

[O-W-023] FINAL RESULTS OF A PROSPECTIVE-MULTICENTRE STUDY TO EVALUATE PHARMACOKINETICS, EFFICACY AND SAFETY OF A SOLVENT-DETERGENT TREATED AND 15 NANOMETER-FILTERED PLASMA-DERIVED FACTOR VIII

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Introduction: Factane^R (100 IU/ml), was developed as Facteur VIII-LFB^R, with 35 and 15 nm filtration steps added to pre-existing validated solvent-detergent treatment. It contains 20 to 30 IU of von Willebrand factor per 100 IU of FVIII.

Methods: Pharmacokinetics were investigated after single administration of the two products, followed by a prospective- European multicentre study evaluating the efficacy, safety and immunogenicity of Factane^R, in at least 50 previously treated patients (PTPs) over a period of ≥ 6 months or ≥ 50 exposure days (EDs).

Results: Factane^R was bioequivalent to Facteur VIII-LFB^R with a half-life of 12.7 ± 4.1 h and recovery of 2.7 ± 0.7 IU/dl per IU/kg (n=19). Of 1698 bleeding episodes treated at home in 64 patients, 91% required one or two infusions, and 92% were rated as excellent or good. In 34 severe- or high-risk bleeding situations (5 severe episodes, 29 surgical procedures), efficacy was excellent or good in all cases. The median number of bleeding episodes experienced in 11 patients during long-term prophylaxis (median duration: 19 months) was 2.3 per year. More than 12.4 million units (40 batches) were administered during the study in 73 PTPs. The median treatment duration was 8 months and 50 EDs. Few adverse reactions (12/6000 infusions) related to the product were reported. Absence of immunogenicity was demonstrated: 1° Bethesda assays were negative in 72 patients at baseline and remained negative. 2° Recovery (n=47) and pharmacokinetic (n=12) profiles were unchanged after 3-6 months of exposure (median: 30 EDs).

Conclusions: This study confirms that 15 nm filtration has no impact on the efficacy or safety profiles of Factane^R.

Rothschild C, Windyga J, Peerlinck K, Hermans C, Tellier Z, Souquieres M, Bridey F, French FVIII SD-35-15 Study Group. FINAL RESULTS OF A PROSPECTIVE-MULTICENTRE STUDY TO EVALUATE PHARMACOKINETICS, EFFICACY AND SAFETY OF A SOLVENT-DETERGENT TREATED AND 15 NANOMETER-FILTERED PLASMA-DERIVED FACTOR VIII. *J Thromb Haemost* 2007; **5** Supplement 2: O-W-023

Date: Wednesday, July 11, 2007

Session Info: Oral Communications: Bleeding disorders

Room: Room D