

# The evidence you cant ignore.

Wilate now approved for prophylaxis in Canada

## WIL-31 study confirms Wilate<sup>®</sup> prophylaxis in reducing bleeding in VWD patients

The WIL-31 study is a significant prospective prophylaxis study on von Willebrand disease (VWD), the largest of its kind. It uniquely includes a prospective on-demand run-in as an intra-individual comparator. The study demonstrates that prophylaxis with Wilate<sup>®</sup>, a von Willebrand factor/factor VIII (VWF/FVIII) concentrate, is highly effective in reducing bleeding rates in both children and adults with all types of VWD compared to previous on-demand treatment.

Octapharma announced these results, which were published in Blood Advances by Sidonio RF Jr et al., under the title "Von Willebrand factor/factor VIII concentrate (Wilate<sup>®</sup>) prophylaxis in children and adults with von Willebrand disease."

The study included a diverse patient population, covering young children and adults of both genders and all types of VWD.

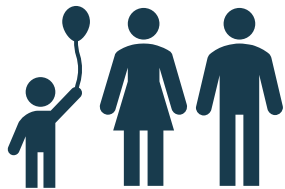
The findings support the use of VWF prophylaxis and have led to the addition of Wilate<sup>®</sup> prophylaxis as a therapeutic indication for VWD in the US, thereby increasing access for the patient population.

## WIL-31 is the largest prospective prophylaxis study in VWD with an on-demand run-in study as an intra-individual patient comparator

6 months on-demand with any VWF-containing product



12 months wilate<sup>®</sup> prophylaxis (2–3 × per week at 20–40 IU/kg)



**Eligible for WIL-31 if during WIL-29:**

- Experienced  $\geq 6$  BEs\*
- $\geq 2$  of these BEs treated with a VWF-containing product

**Aim: To investigate the efficacy and safety of wilate<sup>®</sup> during prophylaxis in previously treated patients with VWD**

\* Excluding menstrual bleeds.

BE: bleeding event; IU: international units; VWD: von Willebrand disease; VWF: von Willebrand factor.

1. <https://clinicaltrials.gov/ct2/show/NCT04053699>; 2. <https://www.clinicaltrials.gov/ct2/show/NCT04052698>.

For full prescribing information, please refer to the product monograph.

# WIL-31: wilate prophylaxis reduced total and spontaneous bleeding vs on-demand treatment

**84.4% decrease in mean (SD) total ABR**

○ On-demand: 33.4 (23.6)

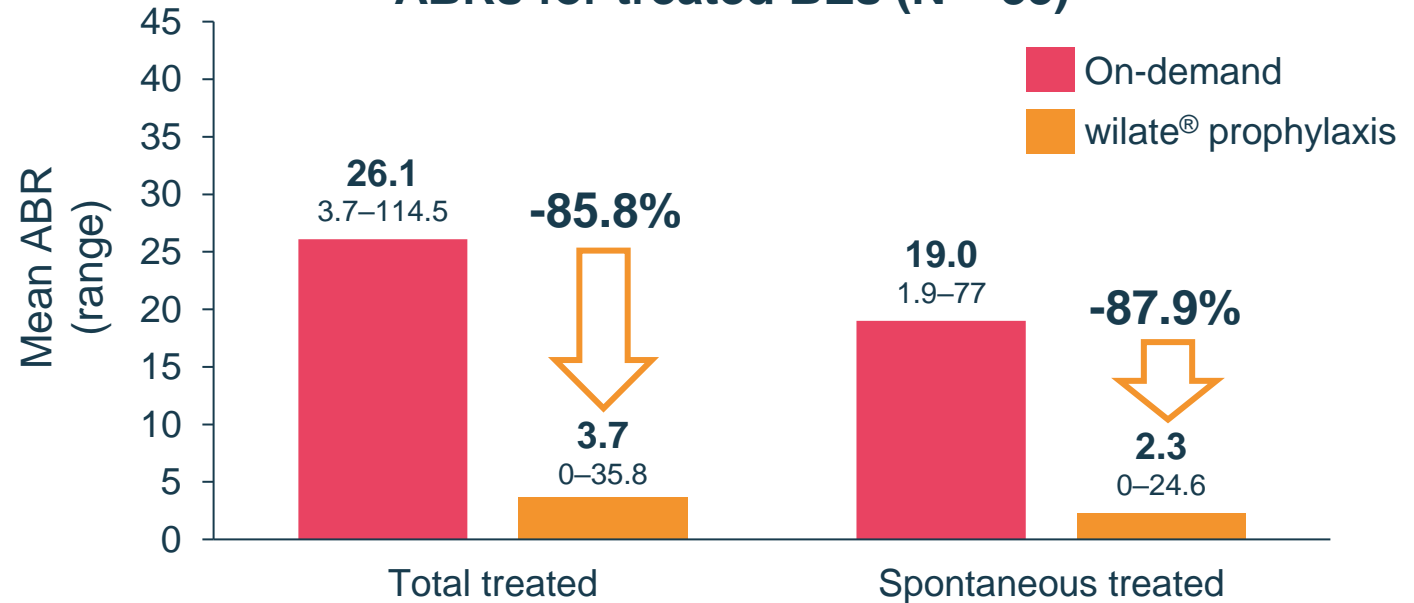
○ wilate<sup>®</sup> prophylaxis: 5.2 (7.7)



