Innovation all for the patients

CHUGAI

Roche A member of the Roche group

HEMLIBRA®
Subcutaneous Injection
30 mg, 60 mg, 90 mg, 105 mg, 150 mg
Product Overview

Hiroshi Motegi
HEMLIBRA Lifecycle Leader
Chugai Pharmaceutical Co., Ltd.

HEMLIBRA™
emicizumab

Forward-Looking Statements

This presentation may include forward-looking statements pertaining to the business and prospects of Chugai Pharmaceutical Co., Ltd. (the “Company”). These statements reflect the Company’s current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company’s businesses.

Although this presentation includes information regarding pharmaceuticals (including products under development), the information is not intended as any advertisement and/or medical advice.

These presentation slides are created for the purpose of “Information Meeting on HEMLIBRA®” (June 1, 2018) for investors and media, and not intended for the general public. Transfer and republication need permission.

Product Outline

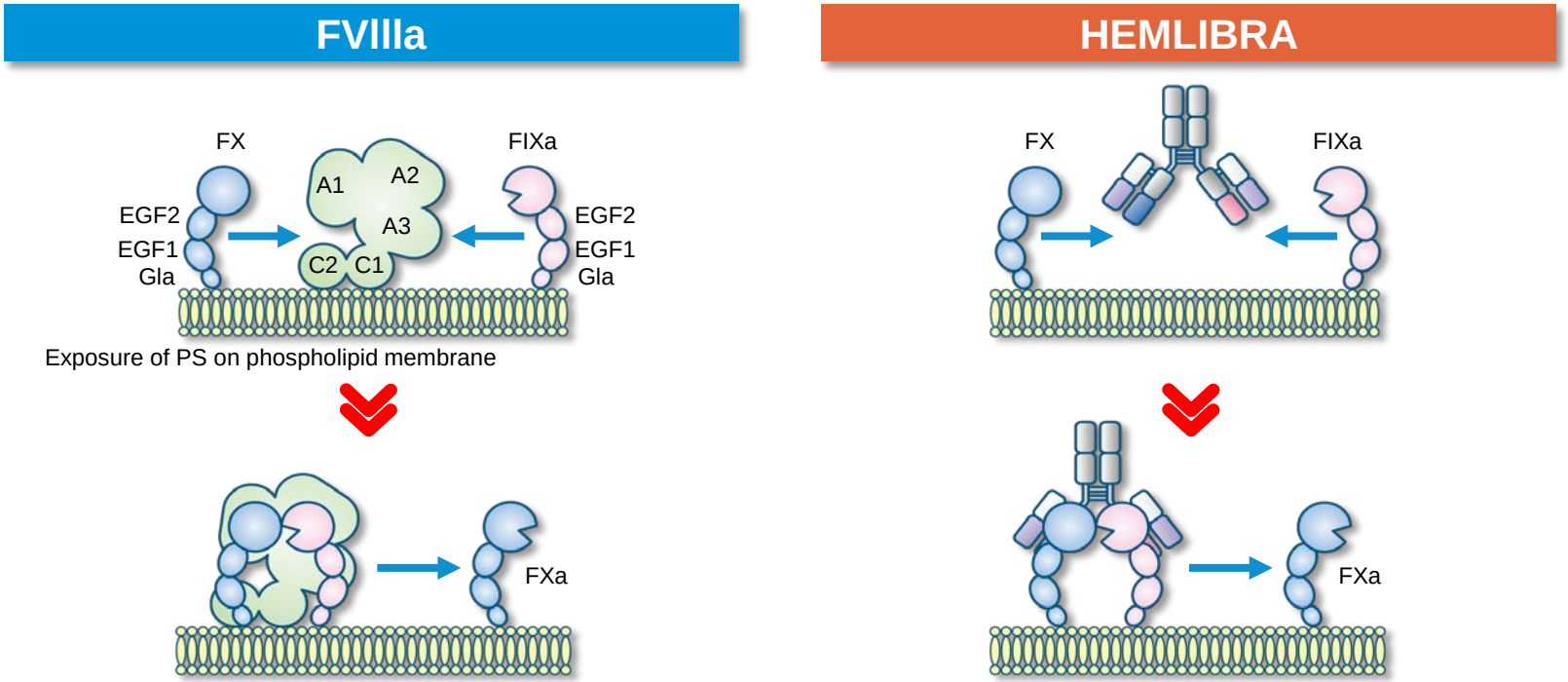
Product Classification:	Anti-coagulation factor IXa/X humanized bispecific monoclonal antibody Coagulation factor VIII substitute
Product name:	HEMLIBRA® Subcutaneous Injection 30 mg, 60 mg, 90 mg, 105 mg, 150 mg
Generic name:	emicizumab (genetical recombination)

Package:

Characteristics of HEMLIBRA

- Bispecific antibody created by Chugai Pharmaceutical
- HEMLIBRA binds to activated blood coagulation factor IX (FIXa) and blood coagulation factor X (FX) and maintains both factors in position on the phospholipid membrane. It is considered that the mechanism enables to replace the cofactor function of FVIIIa and to promote the downstream blood-clotting reaction.

FVIIIa and HEMLIBRA cofactor activity [conceptual illustration]



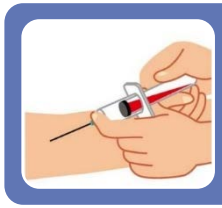
Kitazawa, Takehisa, et al., *The Journal of Japanese Biochemical Society*, 89 (3): 325-32, 2017

The authors include an employee of Chugai Pharmaceutical

Treatment that HEMLIBRA Aims to Contribute

Meet the unmet medical needs of hemophilia A with inhibitors

Efficacy
(inhibitory effect on bleeding)



Administration technique
(intravenous administration)

Time and effort due to frequent administration

Advancement of inhibitory effect on bleeding

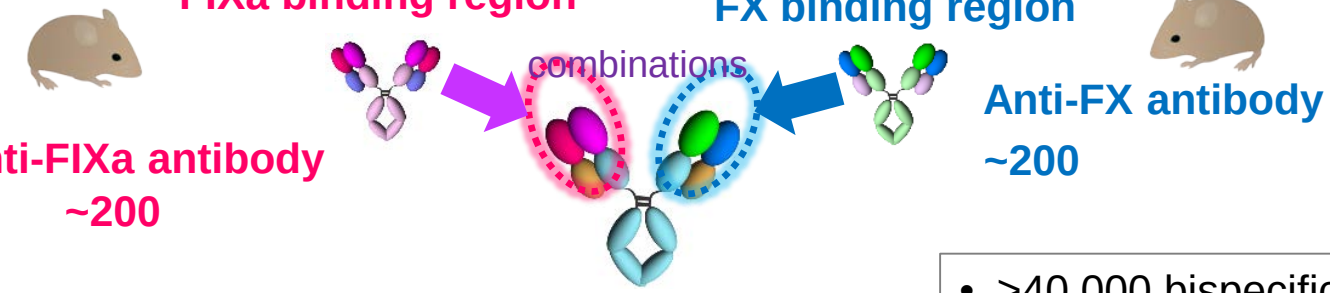
Subcutaneous injection

Once-weekly administration

HEMLIBRA: History of Development 1

Creation at Fuji Gotemba Research Laboratories

Lead identification



- >40,000 bispecific antibodies were screened to obtain lead antibody
- >2,000 engineered antibodies were evaluated

