Munich, Germany, June 4, 2019 - apceth Biopharma GmbH, a leading company for the manufacturing of cell and gene therapeutics, will operate as the commercial manufacturer in Europe for Zynteglo™, a product of bluebird bio. Yesterday the European Commission (EC) has granted conditional marketing authorisation for Zynteglo™, a gene therapy for patients 12 years and older with transfusion-dependent β-thalassemia (TDT) who do not have a β°/β° genotype, for whom haematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen (HLA)-matched related HSC donor is not available.

“We are proud to be the commercial manufacturing partner of bluebird bio and to be part of bringing this life-changing therapy to TDT patients in Europe”, commented Dr Christine Guenther, CEO of apceth Biopharma. “Being one of the very few companies worldwide to manufacture a cell-based gene therapy for commercial use marks a milestone for our company.”

“We are looking forward to continue supporting bluebird bio with its other programs”, announced Dr Guenther. apceth Biopharma is bluebird bio’s clinical and commercial manufacturing partner for Europe not only for Zynteglo™, but also for bluebird bio’s product candidate Lenti-D for cerebral adrenoleukodystrophy. Following a successful long-term manufacturing relationship, apceth Biopharma and bluebird bio entered a commercial drug product manufacturing agreement in 2016.

About apceth Biopharma GmbH
apceth Biopharma, a subsidiary of Hitachi Chemical Co., Ltd. is a pioneering company in regenerative medicines and a leading and certified Contract Development and Manufacturing Organization for cell and gene therapeutics with a broad international customer base. apceth owns state-of-the-art manufacturing facilities with Grade B/A, C and D cleanrooms (ISO 5, ISO 7, ISO 8, BSL2) and is certified according to regulatory requirements for cell and gene therapies (Advanced Therapy Medicinal Products, ATMPs). The company has a comprehensive expertise in GMP manufacturing of autologous and allogeneic cell types that are either native or genetically modified. It has long-standing experience with various cell products, including mesenchymal stem cells (MSCs), hematopoietic stem cells (HSC), lymphocytes, monocytes, dendritic cells, cord blood derived stem cells, and has the potential to expand to CAR-T and
induced pluripotent stem cell (iPSC) technologies. apceth has successfully obtained manufacturing licenses for multiple cell therapy products for clinical as well as commercial use. apceth’s CDMO team provides fully customized solutions in the development and production of every customer product and process. Located centrally in the heart of Europe, apceth can perform efficient and fast supply for patients all over the continent. For more information on apceth, please visit www.apceth.com

About Hitachi Chemical Co., Ltd.
Hitachi Chemical Co., Ltd. (TSE : 4217), headquartered in Tokyo, Japan, delivers wide range of innovative products, such as electronic materials, automobile parts, energy storage devices and systems, in global markets. The company’s consolidated revenues for fiscal 2017 (ended March 31, 2018) totaled 669 billion yen (5.4 billion euros*). For more information on Hitachi Chemical, please visit the company’s website at http://www.hitachi-chem.co.jp/english/ *The conversion rate is 1 euro = 124 yen.

About the Hitachi Chemical Regenerative Medicine Business Sector
The Hitachi Chemical’s Regenerative Medicine Business Sector provides contract development and manufacturing organization (CDMO) services at current Good Manufacturing Practices (cGMP) standards, including clinical manufacturing, commercial manufacturing, and manufacturing development. The global footprint of the business is over 180,000 square feet and includes operations in North America (Allendale, New Jersey and Mountain View, California), Europe (Munich, Germany), and Japan (Yokohama). The business leverages two decades of experience exclusively focused on the cell therapy industry.

Contact
For more information on North America services, please visit www.pctcelltherapy.com.
For more information on Europe services, please visit www.apceth.com.
For more information on Japan services, please visit www.hitachi-chem.co.jp/english/

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