Biotest

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PRESS RELEASE

US Food and Drug Administration FDA accepts marketing authorization application for immunoglobulin Yimmugo

- **First marketing authorization application for a Biotest product from new "Biotest Next Level" production facility for the USA**
- **Important milestone in the approval process of Yimmugo for the USA**

Dreieich, 7 September 2023. Biotest AG announced today that the Biologics License Application (BLA) for the polyspecific immunoglobulin preparation Yimmugo (IgG Next Generation) has been accepted for review by the U.S. Food and Drug Administration (FDA) after the 60-day validation phase. With this filing notification the marketing authorization application will enter the next phase, in which the application dossier will be subjected to an in-depth substantive review.

The marketing authorization application covers the indication primary immunodeficiencies (PID). After receiving approval, Biotest plans to expand the indication to include chronic primary immune thrombocytopenia (ITP).

"We are pleased that the FDA has accepted our Yimmugo dossier for review, which reflects the completeness and required level of detail of the submitted application dossier. This is an important milestone in the approval process for Yimmugo. Over the next ten months, we will convince the FDA that Yimmugo is safe, effective and manufactured to the highest quality standards and also meets the FDA's requirements," said Dr. Reto Bisaz, the manager responsible for the US approval.

The FDA's decision on the marketing authorization application of Yimmugo is expected on June 29, 2024.

Biotest's new immunoglobulin is manufactured in an innovative production process and is the main product of the new Biotest Next Level production facility. The new production facility, which uses state-of-the-art technologies, represents Biotest's increased commitment to the global immunoglobulin market.

About Yimmugo (IgG Next Generation)

Yimmugo is a newly developed polyvalent immunoglobulin G preparation from human blood plasma for intravenous administration (IVIG). The sugar-free ready-to-use solution is approved for replacement therapy in primary antibody deficiency syndromes and secondary immune deficiency, as well as for immunomodulation in autoimmune diseases such as ITP, GBS, CIDP, MMN and Kawasaki's disease. Yimmugo is the first approved product from the new Biotest Next Level production facility. The modern production process stands for highest product quality and an extremely responsible use of resources.

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 2,300 employees worldwide. The ordinary and preference shares of Biotest AG are listed in the Prime Standard on the German stock exchange. Since May 2022, Biotest has been a part of the Grifols Group, based in Barcelona, Spain (www.grifols.com).

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