Multi-dimensional optimization

Improved

- ✓ FVIII mimetic activity
- ✓ pharmacokinetics (half-life and bioavailability)
- ✓ physicochemical properties
- ✓ immunogenicity (humanization and *in silico* deimmunization etc.)
- ✓ manufacturability of bispecific antibody

Sampei et al. PLoS One 8 e57479 (2013)

Identified HEMLIBRA: humanized anti-FIXa / X asymmetric bispecific IgG_4

HEMLIBRA: History of Development 2

- **Research and creation at Fuji Gotemba Research Laboratories (from 2001)**
- **Conduct clinical development in Japan (from 2012): from FIH to proving PoC (Ph1, Ph1/2)**
  - Received BTD from U.S. FDA based on the phase 1 clinical study in Japan (Sep. 2015)
- **Start of global development in collaboration with Roche (from Jul. 2014)**
  - Global phase 3 studies were carried out (HAVEN 1 to HAVEN 4)
- **Simultaneous application for the indication of hemophilia A with inhibitors in Europe, U.S. and Japan (Jun. to Jul. 2017)**
  - U.S. (priority review), EU (fast-track review), Japan (priority review under orphan drug designation)
- **Approval: U.S. (Nov. 2017), Europe (Feb. 2018)**

  Japan (Approved in Mar. 2018, Launched in May 2018)

*FIH：first in human, PoC: proof of concept, BTD: breakthrough therapy designation

HEMLIBRA
Indication, Dosage and Administration

INDICATION

Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in patients with congenital factor VIII deficiency with factor VIII inhibitors

DOSAGE AND ADMINISTRATION

The usual dosage is 4 once-weekly subcutaneous doses at 3 mg/kg (body weight) emicizumab (genetical recombination) per dose, followed by once-weekly subcutaneous doses at 1.5 mg/kg (body weight)

＜Precautions related to DOSAGE AND ADMINISTRATION＞

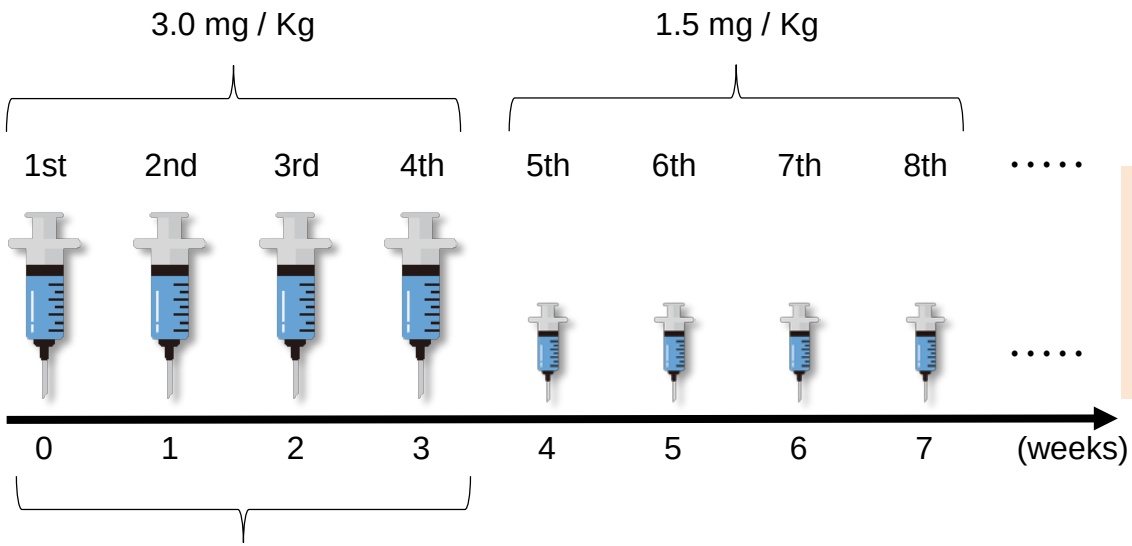
HEMLIBRA should be used in routine prophylaxis to prevent or reduce the frequency of bleeding episodes and should not be used for on-demand hemostatic treatment.

Source：HEMLIBRA® Package insert（version 3 as of May 2018）

HEMLIBRA
Timing and Dosage of Administration

Illustration of HEMLIBRA administration

Discontinue BPA prophylaxis by the day before the start of HEMLIBRA treatment.



If HEMLIBRA treatment is discontinued, do not use BPA prophylaxis for six months thereafter.

Administration at specialized medical facilities are recommended for the first four administration until stable blood concentration is achieved

Start self-administration at home after training at medical facilities

Source：HEMLIBRA® Subcutaneous Injection Appropriate Use Guide（as of May 2018）

Conditions for Approval

1. A risk management plan should be created and appropriately implemented.

2. Because the number of participants in Japanese clinical trials was very limited, post-marketing drug use surveillance of all patients receiving HEMLIBRA treatment should be conducted until data for a certain number of patients have been accumulated, in order to understand background information on people using HEMLIBRA as well as to collect safety and efficacy data on HEMLIBRA promptly, and take necessary measures for the appropriate use of HEMLIBRA.

3. Early phase post-marketing vigilance should be conducted.

Source：HEMLIBRA® Package insert（version 3 as of May 2018）

Overview of HEMLIBRA RMP

Overview of RMP Regarding HEMLIBRA® Subcutaneous Injection 30 mg, 60 mg, 90 mg, 105 mg, 150 mg

Product name	HEMLIBRA® Subcutaneous Injection	Active ingredient	emicizumab (genetical recombination)
Company	Chugai pharmaceutical Co., Ltd.	Therapeutic classification	876349

1.1. Safety concerns

【Important identified risks】	【Important potential risks】	【Important missing information】
Thromboembolic events (associated with emicizumab and aPCC)	Thromboembolic events (associated with emicizumab and FVIIa/FX)	Not applicable
Thrombotic microangiopathy (associated with emicizumab and aPCC)	Thrombotic microangiopathy (associated with emicizumab and FVIIa/FX)	
	Serious bleeding due to inadequate control of bleeds based on coagulation test interference by emicizumab	
	Shock, Anaphylaxis	
	Immunogenicity	

1.2. Efficacy concerns

Inhibitory effect on bleeding of long-term use in hemophilia A with inhibitors to FVIII

▼ Safety monitoring activities

2. Overview of pharmacovigilance plan

Routine activities:

- Evaluation of case report, research report, and overseas action
- Periodic signal detection and evaluation of AE (including death)

