

## CORPORATE NEWS

### **Deutsche Biotech Innovativ AG: Sepsis drug Adrecizumab shows high degree of efficacy in preclinical studies**

*Hennigsdorf, 6 August 2015* –Deutsche Biotech Innovativ AG ("DBI") successfully completed the preclinical studies with Adrecizumab, an innovative "first-in-class" drug candidate for treating sepsis (blood poisoning). Results from animal model studies demonstrated a high degree of efficacy in regard to several clinically relevant parameters.

Sepsis is one of the biggest challenges facing intensive-care medicine. It results in severe infections throughout the body that can lead to a drop in blood pressure and eventually to multiple organ failure and death. The mortality rate is approximately 30 per cent.

In the course of conducting the preclinical studies with Adrecizumab, DBI was especially interested in investigating its effects on the concentration of various hormones and protein compounds that are related to severe infections and organ functioning during sepsis. In addition, researchers used animal models to examine changes in the kidneys' filtering performance and in blood pressure when Adrecizumab was administered, compared to the untreated control group.

#### **Mortality rate declines by more than 50 per cent with Adrecizumab**

The results from preclinical studies are promising: The kidneys' filtering function and thus the fluid balance in the body improved during the treatment with Adrecizumab. Blood pressure also stabilized, whereas a life-threatening drop in blood pressure was observed in the control group. The proof of Adrecizumab's blood pressure-stabilizing effect was obtained in rats, in which sepsis had been artificially induced. The rats' blood pressures, which had dropped dangerously low due to the sepsis, stabilized to almost normal values for as long as 18 hours after being administered Adrecizumab. A correspondingly lower dose of the blood pressure-increasing hormone noradrenaline was needed in the test animals treated with Adrecizumab.

Likewise, vascular damage was reduced by two-thirds with Adrecizumab. In particular, dangerous infection reactions – measured using the concentration of IL-6 plasma and tumor necrosis factor (TNF-alpha) in the entire body – decreased thanks to Adrecizumab to one-tenth of the control group's value.

In addition, Adrecizumab administration resulted in a significant improvement of the kidney function and the fluid balance, which corresponds to a restoration of organ

functions. For example, in septic pigs treated with Adrecizumab there was considerable improvement in the fluid balance while oedemas were prevented from forming.

As a result, the mortality in the group treated with Adrecizumab decreased substantially. While this group had a survival rate of about 50 per cent after seven days, the control group's mortality rate in that time was 100 per cent.

In summary, when Adrecizumab was administered in animal trials, all major symptoms of severe sepsis were demonstrably reduced.

### **Stabilizing instead of blocking**

Adrecizumab is a humanized antibody that binds specifically to the endogenous peptide hormone Adrenomedullin (ADM). The hormone's bioactivity is not fully blocked, but only inhibited to a healthy level. Accordingly, Adrecizumab is the first therapeutic agent that can stabilize the entire organism in the case of severe sepsis. The excess of ADM during sepsis leads to excessive vascular dilation, which in turn results in decreased circulation, and consequently a dangerous drop in blood pressure. If the organs are not sufficiently supplied with blood, the ultimate outcome will be multiple organ failures or septic shock, which leads to death in more than 60,000 cases per year in Germany alone.

Adrecizumab is intended for use as a safe, causal treatment for sepsis patients. After the successful completion and promising results of the preclinical studies, DBI is currently preparing the Phase I clinical study, expected to begin at the end of 2015.

DBI will present the results from the preclinical studies with Adrecizumab at the MEMC – GREAT 2015 Joint Congresses in Rome in September as well as at the ESICM LIVES 2015 in Berlin.

### **About Deutsche Biotech Innovativ AG**

Deutsche Biotech Innovativ AG ("DBI") is a biotechnology company that uses innovative blood biomarkers to research and clinically develop unique therapeutic solutions for serious illnesses for which no adequate medical solutions have yet been found. The focus of the R&D is on drugs for sepsis and cancer. The company's main product is the patented drug Adrecizumab for decreasing mortality due to organ failure in septic shock. Adrecizumab has successfully completed the preclinical phase and will be tested in a Phase I study starting in 2015.

The preclinical and clinical studies are mainly carried out by project companies in which the DBI AG is involved. Currently, the DBI AG holds 26 percent of AdrenoMed AG, 25 percent of Oncoprevent GmbH, 50 percent of My Life Diagnostics GmbH and 100 percent of AngioBiomed GmbH.

DBI aims to further expand its drug pipeline and invests in the research and development of drugs that possess a high unique selling point potential.

The members of the DBI Management Board, Dr. Bernd Wegener and Dr. Andreas Bergmann, have long-standing experience in the biotechnology field. Both were part of the founders' and management team of B.R.A.H.M.S. AG, a very successful biotechnology company specializing in the determination of blood biomarker levels for treating serious illnesses, which was sold in 2009 for around EUR 330 million. Dr. Bernd Wegener is a member of the Executive Board of the Association of the German Pharmaceutical Industry (Bundesverband der Pharmazeutischen Industrie).

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