VWD Prophylaxis Works: the Evidence You Can't Ignore

The WIL-31 study, the largest prospective, non-controlled, international, multicenter phase 3 trial, has demonstrated that prophylactic treatment of Von Willebrand Disease (VWD) with Wilate® can significantly reduce Annualized Bleeding Rates(ABR) across various patient demographics—children and adults, males and females, and across all types of VWD.

Octapharma Canada is pleased to announce the Canadian approval of Wilate® for use in prophylaxis treatment of VWD in adults and pediatric patients aged 6 and older with any type of VWD.

This document provides a summary of the study's findings related to ABR reduction, efficacy of Wilate® for the prevention of bleeds by VWD type, and bleeding across all sites. For detailed report, please write to us at vwd.canada@octapharma.com

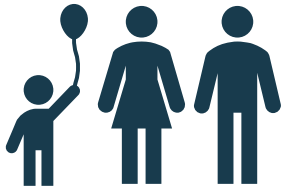
For full prescribing information, please refer to Product Monograph.

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® prophylaxis (2–3 × per week at 20–40 IU/kg)

WIL-29[1] → WIL-31[2]



Eligible for WIL-31 if during WIL-29:

- Experienced ≥ 6 BEs*
- ≥ 2 of these BEs treated with a VWF-containing product

Aim: To investigate the efficacy and safety of wilate® 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.

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

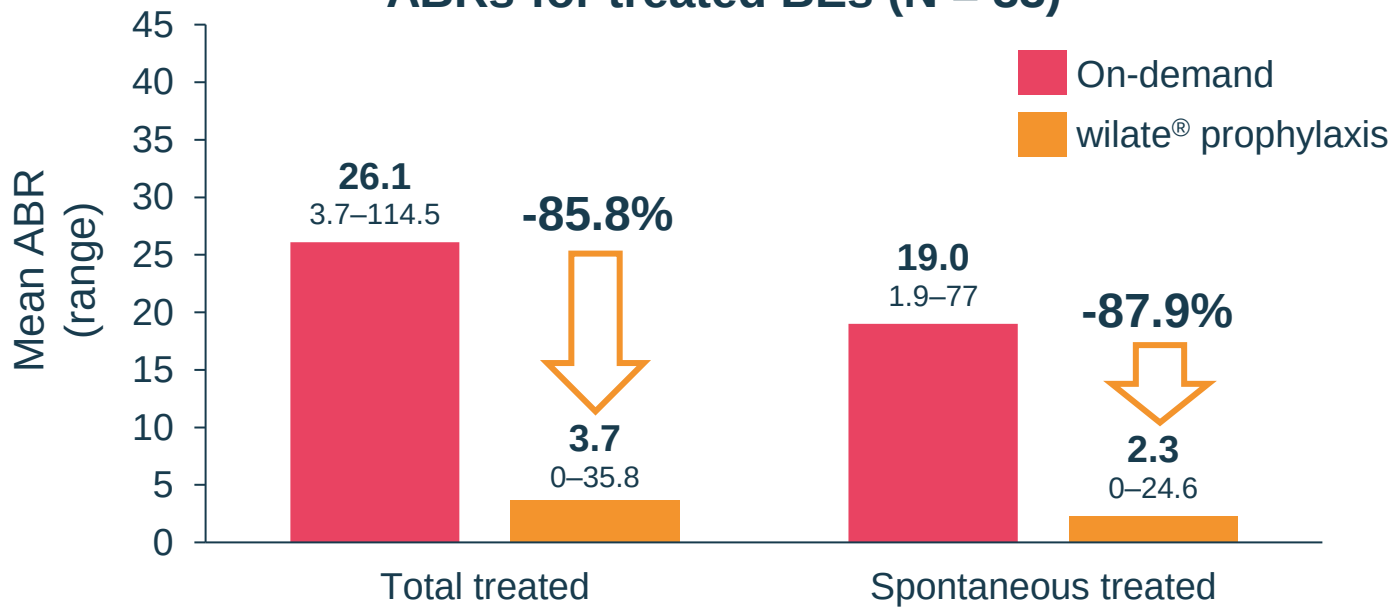
84.4% decrease in mean (SD) total ABR

- On-demand: 33.4 (23.6)
- wilate® prophylaxis: 5.2 (7.7)

Primary endpoint met

≥50% reduction in mean total ABR

ABRs for treated BEs (N = 33)