Additional activities:

- Post-marketing surveilance
- Postmarketing clinical trials in people with hemophilia A with inhibitors（ACE002JP,BH29884,BH29992）
- Drug use surveillance programs

3. Overview of surveys and trials on efficacy

- Postmarketing clinical trial in people with hemophilia A with inhibitors（ACE002JP）

▼ Risk minimization activities

4. Overview of risk minimization activities

Routine activities:

- Precaution by J-PI
- Patients Guides

Additional activities:

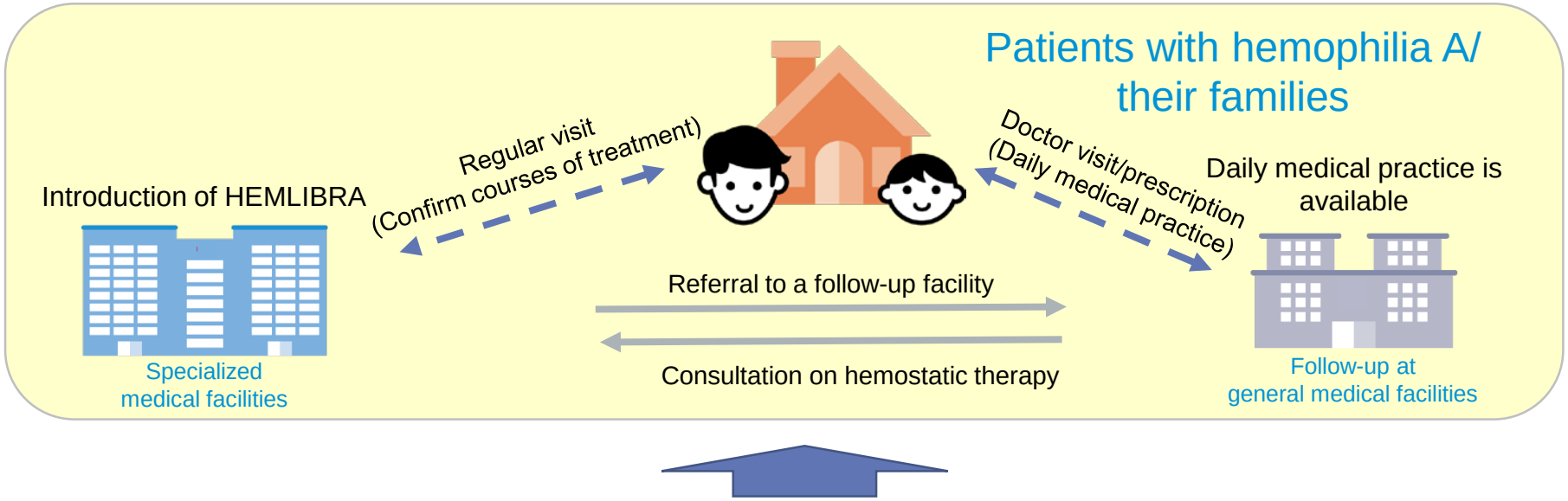
- Providing information through the post-marketing surveillance
- Restricted Access
- Provision of information to healthcare professionals（Appropriate Use Guide）
- Provision of information to patients（Handbooks for patients）

aPCC：Activated prothrombin complex concentrate
FVIIa/FX：Freeze-dried activated human blood coagulation Factor VII concentrate containing Factor X

Source：HEMLIBRA® Subcutaneous Injection Appropriate Use Guide（as of May 2018）

Structure to Promote Proper Use of HEMLIBRA

- A structure to ensure safety has been established through the nationwide assignment of MRs specialized in HEMLIBRA and collaboration with safety experts and medical science liaisons.



Innovation all for the patients

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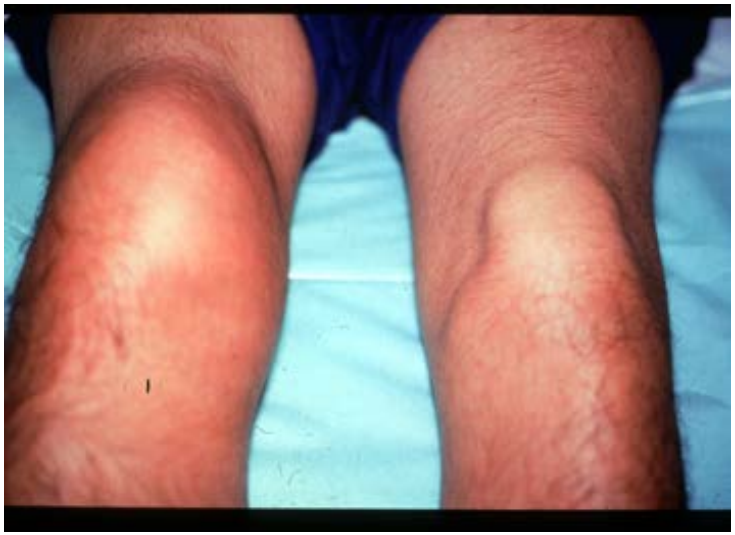
Safety Experts

Specialized MRs and General MRs

Medical Science Liaisons

Current Status of Hemophilia Treatment and Expectations for HEMLIBRA



Professor Midori Shima, M.D., PhD.
Department of Pediatrics

Nara Medical University

Conflicts of Interest

Presenter: Midori Shima

Affiliation: Nara Medical University

- Lecture fees etc.
  Roche, Chugai, Bayer, Bioverativ Japan, CSL Behring, Novo Nordisk, Baxalta, Pfizer

- Research expenses
  Chugai, Bayer, CSL Behring, Novo Nordisk, Baxalta, Pfizer

The World's Oldest Text concerning Hemophilia

The Talmud—the Jewish holy book

"If the first son is circumcised and bleeds, and the second son does similarly, the third son must not be circumcised."

Nashim (Laws on marriage, divorce, and vows)

