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## 3797 Pharmacokinetics, Efficacy and Safety Evaluation of FRSW107 in Previously Treated Hemophilia a Patients: A Multicentre, Open-Label, Non-Randomized Phase III Study

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Program: Oral and Poster Abstracts

Session: 322. Disorders of Coagulation or Fibrinolysis: Clinical and Epidemiological: Poster III

Hematology Disease Topics & Pathways:

Research, clinical trials, Bleeding and Clotting, hemophilia, Clinical Research, drug development, Diseases, Therapies, Adverse Events

Monday, December 12, 2022, 6:00 PM-8:00 PM

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**Background:** FRSW 107, a novel homodimer recombinant factor VIII (rFVIII) Fc fusion protein, is the first domestic extended half-life (EHL) rFVIII under development in China, and is currently at stage of Biologics License Application (BLA) in NMPA for the prophylaxis and treatment of bleeding episodes in adolescent and adult ( $\geq 12$  yr) with hemophilia A (HA).

**Aims:** This phase III (NCT04456387, CTR20201212), open-label, non-randomized, multicenter trial aimed to evaluate the pharmacokinetics (PK), safety, and clinical efficacy of FRSW 107 for prophylaxis and treatment of bleeding in previously treated HA patients  $\geq 12$  yr.

**Methods:** Eligible patients included male severe HA (FVIII:C < 1%)  $\geq 12$  yr, previous treatment with FVIII concentrates for  $\geq 150$  exposure days (EDs), and absence of FVIII inhibitors (< 0.6 Bethesda Units/mL). A total of 119 patients received FRSW 107 for prophylaxis treatment (n=83) or on-demand treatment (n=36). The patients in the prophylaxis group were administered one dose of 50 IU/kg of FRSW 107 every three days for at least 50 EDs for a minimum period of 6 months, and the primary efficacy endpoint was annualized bleeding rate (ABR). The patients in the on-demand treatment group received 30 to 50 IU/kg of FRSW 107 over 6 months, according to the severity and location of the bleeding, and the primary efficacy endpoint was hemostatic effect (excellent, good). The single-dose and repeat dose PK parameters of 15 patients in the prophylaxis group were analyzed at ED1 and ED35, respectively.

**Results:** In the prophylaxis group, the mean and median annualized bleeding rate (ABR) were  $1.61 \pm 3.74$  and 0.00 (IQR, 0.00-

2.02), decreased by 95.01% versus the baseline 32.24±23.98 and 26.00 (IQR, 16.00-46.00), and 56 (67.5%) patients had no bleeds during the trial. Detailed ABR data for prophylaxis group was included in the table below. In the on-demand treatment group, hemostatic efficacy was rated as “excellent” or “good” for 98.9% of bleeds. 97.9% of 721 reported bleeds were treated with ≤2 injections. No FVIII inhibitors have been reported in this study. Drug-related adverse events (AEs) occurred in 10.1% of the patients. No SAE was judged to be related to FRSW107 treatment. No thromboembolic events were reported, and there are no unexpected safety concerns. The terminal half-life of FRSW 107 ranged between 20 to 22 hours. The incremental recovery (IR) was approximately 2.14 (IU/dL)/(IU/kg). The PK parameters and profiles remained consistent between ED1 and the repeated dosing at ED35.

**Conclusions:** The data indicate that FRSW 107 was safe and effective for prophylaxis and treatment of bleeding episodes in previously treated adolescent and adult HA patients.

**Table: Annualized bleeding rate (ABR) for patients in the prophylaxis treatment group (n=83)**

	Baseline	After treatment	P value
<b>Total ABR</b>			<b>&lt;0.0001</b>
Median (IQR)	26.00 (16.00-46.00)	0.00 (0.00-2.02)	
Mean ± SD	32.24 ± 23.98	1.61 ± 3.74	
<b>Spontaneous ABR</b>			<b>&lt;0.0001</b>
Median (IQR)	24.00 (14.00-44.00)	0.00 (0.00-0.00)	
Mean ± SD	30.29 ± 23.21	0.86 ± 2.33	
<b>Traumatic ABR</b>			<b>0.7252</b>
Median (IQR)	0.00 (0.00-0.00)	0.00 (0.00-0.00)	
Mean ± SD	1.61 ± 8.52	0.77 ± 2.04	

Abbreviations: IQR, interquartile range.

**Disclosures:** **Jin:** Suzhou Zeigen Biopharmaceuticals Co.,Ltd.: Honoraria. **Yang:** Suzhou Zeigen Biopharmaceuticals Co.,Ltd.: Honoraria.

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\* *signifies non-member of ASH*



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