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Hitachi starts commercial manufacturing of Zynteglo

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apceth Biopharma GmbH, a subsidiary of Japan headquartered Hitachi Chemical Co., Ltd. and a leading company for the manufacturing of cell and gene therapeutics, starts the commercial manufacturing of Zynteglo™Ã¢â??Ã¼, a product of bluebird bio, Inc.

bluebird bio has announced the market entry of its gene therapy Zynteglo in Germany, the first country globally where Zynteglo is commercially available.

Zynteglo is conditionally approved in the EU as a gene therapy for patients 12 years and older with transfusion-dependent?-thalassemia (TDT) who do not have a $?^0/?^0$ genotype, for whom hematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen (HLA)-matched related HSC donor is not available.

“Manufacturing this life-changing therapy for TDT patients in Europe marks a milestone for our company and the global Regenerative Medicine Business Sector at Hitachi Chemical Co., Ltd.”, commented Dr Christine Guenther, CEO of apceth Biopharma GmbH. “I am very proud of the teams of apceth and bluebird bio working together to make this happen. Our trustful partnership and persistent efforts over many years have made this vision come true for the patients.”

“We appreciate the team at apceth for all of their hard work and commitment to patients living with TDT,“ said Nick Leschly, chief bluebird. “This is a critical step along our journey as we advance our launch and access activities in Europe. We look forward to continuing our work with our partners, the TDT community and health systems to bring Zynteglo to patients.”