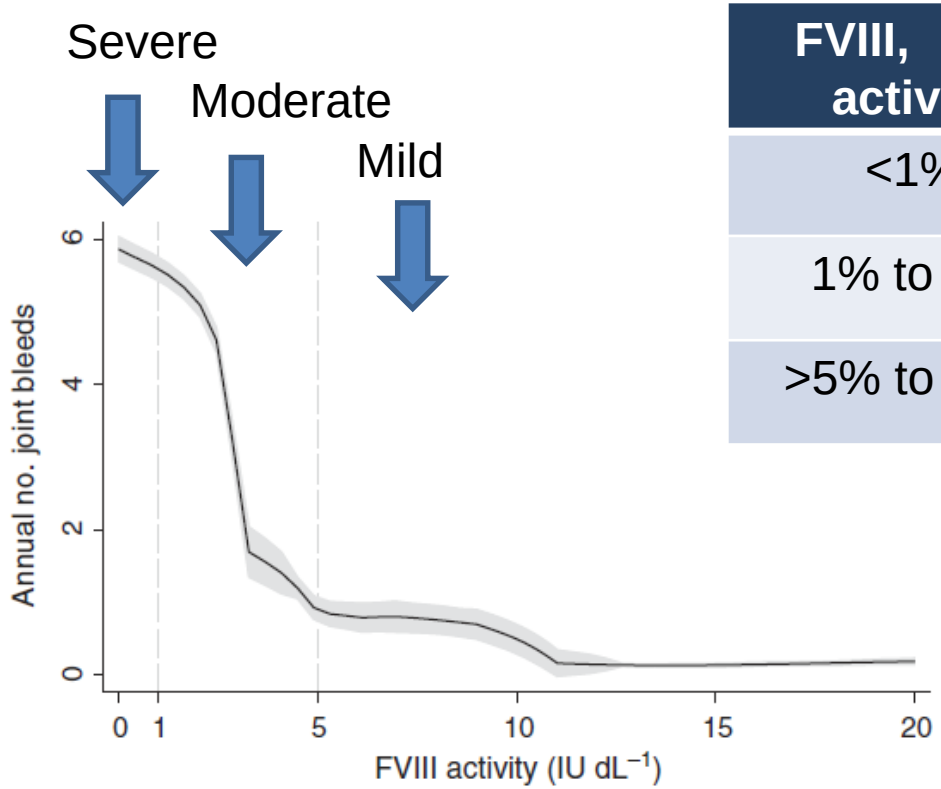
Numbers and Inheritance Modes of Surviving Patients with Congenital Coagulation Disorders in Japan

Disease	No. of pts	Inheritance mode
Hemophilia A	5,326	XLR
Hemophilia B	1,129	XLR
Hemophilia AB	2	XLR
Von Willebrand disease	1,283	AD, AR
Congenital fibrinogen deficiency, low or impaired	75	AD, AR
Congenital prothrombin deficiency, low or impaired	7	AR
Congenital Factor V deficiency, low or impaired	45	AR
Congenital Factor VII deficiency, low or impaired	106	AR
Congenital Factor X deficiency, low or impaired	23	AR
Congenital Factor XI deficiency, low or impaired	39	AR
Congenital Factor XII deficiency, low or impaired	31	AR
Congenital Factor XIII deficiency, low or impaired	72	AR
Congenital Factor V/VIII deficiency, low or impaired	7	AR

XLR: X-linked recessive; AD: autosomal dominant; AR: autosomal recessive

Source:Project entrusted by Ministry of Health, Labour And Welfare. Nationwide Survey on Coagulation Disorders 2017. Published by Japan Foundation for AIDS Prevention.

Number of Bleeds and Differences in FVIII Activity



FVIII, FIX activity	classification
<1%	Severe
1% to 5%	Moderate
>5% to 30%	Mild

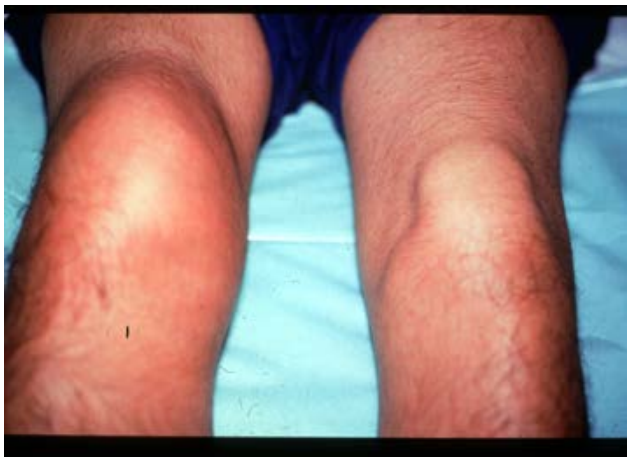
Uijl et al. Haemophilia 2011

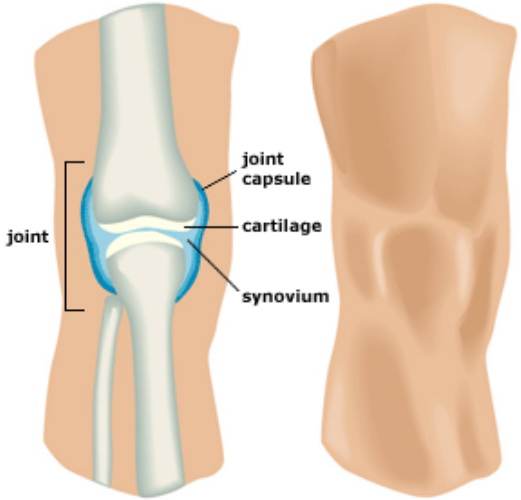
Number of Treated Bleeds by Bleeding Site in Hemophilia

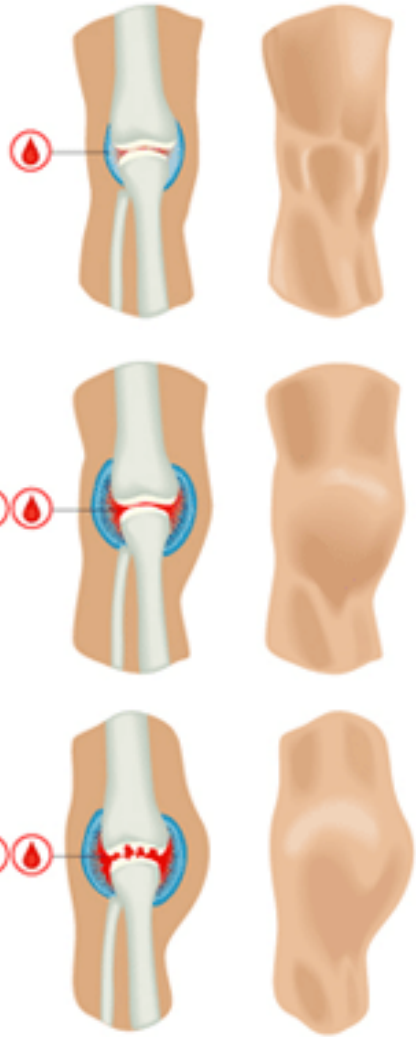
Type of bleed	No. of bleeds
Joint bleed	1,776 (60.8%)
Muscle bleed	446 (15.3%)
Subcutaneous bleed	328 (11.2%)
Nosebleed	68 (2.3%)
Blood in urine	45 (1.5%)
Mouth bleed	41 (1.4%)
Gastrointestinal bleed	8 (0.3%)
Others	159 (5.4%)
Unknown	18 (0.6%)
Total	2,920 (100%)

Source：Kogenate interview form Revised, http://www.bayer-hv.jp/hv/products/if/kobs.pdf

