

PRESS RELEASE

Number 01

WACKER Obtains FDA Approval to Manufacture the Drug Substance in Retavase[®], a Thrombolysis Medication by Chiesi

Munich and Halle, January 9, 2018 – Wacker Biotech GmbH will produce the drug substance reteplase, the active ingredient in the drug Retavase[®], which the pharmaceutical company Chiesi will market in the USA. The product recently obtained approval from the US Food and Drug Administration (FDA). The medication is used to treat acute myocardial infarction in adults. Wacker Biotech has successfully transferred and implemented the entire manufacturing process for reteplase to its GMP plant in Halle/Saale (Germany). It already obtained approval from the European Medicines Agency (EMA) in 2012.

In agreement with the original manufacturer of the medication – Swiss pharmaceutical company Roche – Wacker Biotech successfully transferred the production process of the drug substance reteplase to its Halle/Saale plant. Italy-based pharmaceutical firm Chiesi has acquired the marketing rights for the drug for the USA, among other countries, and worked on obtaining the new approval in close cooperation with WACKER. Not only did WACKER successfully transfer the entire manufacturing process for the complex biopharmaceutical to its facility, it also covered the validation of the analytical methods for process control and release testing of the drug substance. In close cooperation with customer Chiesi, WACKER established the supply of this high-quality drug substance for Chiesi's relaunch of Retavase[®] in the US market.

Wacker Biotech obtained approval for the commercial manufacture of the active ingredient for the US market a mere three months after the FDA inspection of the plant in Halle. The reliable process in a modern facility now provides an efficient, secure supply of medication for patients.

The drug Retavase® used to treat acute ST-elevation myocardial infarction (STEMI). Acute STEMI, also known as acute heart attack, is one of the main causes of death and illness worldwide and, in most cases, stems from a blood clot in a coronary artery. This sustained circulatory disorder prevents oxygen and nutrients from getting to the heart and thus results in tissue dying off and long-term damage to the heart muscle. When administered to acute STEMI patients, the enzyme reteplase – a tissue plasminogen activator with twelve disulfide bridges that is folded in a complex manner – causes these blood clots to dissolve.

“We are very pleased with the FDA approval of Chiesi’s product Retavase® for the US market. This allows us, as a contract manufacturer, to contribute to the treatment of serious illnesses such as a heart attack,” said Dr. Susanne Leonhartsberger, managing director of Wacker Biotech. “I am very proud of the entire WACKER team that spent years establishing and implementing the required production process at our plant and has now achieved FDA approval for manufacturing, too. This confirms that our plants and processes are fully compliant with the most stringent of requirements. All of our customers can profit from this extensive expertise and know-how – from generating the cell line, to the transfer and optimization of existing manufacturing processes, to commercial market supply.”

“This approval represents a significant milestone in Chiesi’s work to bring Retavase® back to the US market,” said Alan Roberts, Senior Vice President, Scientific Affairs for Chiesi USA, Inc. “WACKER is a proven

leader in microbial technology. The collaborative effort and partnership have been outstanding.”

About Wacker Biotech

Wacker Biotech GmbH is a full-service contract manufacturer of biopharmaceutical proteins 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, FDA and EMA-certified 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. Wacker Biotech is a wholly-owned WACKER subsidiary.

For further details, please visit the following website: www.wacker.com/biologics




About Chiesi USA, Inc.

Chiesi USA, Inc. is a specialty pharmaceutical company headquartered in Cary, N.C. Key elements of the company's strategy are to focus its commercial and development efforts in the hospital and adjacent specialty sector within the U.S. pharmaceutical marketplace; continue to seek opportunities to acquire companies, marketed or registration-stage products and late-stage development products that fit within the company's focus areas; and generate revenues by marketing approved generic products through the company's wholly-owned subsidiary, Aristos Pharmaceuticals, Inc. Chiesi USA, Inc. is a wholly-owned subsidiary of Chiesi Farmaceutici S.p.A. For more information, visit www.chiesiusa.com.

Retavase® is a registered trademark of EKR Therapeutics, Inc. For the full prescribing information, please visit

https://resources.chiesiusa.com/Retavase/RETAVASE_PI.pdf

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The company in brief:

WACKER is a globally active chemical company with some 13,450 employees and annual sales of around €4.6 billion (2016, excluding Siltronic). WACKER has a global network of 23 production sites, 19 technical competence centers and 49 sales offices.

WACKER SILICONES

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

WACKER POLYMERS

Polyvinyl acetate and vinyl acetate co- and terpolymers 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