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November 1, 2016

Baxalta US Inc., now part of Shire, ("Shire") is pleased to announce the market availability of VONVENDI [von Willebrand factor (recombinant)], the first recombinant von Willebrand factor approved by the US Food and Drug Administration on December 8, 2015 for on-demand treatment and to control bleeding episodes in adults (18 and over) diagnosed with von Willebrand disease (VWD). VONVENDI was first commercially available on August 9, 2016.

We have been able to accelerate our manufacturing capacity since our commercial launch. As a result, the limited distribution system for VONVENDI remains in place, but the patient activation program originally in place (the "Activation Program for VONVENDI") is no longer required.

To help manage distribution of VONVENDI, Shire has implemented a limited distribution system with a qualified specialty network that currently includes CVS/Caremark and Option Care. Additionally, hemophilia treatment centers (both 340B and non-340B) and hospitals can purchase VONVENDI directly from Shire. All Eligible Covered Entities will have access to VONVENDI at the 340B ceiling price.

Shire will continue to evaluate production capacity in order to evaluate potential expansion of the limited distribution for VONVENDI while ensuring the unique needs of the von Willebrand patients are met. Shire will notify HRSA of any modification to our distribution plans as they occur.

For information on ordering VONVENDI, contact your Shire Hematology representative or call Shire Customer Service at 800-423-2090.

VONVENDI is available under labeler Baxalta US Inc in the following vial sizes:

Color Code	VWF:RCo Potency Range	Carton NDC	sWFI fill size
Green	450-850 IU per vial	0944-7551-02	5 mL
Dark Red	900-1700 IU per vial	0944-7553-02	10 mL