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## **TECHNOCLONE RECEIVES US FDA MARKETING AUTHORIZATION FOR THE FIRST ADAMTS13 ACTIVITY DIAGNOSTIC TEST**

**West Chester, OH, March 5, 2024** - Technoclone Herstellung von Diagnostika und Arzneimitteln GmbH, world-leading producer of diagnostic tests, equipment, and research products in the field of blood clotting and its exclusive distributor in the USA, DiaPharma Group, Inc., are pleased to announce that the US Food and Drug Administration (FDA) granted De Novo marketing authorization for Technozym ADAMTS13 Activity ELISA. This is the first ADAMTS13 activity test authorized by the FDA.

The Technozym ADAMTS13 Activity assay is an enzyme-linked immunosorbent assay (ELISA) intended for the qualitative determination of ADAMTS13 activity in platelet poor human citrated plasma. The assay is intended to be used in conjunction with other clinical and laboratory findings as an aid in the diagnosis of thrombotic thrombocytopenic purpura (TTP) in adult and pediatric patients being evaluated for thrombotic microangiopathy (TMA).

"In line with our commitment to provide ADAMTS13 diagnostics globally, we are excited about this milestone, having the first ADAMTS13 activity test granted with marketing authorization by the FDA", says Nikolaus Binder, MD, PhD, CSO of Technoclone. "And today we are honored to address this unmet need for laboratories and patients across the U.S."

"We are proud to partner with Technoclone to provide the first in vitro diagnostic assay for ADAMTS13 Activity in the U.S., leading the way for better access to this important parameter", says Madeleine Burmester, President & CEO of DiaPharma.

### **About TTP**

TTP is a very rare, life-threatening blood clotting disorder caused from either a congenital or acquired absence/decrease of the von Willebrand factor-cleaving protease ADAMTS13.

### **About Technoclone**

Technoclone is committed to delivering high-quality test systems for in vitro diagnostics in hemostasis to its worldwide clientele. At Technoclone innovation is seen as its responsibility to address emerging complexities in the diagnosis of hematological and cardiovascular disorders. Since 1987, Technoclone has fostered close collaborations with global partners from academia, clinical laboratories, and industry, positioning itself at the forefront of anticipated diagnostic challenges in the years to come.

### **About DiaPharma**

DiaPharma Group, Inc. sells assay kits, reagents, and instrumentation for laboratory research and clinical applications in the fields of Bleeding and Clotting Disorders and Liver Injury. DiaPharma provides strong personal support and technical competence and experience to ensure customer expectations will be met or exceeded.

### **DiaPharma Group, Inc.**

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