

Press release

Novel recombinant human thrombin provided in innovative stabilized formulation

Scil Proteins and LEUKOCARE develop a stabilized recombinant human thrombin manufactured in bacteria. Partners offer new options for innovative medicinal applications and functionalized medical devices to third parties.

Halle, Germany, and Munich, Germany, 30 October 2013

Scil Proteins GmbH and LEUKOCARE AG, two German based life science companies, today announced results of their strategic partnership to develop a stabilized recombinant human thrombin (rhThrombin). The new, proprietary and highly cost-effective bacterial manufacturing process of rhThrombin is a recent in-house development of Scil Proteins. This recombinant production process does not rely on bovine or human blood derivatives and can be scaled up easily to meet market demands. Combining rhThrombin with a formulation of LEUKOCARE's proprietary Stabilizing and Protecting Solutions (SPS) technology results in increased stability during storage at elevated temperatures as well as during terminal sterilization by irradiation. This offers various opportunities for novel formulations and advanced functionalized medical devices.

Controlling bleeding in surgery and avoiding blood loss during surgical intervention can be managed in several ways. One being the topical application of thrombin as a haemostatic agent.¹ Currently there are three types of thrombin available for use in humans: bovine thrombin, human purified thrombin and only one rhThrombin which is produced in chinese hamster ovary cells. However, bovine thrombin holds the risk of anti-thrombin antibody production in patients. A main concern regarding the use of human purified thrombin is the risk of infectious agents like viruses and limited stability.

Recombinant products are usually free of infectious agents and impurities. Clinical studies with other available rhThrombin demonstrated comparable efficacy but significantly lower immunogenicity. The substrate was safely applied in haemorrhage control in patients with or without pre-existing anti-bovine thrombin antibodies.^{2,3} Hence, products with rhThrombin may offer improved safety in clinical use.

The novel stabilized rhThrombin developed by Scil Proteins and LEUKOCARE may be used in different medical applications and medical devices to control bleeding for example sponges, glues, sealants or advanced wound dressings. “We are able to provide access to high quality rhThrombin, free of blood derived components and with a fully scalable manufacturing process in bacteria” said Dr. Ulrike Fiedler, CEO of Scil Proteins. Michael Scholl, CEO of LEUKOCARE added “As rhThrombin protected by our SPS technology is stable during irradiation it offers the opportunity for end sterilization as common in the medical device industry and as requested by regulatory agencies.”

Scil Proteins and LEUKOCARE are currently evaluating partners in the pharmaceutical and the medical device industry for the clinical development and commercialisation of the stabilized rhThrombin.

Notes for editors:

About Scil Proteins

Scil Proteins is a biopharmaceutical company working with industry partners in the development and manufacture of protein therapeutics and diagnostics as well as discovering and developing proprietary Affilin[®] molecules. The Company has a longstanding expertise in protein production and development and offers GMP contract biomanufacturing and process development to biotech and pharma companies. With state of the art equipment and a particular expertise at refolding proteins, Scil Proteins has an excellent track record in supplying a top level support for its partners. Scil Proteins has supported a number of different companies in process development and biomanufacturing. Scil Proteins also has a discovery platform that is a fully patent protected screening technology for the identification of target-specific Affilin[®] molecules using advanced selection systems. Affilin[®] molecules are therapeutics and diagnostics based on a scaffold derived from the human protein Ubiquitin to form highly stable molecules with strong binding specificity and low immunogenicity. Scil Proteins is a well-established private company located in Halle, Germany.

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About LEUKOCARE

LEUKOCARE is a leading provider of technologies for stabilizing proteins to extend shelf-life and to enable terminal sterilization. Based on these technologies, LEUKOCARE can improve biopharmaceutical products and vaccines as well as functionalize a wide variety of surfaces including implant surfaces, wound dressings, stents, catheters and others.

LEUKOCARE developed and successfully brought to clinic a Leukocyte Inhibition Module (LIM) which applies antibodies coupled to the membrane of a filter device to inactivate Leukocytes, thus avoiding inflammation in patient undergoing heart surgery. This anti-inflammatory coating technology has been successfully out-licensed for the use in extracorporeal medical devices.

LEUKOCARE leverages its comprehensive expertise in product-focused industrial partnerships. The company offers its know-how in biofunctional coatings, formulation of biologics and product development to interested parties ranging from service-based collaborations to co-development partnerships. LEUKOCARE was founded in 2003 and is headquartered in Martinsried near Munich, Germany.

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