

PRESS RELEASE

Number 13

Wacker Biotech and Fresenius Medical Care Successfully Produce Antibody Fragment with FOLDTEC®

Munich / Jena, March 8, 2017 – Wacker Biotech and Fresenius Medical Care Adsorber Tec, a subsidiary of the globally active healthcare Group Fresenius, have reached an important milestone in their collaboration aimed at producing a scFv-class antibody. Using its *E. coli*-based FOLDTEC® technology, WACKER completely overhauled a process employed by Fresenius Medical Care to facilitate production on an industrial scale. WACKER's proprietary refolding technology was able to produce the desired recombinant product in enhanced yields and higher purity than was hitherto possible while slashing buffer volumes. Moreover, the new process has already been transferred into a GMP-compliant industrial-scale production. The manufactured antibody fragment is used in apheresis products for selective dialysis.

In its search for an efficient process capable of industrial-scale production of its antibody fragment for an apheresis application, Fresenius Medical Care turned to WACKER for assistance. WACKER was tasked with developing a stable process which would employ microbial systems to produce the therapeutic candidate and which could be scaled up from the laboratory to the industrial level.

WACKER subsequently completely overhauled Fresenius Medical Care's existing process and deployed its own proprietary FOLDTEC® refolding technology. With this technology, microbially produced pharmaceutical

proteins, which form inclusion bodies during production, can be manufactured cost-effectively and reliably in high yields and extremely high purity. The patented process utilizes specifically developed and optimized *E.coli* bacterial strains and a patented, antibiotic-free expression system. The FOLDTEC® toolkit gives Wacker Biotech extensive expertise in the targeted screening of optimum refolding conditions needed for converting the insoluble target-protein aggregates into a biologically active form.

Not only did the results confirm that the FOLDTEC® technology is suitable for the production of the single-chain variable fragment (scFv) from Fresenius Medical Care. The new process was also found to slash buffer volumes while enhancing yields and boosting purity. Since then, WACKER has already succeeded in rendering the industrial-scale production process GMP-compliant. The upscaled, efficient process is essential for ensuring security of supply for Fresenius Medical Care and ultimately ensuring that the apheresis product is available in sufficient quantities for patients.

“We are delighted with the successful collaboration with Fresenius Medical Care,” said Dr. Thomas Maier, managing director of Wacker Biotech GmbH. “Having successfully established our ESETEC® technology for Fab fragments, FOLDTEC® demonstrates what we can now do for scFv fragments – and underscores our leading position in the efficient production of antibody fragments. Our customers really appreciate our unique technological solutions for these new product classes because it means they can provide their patients with better products faster,” emphasized Maier.

“In WACKER we have found a highly competent partner for ensuring that we have a secure supply of raw materials for our industrial scale production,” said Dr. Wolfram Strobl, General Manager of Fresenius Medical Care Adsorber Tec GmbH.

About Wacker Biotech: The Microbial CMO

Wacker Biotech GmbH is a full-service contract manufacturer of biopharmaceutical products based on microbial systems. The company's services range from molecular biology, analytical services and process development through to the GMP-compliant manufacture of clinical test samples and pharmaceutical actives for the commercial market at the GMP-compliant production plants in Jena and Halle, Germany. Above all, Wacker Biotech offers proprietary technologies that satisfy market needs for cost-efficient production and maximum quality. Based in Jena and Halle, Wacker Biotech is a wholly-owned WACKER subsidiary.

For further details, visit the following website:

<http://www.wacker.com/biologics>

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The company in brief:

WACKER is a globally-active chemical company with some 17,000 employees and annual sales of around €5.3 billion (2015). WACKER has a global network of 25 production sites, 22 technical competence centers and 50 sales offices.

WACKER SILICONES

Silicone fluids, emulsions, rubber and resins; silanes; pyrogenic silicas; thermoplastic silicone elastomers

WACKER POLYMERS

Polyvinyl acetates and vinyl acetate copolymers in the form of dispersible polymer powders, dispersions, solid resins and solutions

WACKER BIOSOLUTIONS

Biotech products such as cyclodextrins, cysteine and biologics, as well as fine chemicals and PVAc solid resins

WACKER POLYSILICON

Polysilicon for the semiconductor and photovoltaic industries

Siltronic

Hyperpure silicon wafers and monocrystals for semiconductor components