Joint Bleeding and Hemophilic Arthropathy



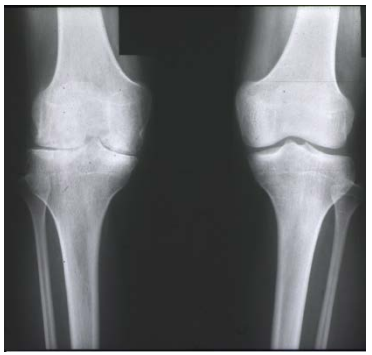


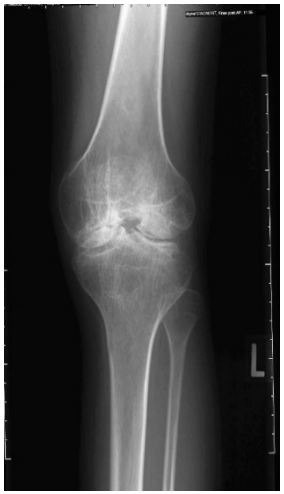


Bubbling
Tingling
Heat

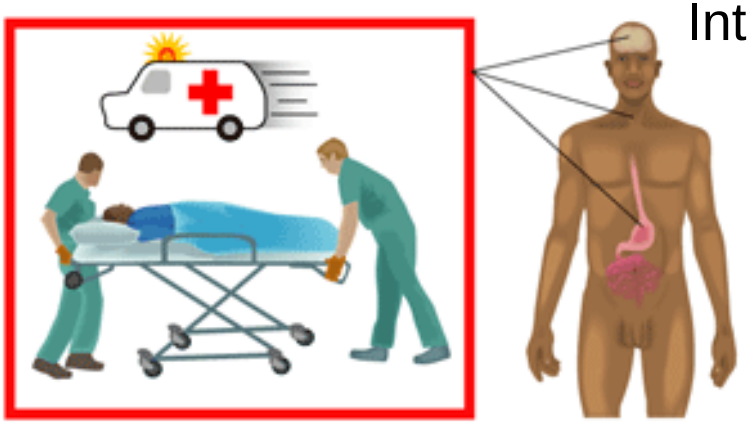
Swelling
Pain
Heat

Boggy
Swollen
Muscle Wasting
Morning Stiffness
Chronic Pain
Limited Movement





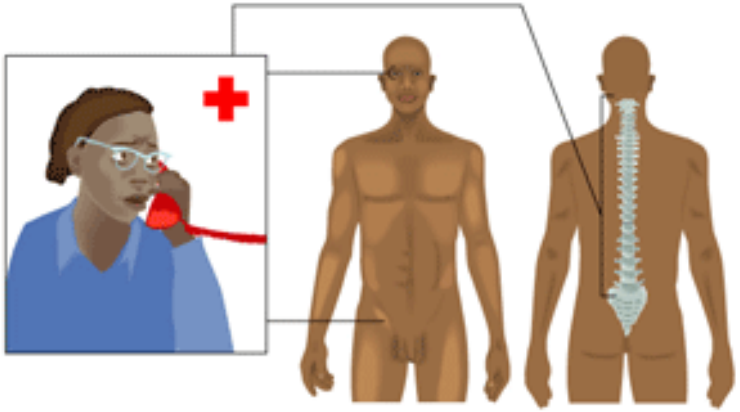
Severe Bleedings



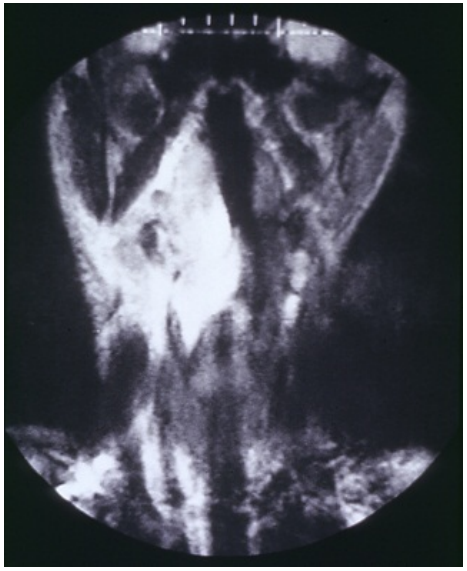
Intra-cranial

Cervical

Gastrointestinal



Spine



Hemostatic Treatment and Drug Products for Hemophilia

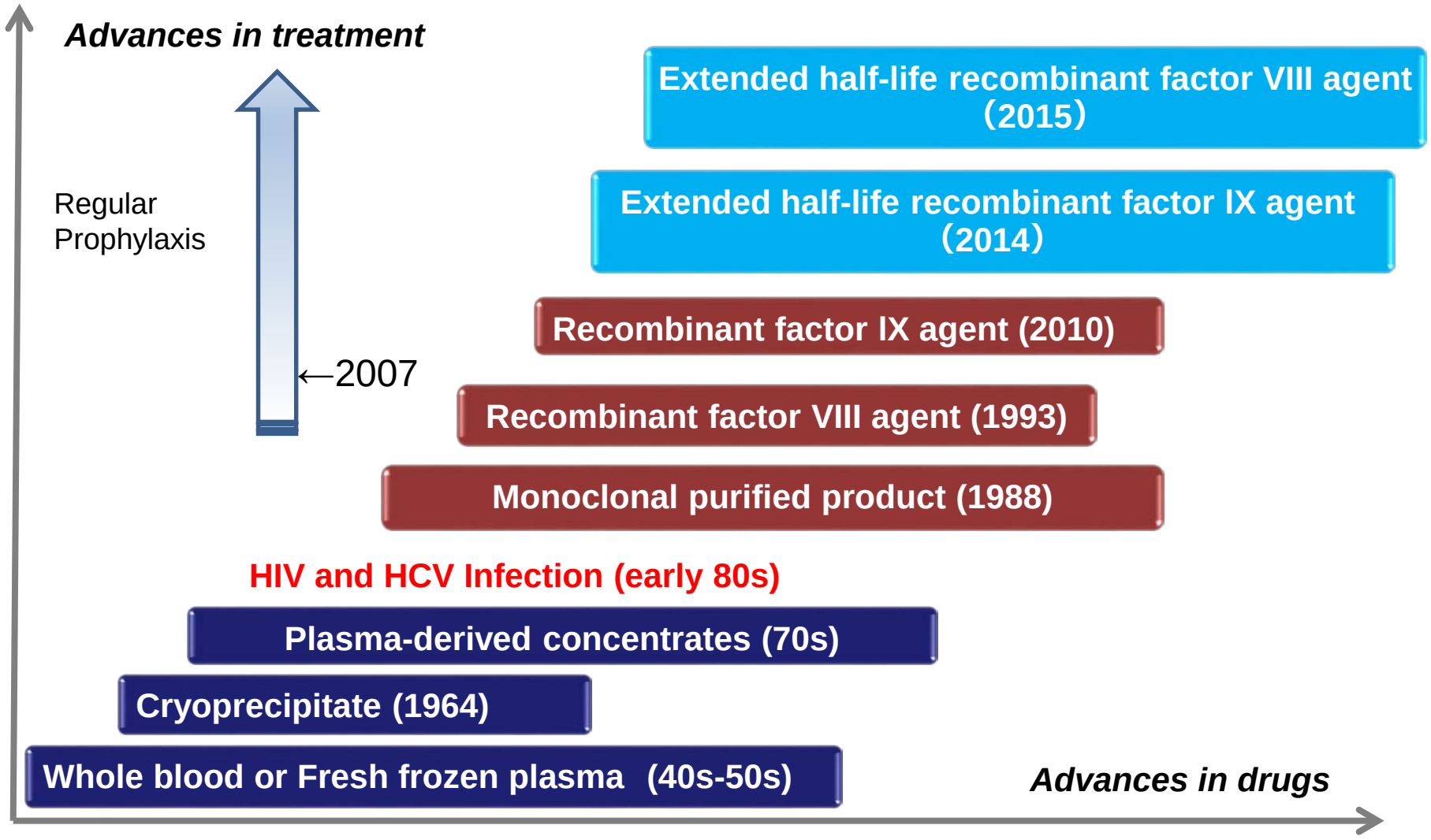
Replacement therapies

- **Hemophilia A: Factor VIII products**
  - Recombinant products
  - Plasma-derived products
- **Hemophilia B: Factor IX products**
  - Recombinant products
  - Plasma-derived products

Other hemostatic therapies

- **Desmopressin acetate (DDAVP)**
- **Tranexamic acid**

Advances in Treatment for Hemophilia



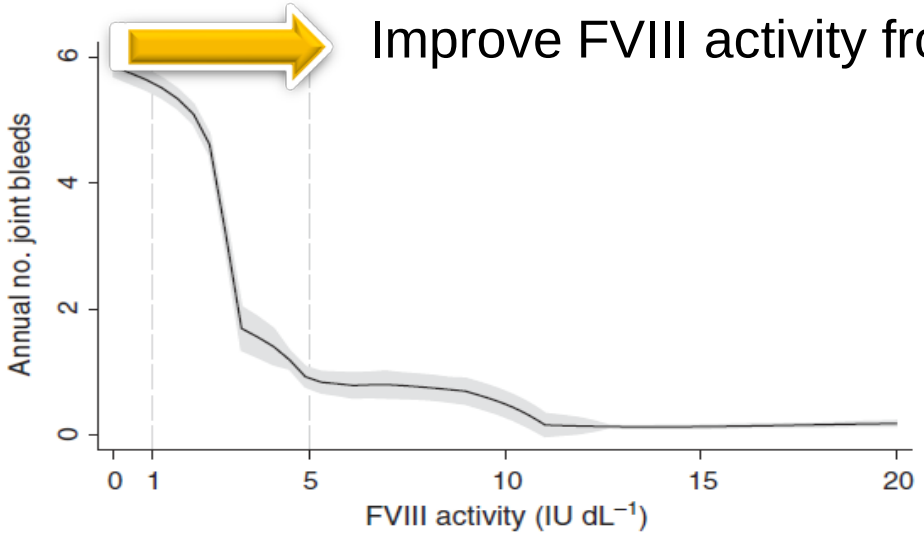
1. Wong T, Recht M. *Drugs.* 2011: 71: 305-320
2. Franchini & Manucci. Orphanet Journal of Rare Diseases. 2012: 7: 24