**Primary endpoint met**

≥50% reduction in mean total ABR

**ABRs for treated BEs (N = 33)**



Median (range)	Total treated		Spontaneous treated	
	WIL-29	WIL-31	WIL-29	WIL-31
	22.4 (3.7-114.5)	1 (0-35.8)	16.4 (1.9-77)	0 (0-24.6)

SD: standard deviation.

Sidonio RF et al. *Blood Adv* 2024; doi:10.1182/bloodadvances.2023011742.

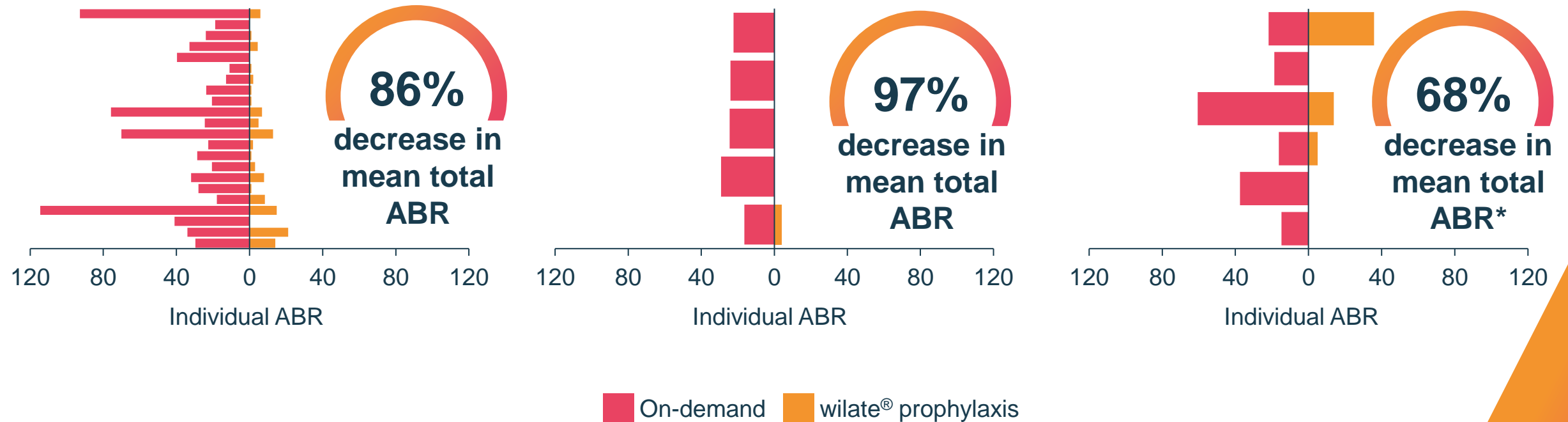
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## WIL-31: Efficacy of wilate<sup>®</sup> for the prevention of bleeds by VWD type

Type 3 (n = 22)

Type 2A (n = 5)

Severe type 1 (n = 6)

