

PRESS RELEASE

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WACKER's New Process-Development Unit Focusses on ESETEC[®] and Supplies First Customers with Double-Digit Gram Quantities of Biologics for Preclinical Development

Munich/Jena, March 13, 2009 – As part of its ongoing investment in biotech, WACKER recently opened a new process-development building for the production of pharmaceutical proteins, or biologics, in Jena (Germany). The new unit has already started shipping to customers. WACKER is thereby optimizing the entire process-development chain, from gene to purified protein. The new unit can now ship double-digit gram quantities of highly pure proteins for pre-clinical development, prior to scale-up in the GMP plant. The infrastructure of the new building has been specifically designed to cater for the sophisticated process and analytics development necessitated by modern biologics based on microbial systems. The extension is WACKER's response to fast-growing demand for ESETEC[®], its *E. coli* secretion technology. This proprietary technology can be used to simplify and streamline production of a successful new class of biotherapeutics called antibody fragments in high yield.

WACKER is substantially boosting production capacity at its Jena site in order to cope with a growing need for high-efficiency biologics production and to meet rising customer demand. Covering some 1.700 m², the recently completed building is dedicated to process development and protein analysis along the entire process chain, from gene

to highly pure protein. The equipment used for fermentation (capacities up to 30 liters), primary processing (centrifugation, filtration, homogenization), downstream processing and protein modification (e.g. PEGylation) is designed to allow the processes to be upscaled to WACKER's GMP production. The latest principles of quality-by-design (QbD) are observed throughout process development, and necessitate detailed prior knowledge of products and processes.

Aside from the actual process laboratories, the new unit boasts modern analytical laboratories for safeguarding the development of methods of process and product characterization right through to GMP analysis. As a result, Wacker Biotech GmbH will fully and optimally satisfy approval agencies' standards for ever stricter analytical characterization of products and processes. The full range of analytical tools is available: from biochemical assays to chromatography, electrophoresis, photometry, protein sequencing, and spectroscopy, through to trace analysis of impurities (DNA, HCP, endotoxins). Customers thus take delivery of a full process and analysis package provided by a single source.

Traditional production methods aside, one focus of the new unit is on ESETEC® and DENSETEC®, which are proprietary WACKER technologies that make for simpler, more cost-efficient, high-yield production of biologics for the pharmaceuticals industry. ESETEC® is based on a patented *E.coli* K12 strain, which is employed during fermentation to secrete recombinant proteins into the culture broth in native conformation. Such extra-cellular production facilitates cleanup of recombinant products and eliminates the complicated backfolding stage. The net effect is to render production much more efficient and more cost-effective.

The ability to combine ESETEC[®] secretion technology with DENSETEC[®], a special high-cell-density process for fermenting *E.coli*, gives Wacker Biotech the capacity to produce active biologics both efficiently and in optimized space-time yields. These robust, validatable fermentation processes afford products in high, reproducible yields.

A second extension at the Jena site will double the production area in the existing GMP plant and include a brand new downstream processing facility. It will satisfy the US Food and Drug Administration's GMP requirements, as well as those of the European Medicines Agency. This extension will likely come on full stream in early 2010.

About Wacker Biotech

Wacker Biotech GmbH is a full-service contract manufacturer of biopharmaceutical products based on microbial systems. Its service portfolio ranges from molecular biology and process development, through GMP-compliant production of clinical test samples and active ingredients, to commercial market supply and comprehensive analytical services. Above all, Wacker Biotech offers proprietary technologies that satisfy market needs for cost-efficient production and very high quality. Jena-based Wacker Biotech is a wholly-owned WACKER subsidiary.

For further details, visit the following websites:

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

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The company in brief:

WACKER is a globally active chemical company with some 15,000 employees and annual sales of around €3.78 billion (2007).
WACKER has 27 production sites and over 100 sales offices worldwide.

WACKER SILICONES

Silicone fluids, emulsions, rubber and resins; silanes; pyrogenic silicas; thermo-plastic silicone elastomers

WACKER POLYMERS

Polyvinyl acetate and vinyl acetate copolymers in the form of dispersible polymer powders, dispersions and solid resins used as binders for construction chemicals, coatings, adhesives, paints, plasters and nonwovens

WACKER FINE CHEMICALS

Fine chemicals, biologics and other biotech products, such as cyclodextrins and cysteine

WACKER POLYSILICON

Polysilicon for the semiconductor and photovoltaics industries; solar wafers

Siltronic

Hyperpure silicon wafers and monocrystals for semiconductor devices