Principle of Hemophilia Treatment

On demand

Regular prophylaxis

Improve FVIII activity from severe to moderate



Uijl et al. Haemophilia 2011

Types of Regular Prophylaxis

- **Primary regular prophylaxis**

  <2 years of age or >1 joint bleed

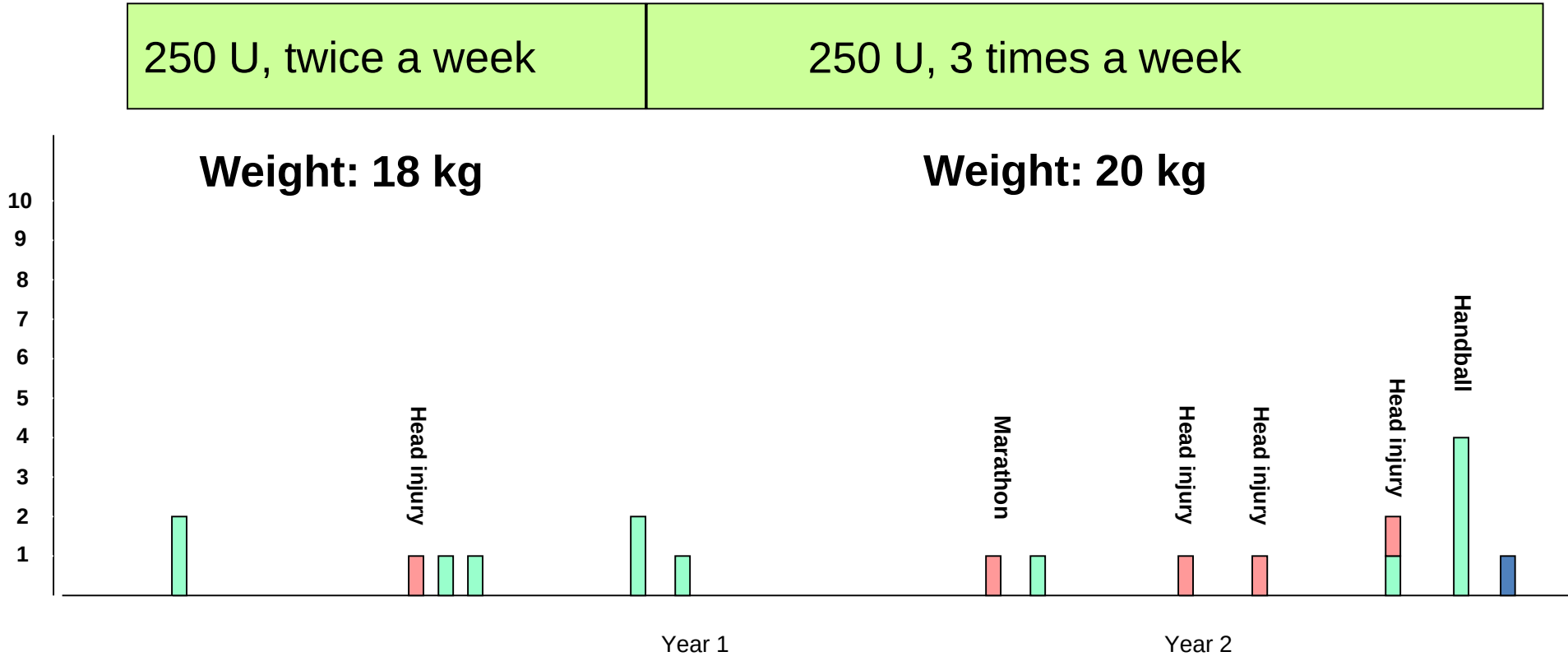
  Severe disease

  25 – 40 U/kg, 3 times a week or every other day

- **Secondary regular prophylaxis**

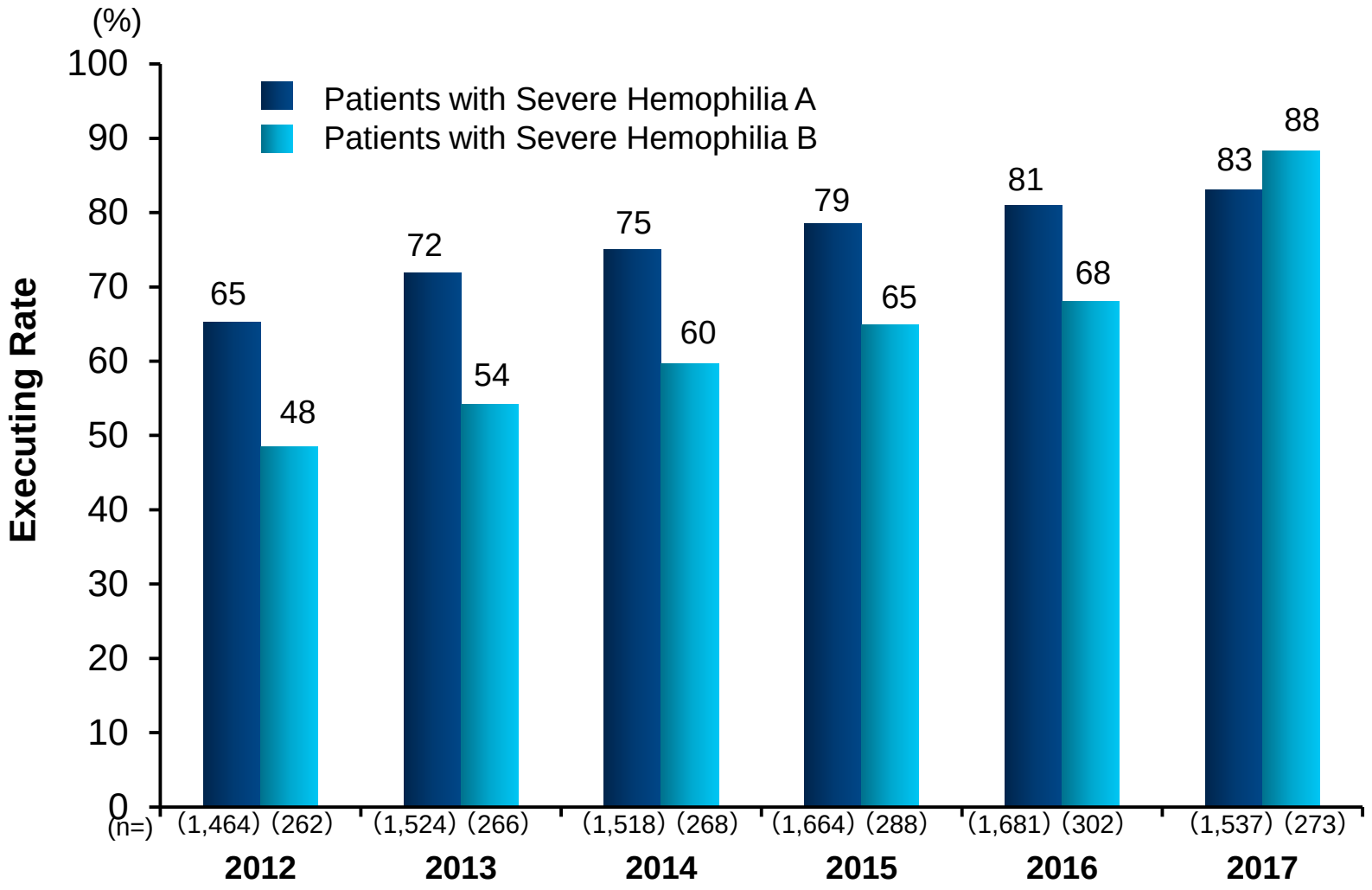
Patient Receiving Regular Prophylaxis

Patient: MS
