Press Release

Sartorius Stedim Biotech Introduces BIOSTAT® RM TX with Flexsafe® RM TX for Producing Consistent Quality Cellular Products

- **New rocking motion single-use bioreactor system to culture cell products in working volumes up to 5 L**
- **Flexsafe® RM TX bags enable reliable process performance for optimal cell growth**
- **Premiers at Phacilitate Leaders World 2019 in Miami**

Goettingen / Germany – 21 January 2019: Sartorius Stedim Biotech (SSB), a leading international supplier for the biopharmaceutical industry today announced the launch of the BIOSTAT® RM TX single-use bioreactor, a new wave mixed system developed specifically for closed, automated expansion of consistent quality cell products such as ex vivo cellular immunotherapies. This new GMP platform, which combines SSB's established single-use Flexsafe® bag technology with the company's expertise in biopharmaceutical automation, will be introduced at **Phacilitate Leaders World 2019** in Miami, USA (January 22-25 / Booth 410).

SSB's new bioreactor is designed for scale-out expansion of cells including patient-specific T cells and is a closed system, consisting of an automated control unit and a up to two rocking platforms to gently agitate single-use Flexsafe® RM TX bags (up to 5L working volume). The bag is the core of the system and built on SSB's Flexsafe® film, which is already well-established from clinical development to GMP manufacturing of vaccines and biologics by major global biopharma companies. The film formulation is developed to minimize leachables and extractables, guaranteeing consistent batch-to-batch culture performance of even sensitive cell types, such as genetically modified T cells.

The proprietary Flexsafe® RM TX bag is designed with a special port for hands-free gravity harvesting. In combination with the innovative Flexsafe® RM TX Harvest Device it reduces the contamination risks from manual handling, maintaining cell integrity and cell viability. Unlike other cell therapy expansion systems which use pumps for cell recovery, this unique gravity harvest concept reduces the risk of shear stress on these delicate cells, to maximize cell number recovery.

A benefit of using the BIOSTAT® RM TX bioreactor in combination with the Flexsafe® RM TX bag for cell culture is the possibility for walk-away monitoring and culture control. The bags include single-use sensors for pH, DO and viable biomass. These sensors are integrated in the BIOSTAT® B control unit, and the system's sophisticated software is set-up for fully automated process

control of gases, flow rate, filling volume and substrate addition. With culture volumes greater than 500 mL, on-line analysis of viable biomass is also possible by connecting the single-use BioPAT® ViaMass sensor. These sensors make the system suitable for running continuously in fed-batch or perfusion modes, saving labor, time and effort with manual sampling and also minimizing contamination risks to precious patient cells.

Utilizing this bioreactor system, manufacturers can attach a second rocking platform and Flexsafe® RM TX bag to each BIOSTAT® B control unit to scale-out their production. The system also provides a standard interface to common Supervisory Control and Data Acquisition as well as Distributed Control Systems such as BioPAT® MFCS and DeltaV™.

"Combining single-use technology with advanced automation for the expansion of cell products ensures control of process variability and enables safe, robust and affordable cell production," explained Dr. Franziska Faulstich, Global Product Manager Regenerative Medicine and RM Bioreactors at Sartorius Stedim Biotech. "Working extensively with leaders in the cellular immunotherapy field, we have identified the right technologies and best practice workflows, which we have incorporated into our new BIOSTAT® RM TX bioreactor," she added.

Cell product developers visiting **Booth 410** at **Phacilitate World Leaders 2019** will discover how using this cleverly designed system can help improve their process performance, and as a result the integrity and consistency of their promising cell therapies in development.

BIOSTAT® RM TX and Flexsafe® RM TX bags are for research and further manufacturing use only – not for use in therapeutic or diagnostic procedures. They are not CE marked for in vitro diagnostic use nor are they medical devices. Drug manufacturers and clinicians are responsible for obtaining the appropriate IND | BLA | NDA approvals for clinical applications.

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Image Files:

Photo 1 (shown above): BIOSTAT ® RM TX automated twin system for culturing of consistent quality cells.
Download: Single use bioreactor BIOSTAT RM TX

Photo 2: Flexsafe® RM 2L TX bag with single-use BioPAT® ViaMass, Sartopore® Air vent filters and patented perfusion filter.
Download: Flexsafe RM 2L TX single-use bag

Photo 3: Flexsafe® RM TX Harvest Device for hands-free gravity harvest of the cell culture with maximum recovery.
Download: Flexsafe RM TX Harvest Device

A profile of Sartorius Stedim Biotech

Sartorius Stedim Biotech is a leading international supplier of products and services that enable the biopharmaceutical industry to develop and manufacture drugs safely and efficiently. As a total solutions provider, Sartorius Stedim Biotech offers a portfolio covering nearly all steps of biopharmaceutical manufacture. The company focuses on single-use technologies and value-added services to meet the rapidly changing technology requirements of the industry it serves. Headquartered in Aubagne, France, Sartorius Stedim Biotech is quoted on the Eurolist of Euronext Paris. With its own manufacturing and R&D sites in Europe, North America and Asia and a global network of sales companies, Sartorius Stedim Biotech has a global reach. In 2017, the company employed approx. 5,100 people, and earned sales revenue of 1,081 million euros.

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