neuroblastoma, particularly those who have keenly followed the positive clinical trial results for dinutixumab beta and long anticipated its approval in Europe," commented Dr Juliet Gray, Associate Professor and Consultant in Paediatric Oncology at University of Southampton, UK. "As a clinician working in a highly specialised disease area with limited treatment options, I greatly welcome the availability of this targeted immunotherapy treatment that offers improved results for high-risk neuroblastoma patients used alone or in combination with existing therapies."

"Steve Richards, CEO of the neuroblastoma charity Solving Kids' Cancer Europe, added: "In the absence of any other targeted immunotherapy for children with high-risk neuroblastoma, the European regulatory body that approves medicines to be marketed in Europe, expedited the review of dinutuximab beta. Today's approval means that EUSA Pharma who manufactures dinutuximab beta is able to make it available for use by hospitals across Europe, improving access for thousands of children and their families to this new treatment, with proven improved survival rates. The next challenge will be for EUSA Pharma to engage with relevant access bodies throughout Europe, including NICE in the UK, to ensure timely review through the new drugs processes and secure access to this medicine for patients. The young innocent victims of this cruel and devastating disease deserve nothing less."

Lee Morley, CEO of EUSA Pharma, commented, "We are delighted that the EC has recognised the urgent need to accelerate approval of dinutuximab beta in order to provide an effective and targeted treatment for this debilitating disease. EUSA Pharma in partnership with Apeiron and SIOPEN has believed strongly in the potential of this treatment throughout the clinical trial process and today's announcement is final acknowledgement of its value to address the serious unmet need of children and their families affected by high-risk neuroblastoma."

Date of preparation: May 2017
NP/GLB/DNB/2017.01.01

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NOTES TO EDITORS

About dinutuximab beta

Dinutuximab beta is a monoclonal chimeric antibody developed to target a specific antigen, GD2, on neuroblastoma cells. It has been investigated in clinical trials for high-risk neuroblastoma, with more than 1000 patients having received treatment to date. Dinutuximab beta has orphan drug designation in the US and EU, and EUSA plans to file the product for approval in the United States in 2017.

About EUSA Pharma

Founded in March 2015, EUSA Pharma is a specialty pharmaceutical company with commercial operations across Europe and the USA, and a wider distribution network in approximately 40 further countries. The management team comprises highly experienced pharmaceutical professionals with a broad experience and proven track record of successfully identifying, developing and commercializing innovative medicines that advance patient care and improve their wellbeing. For more information visit: http://www.eusapharma.com.

Further information

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