Severe hemophilia A
Age at onset: 6 years



Source: Clinical case at Nara Medical University, Department of Pediatrics. This is an example of one clinical case. The clinical result does not apply to all cases.

Ratio of Patients with Severe Hemophilia Receiving Regular Prophylaxis



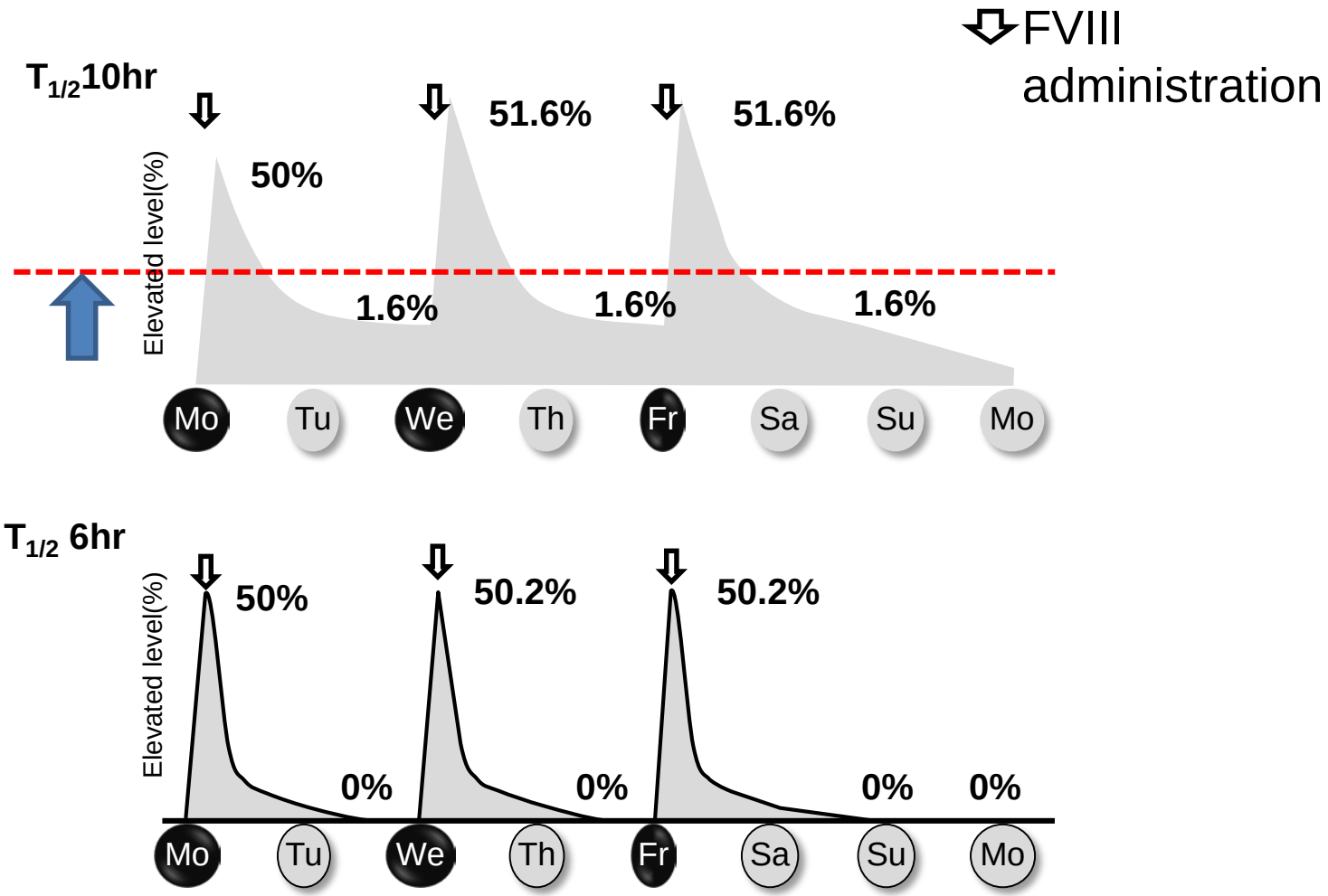
Source: Project entrusted by Ministry of Health, Labour And Welfare. Nationwide Survey on Coagulation Disorders 2017.
Published by Japan Foundation for AIDS Prevention.

