Biotest

From Nature for Life

PRESS RELEASE

Biotest is developing with Trimodulin a COVID-19 therapy for patients with a severe course of the disease

- **Highly innovative plasma protein product with great therapeutic potential**
- **Existing study shows: Trimodulin can significantly reduce mortality in mechanically ventilated patients with severe pneumonia**
- **Mode of action transferable to patients with Covid-19 induced pneumonia**
- **With additional funding, patients could benefit in current pandemic**
- **Biotest has already invested a three-digit million amount in drug development and a new production plant**

Dreieich, 3 April 2020. Biotest's innovative antibody product Trimodulin (IgM Concentrate) is ready for advanced clinical testing in Covid-19 patients.

Very good results have already been achieved in a large-scale Phase II study in mechanically ventilated patients with severe pneumonia (severe Community Acquired Pneumonia = sCAP) (CIGMA study). This group of diseases also includes pneumonia caused by the current coronavirus in critically ill patients.

Trimodulin is administered as a adjunct to standard therapy such as antiviral or antibiotic therapy, and intensive care. In the CIGMA study, a relative reduction in mortality of 50-70% was observed in a subgroup of patients with high inflammation markers and/or reduced immune function (low immunoglobulin M levels).[1]

The same conditions also occur in Covid-19 patients with severe course of the disease. According to previous studies, the mode of action of Trimodulin includes not only the ability to support the immunological control of pathogens, but also the ability to dampen an excessive malfunction of the immune system and an excessive inflammation reaction.

Due to the great similarity of the clinical picture to the patients treated in the CIGMA study, Biotest sees Trimodulin as having considerable potential for patients with severe pneumonia after Covid-19 infection. Another IgM- and IgA-enriched immunoglobulin of Biotest AG, Pentaglobin®, has already shown positive results treating f coronavirus infections (SARS 2002/03).[2] No data are yet available on the treatment of Covid-19 with Pentaglobin®.

That is why Biotest is now expanding its planned Phase III study in sCAP to include Covid-19 patients. At the same time, an accelerated phase II study in Covid-19 patients is planned in order to drastically accelerate the development in response to the current Covid-19 pandemic. Biotest has already applied for European funding for the activities necessary to speed up the development. With Trimodulin, Biotest is developing a promising therapeutic option that could help saving numerous lives.

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[1] Welte et al., Intensive Care Med 2018; 44(4): 438–448

[2] Ho et al, IntJ TubercLung Dis 2004, Oct. 8(10):1173-9

Biotest has already invested a three-digit million Euro amount in the development of Trimodulin and the associated new production facility. The funding programs for such advanced clinically innovative approaches for the therapy of Covid-19 are unfortunately still small and very limited. In this context, Biotest is hoping for more public support to accelerate drug development in this critical phase of the COVID-19 pandemic.

About Severe Community-Acquired Pneumonia (sCAP)
Severe Community-Acquired Pneumonia (sCAP) is usually defined as pneumonia acquired outside the hospital that requires intensive medical care. Mortality of sCAP patients admitted to the Intensive Care Unit (ICU) is up to 23-58 % depending on time and admission of the patient and has not improved much in recent years.

About Trimodulin (IgM Concentrate)
Trimodulin (IgM Concentrate) is an innovative immunoglobulin therapeutic derived from human blood plasma with a high content of IgG, IgM and IgA, which is currently being developed for the treatment of severe community-acquired pneumonia (sCAP). According to previous studies, Trimodulin (IgM Concentrate) acts through a wide range of mechanisms interfering pathophysiological processes, which otherwise could lead to severe respiratory disturbances, severe sepsis, multi organ failure and ultimately death of the patient. Besides neutralisation of bacterial endotoxin and exotoxin, IgM mediates increased recognition of pathogens by certain immune cells and promotes their destruction. In addition, IgM can rebalance excessive immune responses and possesses anti-inflammatory properties.

About Pentaglobin®
Pentaglobin® is the first and only IgM-enriched immunoglobulin preparation for intravenous use. Pentaglobin® significantly increases the survival rate of patients with severe bacterial infections and acts against a broad spectrum of bacterial pathogens. Pentaglobin's® mode of action, is both anti-bacterial by fast neutralization of bacterial endo- and exotoxins and anti-inflammatory by scavenging excessively activated complement factors. Pentaglobin® is licensed in several countries, mainly for the treatment of severe bacterial infections in combination with antibiotics.

About Biotest
Biotest is a provider of plasma proteins and biological drugs. With a value added chain that extends from pre-clinical and clinical development to worldwide sales, Biotest has specialised primarily in the areas of clinical immunology, haematology and intensive care medicine. Biotest develops and markets immunoglobulins, coagulation factors and albumin based on human blood plasma. These are used for diseases of the immune and haematopoietic systems. Biotest has more than 1,800 employees worldwide. The ordinary and preference shares of Biotest AG are listed in the Prime Standard on the German stock exchange.

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