

PRESS RELEASE

Joint press release by WACKER, XL-protein and LMU

Number 41

Bavarian Research Foundation supports the development of an immunosuppressive PASylated antibody fragment to support cardiac xenotransplantation

Munich, September 28, 2022 – A research consortium composed of XL-protein GmbH, Wacker Chemie AG and Ludwig-Maximilians-Universität München (LMU) will develop a novel long-acting immunosuppressive anti-CD40 antibody for the selective suppression of organ rejection, in particular in the area of cardiac xenotransplantation. The antibody fragment is expected to reduce toxic side effects that occur with current treatments. In the future, the antibody fragment is also expected to be used in the therapy of autoimmune diseases. The project will be partly funded by the Bavarian Research Foundation.

Markus Blume, Bavarian State Minister of Science, handed over the funding agreement to the research consortium today: "This funding by the Bavarian Research Foundation is a perfect example of the truly impressive results that can be achieved in Bavaria as a center of innovation. The excellent collaboration between first-class university-based researchers and industry makes it possible to perform pioneering scientific work that is clearly focused on specific applications. The basic study conducted by LMU, XL-protein and WACKER on therapy following animal-to-human organ transplants could contribute to finding the answer to the shortage of human donor

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hearts. I congratulate all those involved on receiving their funding and wish them every success in their project,” said Bavarian State Minister Blume. Prof. Dr. Dr. h. c. Arndt Bode, President of the Bavarian Research Foundation added: “The Foundation is very proud of supporting this outstanding research cooperation between Bavarian industrial partners and academia on a subject extremely relevant to the further development of medical treatment.”

The project, headed by XL-protein, will develop a novel immunosuppressive anti-CD40 antibody fragment for the selective suppression of organ rejection with reduced side effects. “This antibody is particularly promising as an immunosuppressant in cardiac xenotransplantation. Although CD40 blockade is essential for heart xenotransplantation from transgenic pigs, no such clinically approved drug is currently available,” stated Prof. Dr. Eckhard Wolf, Professor of Molecular Animal Breeding and Biotechnology at the LMU. To avoid an undesired agonistic effect of the antibody, a monovalent and long-acting Fab fragment will be developed using XL-protein’s PASylation® technology. “XL-protein’s PASylation® technology offers a superior approach to both extend drug half-life and improve patient safety. We expect that this will lead to an innovative biologic with the potential to become a success story not only in cardiac xenotransplantation but potentially also in conventional organ transplantation or in the therapy of autoimmune diseases,” commented Uli Binder, Managing Director of XL-protein.

WACKER will contribute its expertise in the manufacturing of therapeutic proteins to the project. WACKER’s ESETEC® platform technology is used to produce the antibody fragment and evaluate the manufacturing process. The ESETEC® technology enables controlled

secretion of the correctly folded proteins into the culture broth during fermentation. "We are pleased to use our know-how in the field of protein production to contribute to the development of an innovative biologic that is expected to increase the chances of success in organ transplantation and creates new ways of therapy of autoimmune diseases. By continually enhancing our innovative ESETEC[®] technology, we are able to produce complex proteins in high quality and with high yields. ESETEC[®] thus helps to reduce the manufacturing costs of novel drugs," said Dr. Christian Hartel, President & CEO of WACKER.

About PASylation[®] Technology

'PASylation' involves the genetic fusion or chemical conjugation of a therapeutic protein or pharmaceutically active compound with a conformationally disordered polypeptide of defined length and sequence comprising the small natural amino acids Pro, Ala, and/or Ser. Due to the biophysical size effect, the typically rapid clearance of the original drug can be retarded by a factor of 10-100, depending on the length of the PAS chain. PAS sequences are highly soluble while lacking charges, they are biochemically inert, non-toxic and non-immunogenic, they offer efficient recombinant protein production in a variety of biotechnological host organisms, and they show high stability in blood plasma but are biodegradable by intracellular proteases.

About ESETEC[®] Technology

ESETEC[®] is a proprietary WACKER technology with a track record of cost-effective production of proteins and antibody fragments. The expression technology is based on modified E. coli strains, which are designed to secrete the desired pharmaceutical proteins into the

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culture broth in the correctly folded conformation during fermentation. This process can be aided by additional overexpression of proprietary folding helpers. Thus, with ESETEC®, even complex molecules can be produced in high yields and secreted into the culture medium in an active form.

About XL-protein

XL-protein (www.xl-protein.com) is a German biotech company commercializing its ground-breaking PASylation® technology, which enables the design of biopharmaceuticals with extended half-life – in the plasma or the eye – and enhanced action. Based on a strong proprietary technology position, XL-protein focuses on the preclinical as well as clinical development of PASylated proteins in diverse disease areas. XL-protein is engaged in a growing number of partnerships with international pharmaceutical and biotech companies at various levels.

About WACKER

Wacker Chemie AG (www.wacker.com) is a global company with state-of-the-art specialty chemical products found in countless everyday items, ranging from cosmetic powders to solar cells. WACKER's portfolio comprises more than 3,200 products supplied in over 100 countries. The business division WACKER BIOSOLUTIONS supplies customized biotech products such as cyclodextrins, cysteine, polyvinyl acetate solid resins, fine chemicals and biopharmaceuticals. WACKER has a global network of 27 production sites, 23 technical competence centers and 52 sales offices. In 2021, the Group's 14,400 employees generated global sales of €6.21 billion. Wacker Chemie AG is listed on the Deutsche Boerse Prime Standard and on the MDAX (ISIN: DE000WCH8881).

About Ludwig-Maximilians-Universität München

As one of Europe's leading research universities, LMU Munich is committed to the highest international standards of excellence in research and teaching. Building on its more than 500-year-tradition of scholarship, LMU covers a broad spectrum of disciplines, ranging from the humanities and cultural studies through law, economics and social studies to medicine and the sciences. 18 percent of LMU's 50,000 students come from abroad, originating from 130 countries worldwide. The know-how and creativity of LMU's academics form the foundation of the University's outstanding research record. This is also reflected in LMU's designation as a "university of excellence" in the context of the nationwide Excellence Strategy to promote top-level university research.

About Bavarian Research Foundation

The Bavarian Research Foundation was founded in 1990 by the Bavarian state government, in order to boost Bavaria as a site for quality high-tech through efficient and flexible promotion of application-based research. The Research Foundation concentrates on forward-looking projects, the realization of which challenges science and commerce conjointly while assuring close and successful collaboration. Up to now, the Bavarian Research Foundation has granted about €621 million to 1,018 research projects. Bavarian State Minister for Science and Art Markus Blume is a member of the Foundation Council.



Partners and supporters: Prof. Dr. Eckhard Wolf, Professor of Molecular Animal Breeding and Biotechnology at the LMU; Uli Binder, Managing Director of XL-protein; Prof. Dr. Dr. h. c. Arndt Bode, President of the Bavarian Research Foundation; Markus Blume, Bavarian State Minister of Science; and Dr. Christian Hartel, President & CEO of WACKER (from left to right), at the WACKER Consortium in Munich (Photo: WACKER).

Note:

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

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