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**FOR IMMEDIATE RELEASE**

**Octapharma USA: FDA Approves WILATE<sup>®</sup> License Supplement – Perioperative Management of Bleeding in Patients with von Willebrand Disease**

**HOBOKEN, N.J. (August 13, 2015)** – [Octapharma USA](#) today announced the [U.S. Food and Drug Administration \(FDA\)](#) has approved revised product labeling for [WILATE<sup>®</sup> \[von Willebrand Factor/Coagulation Factor VIII Complex \(Human\)\]](#) to include prevention of excessive bleeding during and after minor and major surgery in adult and pediatric von Willebrand disease (VWD) patients. VWD is a complex congenital bleeding disorder that affects one to two percent of the general population or approximately 3 million people in the United States.

The newly approved product label expands the FDA license for [WILATE<sup>®</sup>](#), which formerly included only the treatment of spontaneous and trauma-induced bleeding episodes in patients with severe VWD, as well as patients with mild or moderate VWD in whom the use of desmopressin is known or suspected to be ineffective or contraindicated. [Octapharma USA](#) is a subsidiary of global human protein products manufacturer [Octapharma AG](#), which develops and manufactures high-purity coagulation factor concentrates for patients with bleeding disorders.

“Preventing excessive intra- and post-operative bleeding in pediatric and adult VWD patients is a continuing challenge,” said [Octapharma USA](#) President Flemming Nielsen. “We are extremely pleased that [WILATE<sup>®</sup>](#) is now available for medical providers managing this important issue. Octapharma is committed to providing life saving and enhancing therapeutic options for the bleeding disorders community.”

The overall efficacy rate of [WILATE<sup>®</sup>](#) treatment for surgical procedures was 96.7% in a global, prospective, open-label, single-arm, uncontrolled, multi-center Phase III [clinical study](#), which included nine U.S. hemophilia treatment centers. The clinical trial observed 28 patients with Type 1, Type 2 and Type 3 VWD from 24 centers in eight countries who underwent 30 surgeries and 280 infusions. WILATE<sup>®</sup> treatment was successful in 100% of minor surgeries and 95.2% of major surgeries. The study reported a 100% success rate in surgical procedures for Type 3 patients, the most serious form of VWD.<sup>1</sup>

**About WILATE<sup>®</sup>**

[WILATE<sup>®</sup>](#) is a plasma-derived, highly purified concentrate of freeze-dried human von Willebrand factor (VWF) and coagulation factor VIII (FVIII). Two well-established virus inactivation steps are incorporated into the manufacturing process of WILATE<sup>®</sup>, specifically a solvent/detergent (S/D) and terminal dry-heat (TDH) treatment.

[WILATE®](#) is a von Willebrand Factor/Coagulation Factor VIII Complex (Human) indicated for the on-demand treatment and control of bleeding episodes. WILATE® is also indicated for the perioperative management of bleeding. WILATE® is not indicated for the treatment of hemophilia A.

### **Important Safety Information**

[WILATE®](#) is contraindicated for patients who have known hypersensitivity reactions, including anaphylactic or severe systemic reaction, to human plasma-derived products, any ingredient in the formulation, or components of the container. Thromboembolic events have been reported in VWD patients receiving coagulation factor replacement therapies. FVIII activity should be monitored to avoid sustained excessive FVIII levels. Development of neutralizing antibodies to FVIII and to VWF, especially in VWD Type 3 patients, may occur. WILATE® is made from human plasma. The risk of infectious agents, including viruses and, theoretically, the Creutzfeldt-Jacob disease agent, cannot be completely eliminated. The most common adverse reactions to treatment with WILATE® in patients with VWD were hypersensitivity reactions, urticaria, and dizziness. Seroconversions for antibodies to parvovirus B19 not accompanied by clinical signs of disease have been observed. The most serious adverse reactions to treatment with WILATE® in patients with VWD were hypersensitivity reactions.

For more information and full prescribing information on [WILATE®](#), please visit [www.WILATEusa.com](http://www.WILATEusa.com).

### **About the Octapharma Group**

Headquartered in Lachen, Switzerland, Octapharma is one of the largest human protein products manufacturers in the world and has been committed to patient care and medical innovation since 1983. Its core business is the development and production of human proteins from human plasma and human cell-lines. Octapharma employs approximately 6,000 people worldwide to support the treatment of patients in over 100 countries with products across the following therapeutic areas: Hematology (coagulation disorders), Immunotherapy (immune disorders) and Critical Care. The company's American subsidiary, Octapharma USA, is located in Hoboken, N.J. Octapharma operates two state-of-the-art production sites licensed by the [U.S. Food and Drug Administration](#) (FDA), providing a high level of production flexibility. For more information, please visit [www.octapharmausa.com](http://www.octapharmausa.com), [www.octagamus.net](http://www.octagamus.net), [www.octaplasus.com](http://www.octaplasus.com) or [www.WILATEusa.com](http://www.WILATEusa.com).

### **REFERENCES**

1. Octapharma, Data on file. 2015.

### ***Forward-looking Statements***

This news release contains forward-looking statements, which include known and unknown risks, uncertainties, and other factors not under the company's control. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments. These factors include results of

current or pending research and development activities and action by the FDA or other regulatory authorities.

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