PRESS RELEASE

CEVEC and CellGenix announce the launch of GMP-grade TGF-ß1 for cell and gene therapy applications

- **CEVEC's CAP®Go technology enables CellGenix to offer rh TGF-ß1 in preclinical and now also in GMP-grade quality, allowing a seamless transition from preclinical to clinical development and commercial manufacturing of cell therapy products**
- **With the introduction of GMP rh TGF-ß1, CellGenix further expands one of the broadest portfolios of GMP cytokines and growth factors for the cell and gene therapy industry**
- **CEVEC's CAP®Go technology allows access to GMP-grade cytokines such as TGF-ß1 requiring human post-translational modifications which are not possible by using bacterial expression systems**
- **Successful launch further proves the robustness and efficiency of CEVEC's CAP®Go technology for the production of complex glycoproteins**

Cologne, Germany, December 19, 2019

CEVEC Pharmaceuticals GmbH (CEVEC), the expert in tailor-made recombinant glycoproteins and gene therapy vectors, today announced that the Company's cooperation partner CellGenix GmbH, a leading global supplier of GMP raw materials for cell and gene therapy and regenerative medicine, has launched CellGenix® GMP rh TGF-ß1 for cell and gene therapy applications based on CEVEC's proprietary CAP®Go technology.

CellGenix® GMP rh TGF-ß1 is the third product resulting from an ongoing cooperation between CEVEC and CellGenix, which was established for the development and GMP production of selected cytokines using CEVEC's proprietary expression technology CAP®Go. Other products include CellGenix® rh HGF and CellGenix® preclinical rh TGF-ß1. With the availability of TGF-ß1 in both, preclinical and GMP grade, CellGenix' portfolio of growth factors now covers the entire value chain allowing a seamless transition from preclinical to clinical development and commercial manufacturing of cell therapy products.

"We are very happy to see our successful cooperation with CellGenix resulting in the next product derived from our CAP®Go expression platform," said Dr. Nicole Faust, CEO & CSO of CEVEC. "With more and more advanced therapy medicinal products (ATMPs) in late stage clinical development, we are experiencing an increasing demand for GMP-grade raw materials. We are convinced that our CAP®Go expression platform based on thoroughly documented suspension CAP cell lines is the technology of choice for manufacturing these important reagents."

"We are very pleased with the successful and supportive cooperation with CEVEC. CellGenix® GMP rh TGF-ß1 is the first GMP protein produced by CellGenix using CEVEC's CAP®Go expression system," commented Felicia Rosenthal, Chief Executive Officer of CellGenix. "CEVEC's CAP®Go technology offers us an extensively characterized and animal-derived component-free expression platform that is safe and meets global regulatory standards. The collaboration with CEVEC allows us to further expand and strengthen CellGenix cytokines and growth factors product portfolio and thereby our position as raw material supplier for the cell and gene therapy space."

TGF-ß1 – A highly potent advanced therapies medical product in cell-based treatments

Transforming growth factor-ß1 (TGF-ß1) is a cytokine that promotes the growth of induced pluripotent stem cells, embryonic stem cells as well as mesenchymal stem cells used in cell therapy applications. In addition, TGF-ß1 plays an important role in the differentiation of T cells into regulatory T cells (Tregs) and the expansion of these cells. Tregs are a specialized subpopulation of T cells that act to suppress immune responses, thereby maintaining homeostasis and self-tolerance. It has been shown that Tregs are able to inhibit T cell proliferation and cytokine production and therewith could play a critical role in the treatment of inflammatory diseases including autoimmune diseases.

CEVEC's CAP®Go expression platform allows for the efficient recombinant GMP manufacturing of glycoproteins with authentic human post-translational modifications

The proper glycosylation of proteins such as TGF-ß1 is crucial for the functionality and efficacy of these molecules and can significantly improve physicochemical and pharmacological properties. Glycosylation capabilities are therefore a decisive factor when it comes to choosing the optimal cell lines for the production of these highly complex and difficult to express proteins. CEVEC's CAP®Go expression platform comprises a comprehensive portfolio of glyco-optimized human suspension cell lines that differ in their glycosylation capabilities and allow for the scalable recombinant manufacturing of a variety of ATMPs used for cell-based treatments.

The development history of CAP®Go cell lines is fully known and thoroughly documented to provide full traceability. The CAP cells are grown in serum-free and animal component-free (ACF) medium which makes them a suitable cell substrate for GMP cell and gene therapy raw materials. CEVEC's GMP-manufactured CAP® Master Cell Bank has been tested according to ICH Guidelines and WHO Recommendations for cell substrates. In addition, a Biologics Master File for CAP Technology (BB-MF) has been submitted to U.S. FDA and is referenceable for CAP® Technology Licensees, simplifying regulatory approval process for a CAP®-derived product.

About CEVEC:
CEVEC is a center of expertise for the production of biopharmaceuticals using a unique human cell-based expression system.

CAP®Go enables the **production of high-end biologics**. Complex, glycosylated proteins represent a significant portion of the human proteome and are notoriously difficult to express in conventional cell lines such as CHO. The CAP®Go expression platform comprises a portfolio of glyco-optimized human suspension cell lines for the highly efficient production of a broad range of difficult to express recombinant proteins with authentic human or designed post-translational modifications, including plasma proteins, blood coagulation factors and complex cytokines and growth factors.

CAP®GT is a fully scalable manufacturing platform for **viral vector production.** CEVEC has successfully developed CAP®GT suspension cell-derived viral packaging cell lines, including a stable, helper virus-free AAV production platform, which enable better scale-up and competitive production costs when compared to adherent cell culture systems. CAP®GT suspension cell lines grow to high cell densities and show excellent productivity for a broad range of viruses. Gene therapy vectors such as lentiviral, adenoviral, and adeno-associated viral (AAV) vectors can be produced at industrial scale.

For more information, please visit **www.cevec.com**
Follow CEVEC on **LinkedIn** and on **Twitter**

About CellGenix:
CellGenix is a leading manufacturer and developer of premium-grade reagents for clinical cell culture needs. The company has more than two decades of in-house expertise in GMP manufacturing and development of products in the field of cell and gene therapy and regenerative medicine. The superior quality GMP raw materials are used by leading experts and are proven in clinical trials and commercial manufacturing throughout the world. CellGenix is headquartered in Freiburg, Germany and operates a subsidiary in Portsmouth, New Hampshire, USA, serving the North American market.

For more information, please visit **www.cellgenix.com**.
Follow CellGenix on **LinkedIn**.

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