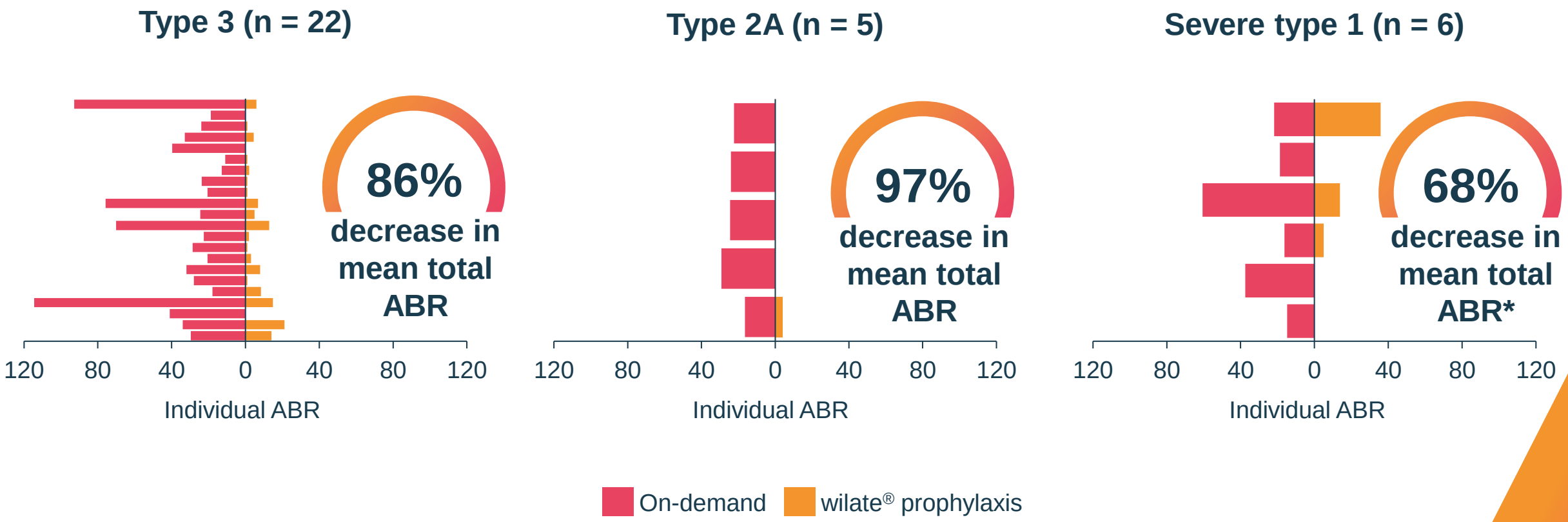
	Total treated		Spontaneous treated	
	WIL-29	WIL-31	WIL-29	WIL-31
Median (range)	**22.4** (3.7–114.5)	**1** (0–35.8)	**16.4** (1.9–77)	**0** (0–24.6)

SD: standard deviation.

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

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

WIL-31: Efficacy of wilate® for the prevention of bleeds by VWD type



* 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.

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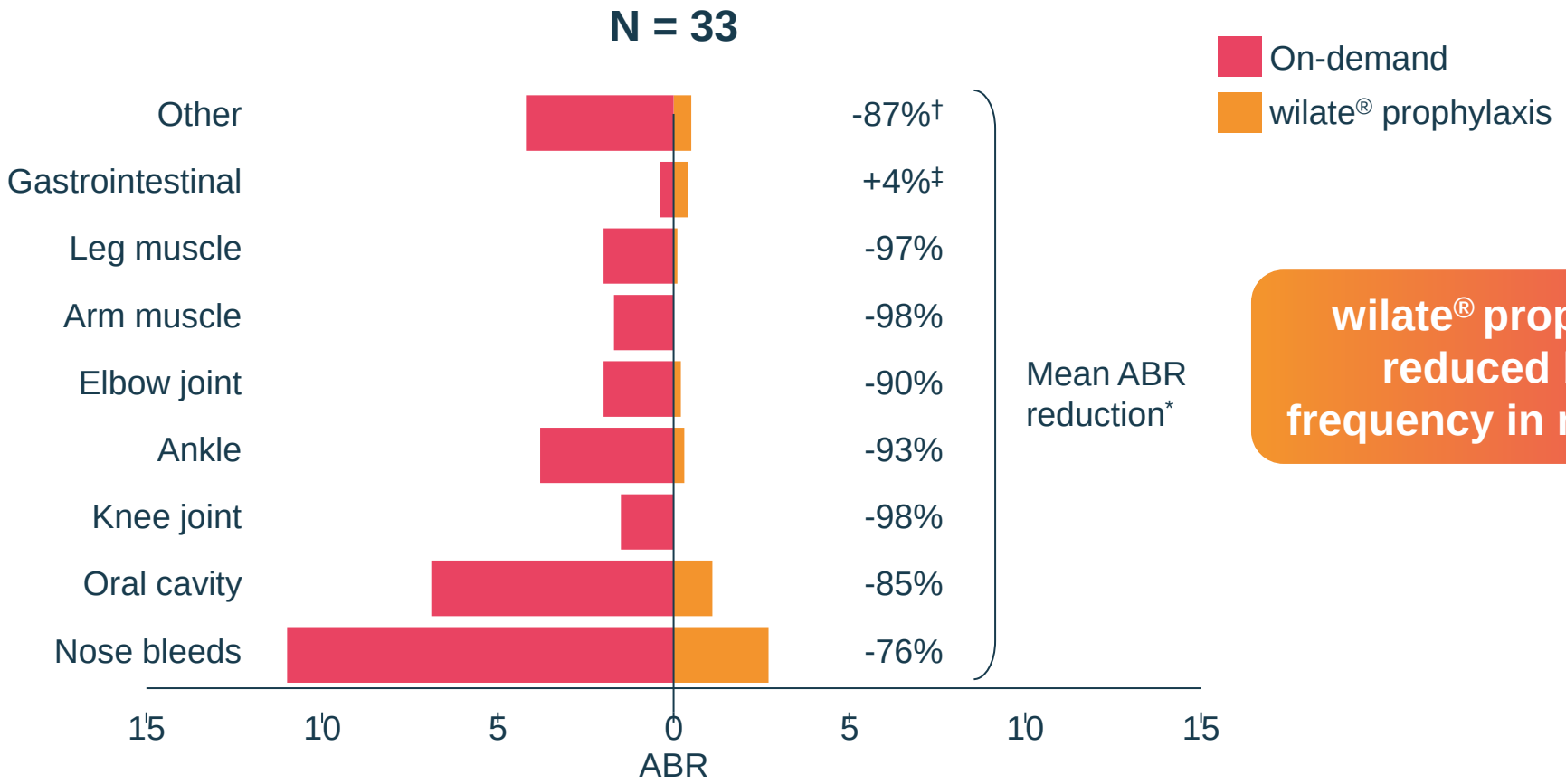
WIL-31: wilate® prophylaxis reduced bleeding across all sites



wilate® prophylaxis reduced bleed frequency in most sites

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

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