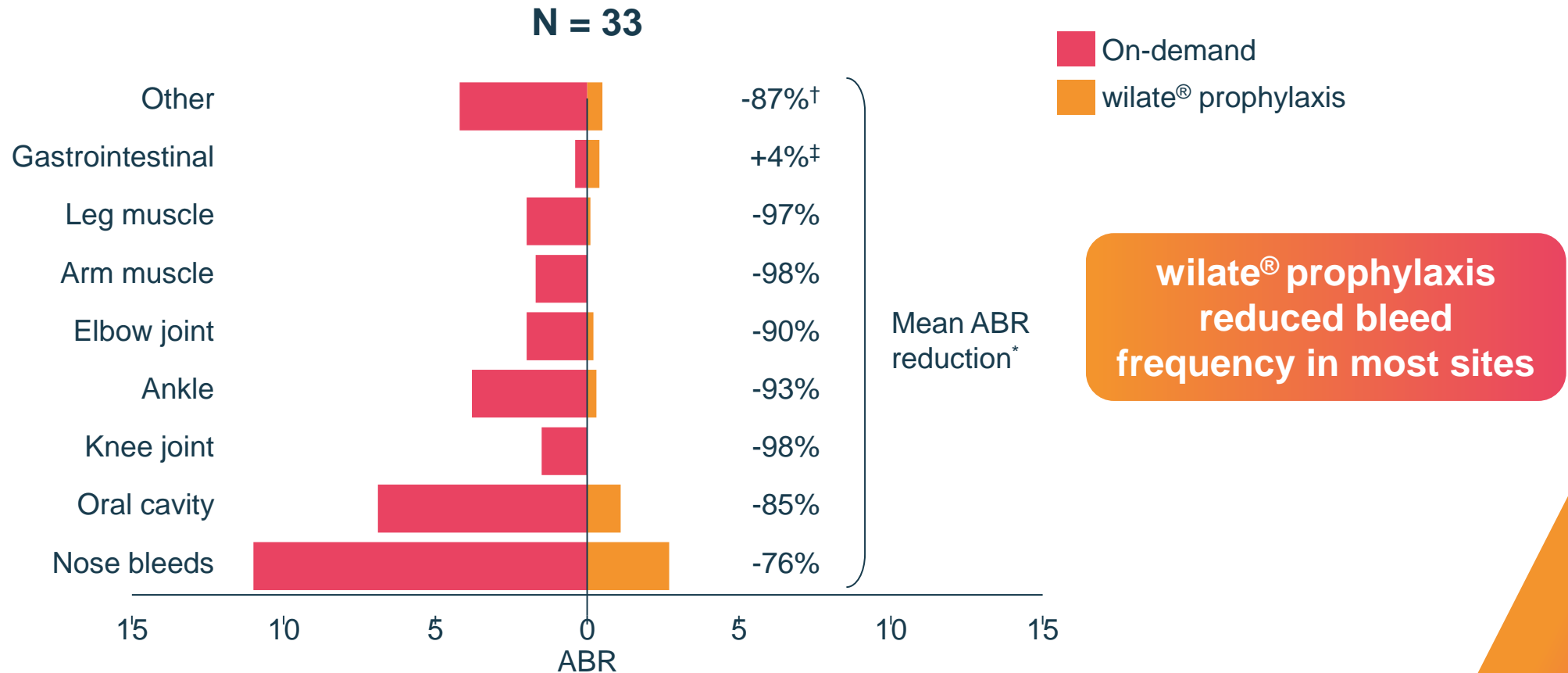


\* One patient experienced many bleeds, including 12 GI bleeds during WIL-31 resulting in a higher ABR in WIL-31 compared with WIL-29. This patient is considered an "outlier" among the severe type 1 population and without this patient the reduction is 87%.

Sidonio RF et al. *Blood Adv* 2024; doi:10.1182/bloodadvances.2023011742.

For full prescribing information, please refer to the product monograph.

## WIL-31: wilate<sup>®</sup> prophylaxis reduced bleeding across all sites



\* Reduction in mean ABR (%) = 100-(Mean ABR WIL-31/Mean ABR WIL-29\*100). Missing in case ABR = 0 in WIL-29.

<sup>†</sup> "Other" bleeds in WIL-29 all years include arm, back, buttock, cutaneous, cyst, ecchymosis, haematuria, haemorrhoid, hand, hip, leg, nasal contraction, post-surgery, shoulder, subcutaneous, thigh, toe, tonsil, uterus, and wrist. "Other" bleeds in WIL-31 all years include cutaneous, haemorrhoid, head, hip, ocular, rectal, toe, and tonsil.

<sup>‡</sup> One patient experienced many bleeds, including 12 GI bleeds during WIL-31 resulting in a higher ABR in WIL-31 compared with WIL-29. This patient is considered an "outlier" without this patient the reduction is 100%. Without this patient the reduction is 100%.

Octapharma, data on file.

For full prescribing information, please refer to the product monograph.

## WIL-31: wilate<sup>®</sup> prophylaxis was well tolerated across all patients

0

Thrombotic events occurred

No patients developed inhibitors during WIL-31

2

Patients had AEs assessed as possibly related to the study treatment by the investigator and led to discontinuation

- 1 patient developed mild chest tightness (3 events)
- 1 patient had hypersensitivity reactions of moderate severity (2 events)

5

Serious AEs occurred in 4 patients, **none considered related to treatment**