Unmet Needs in Hemophilia Treatment

- Need for frequent intravenous injections
- The problem of inhibitors
  (anti-FVIII, IX allo-antibodies)
- Progression of hemophilic arthropathy
- Prevention of microhemorrhage
- Maintain higher trough levels
- Problems of medical expenses

Changes in FVIII Concentrate

Regular Prophylaxis 25 IU/kg, 3/W Dosing



Source: Clinical case at Nara Medical University, Department of Pediatrics. This is an example of one clinical case. The clinical result does not apply to all cases.

Problems of Inhibitors

- **Allo-antibodies**

  Antibodies that recognize Factor VIII or Factor IX in drug products as non-self

- **Inhibitor titer**

  High titer: ≥5 BU/mL
  Low titer: <5 BU/mL

- **Inhibitor responsiveness**

  Low responder
  High responder
  Transient

Why is the Development of Inhibitors a Problem?

- Reduction / disappearance of hemostatic effect of FVIII, the standard of care
- Increase in bleeding
- Increase in target joints
- Rapid progress in arthropathy
- Reduction of physical activity
- Reduction of quality of life

Clinical deterioration will have a significant impact on patient's life, and make treatment more difficult

Treatment for Inhibitor Patients

Hemostasis during acute bleeding episodes or surgery

- Inhibitor neutralization: replacement products
- Hemostasis with bypassing agents:

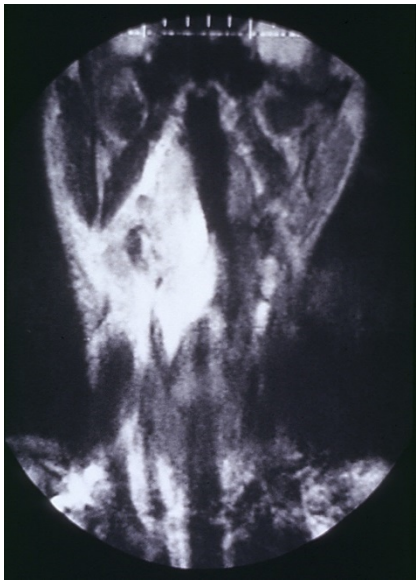
  Activated prothrombin complex concentrate

  Recombinant activated Factor VII

Treatment to prevent bleeding

Treatment to eliminate inhibitors

- Immune tolerance induction (ITI) therapy
  - The success rate of ITI therapy in the good risk group is about 70%
  - There are no effective inhibitor treatment options for patients in the bad risk group



A patient with cervical bleeding who presented dyspnea

*Source：Blood Products Research Organization ”Survey on immune tolerance induction therapy for hemophilia with inhibitors” 57 sites, (2000 and beyond)

Treatment Cost for Hemophilia

■ Hemophilia A

- Without inhibitors
  - 1000 IU（74,000 yen/unit）

    3　injections / week：approx. 10 million yen / year

    3.5　injections / week：approx. 12 million yen / year

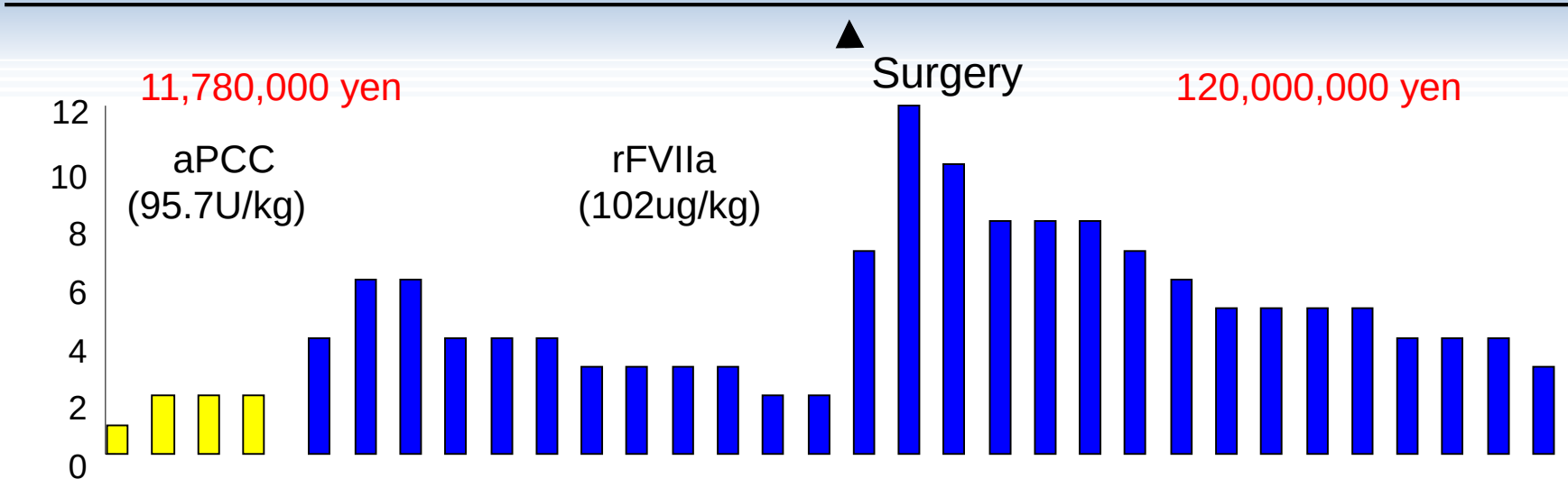
  - 2000 IU

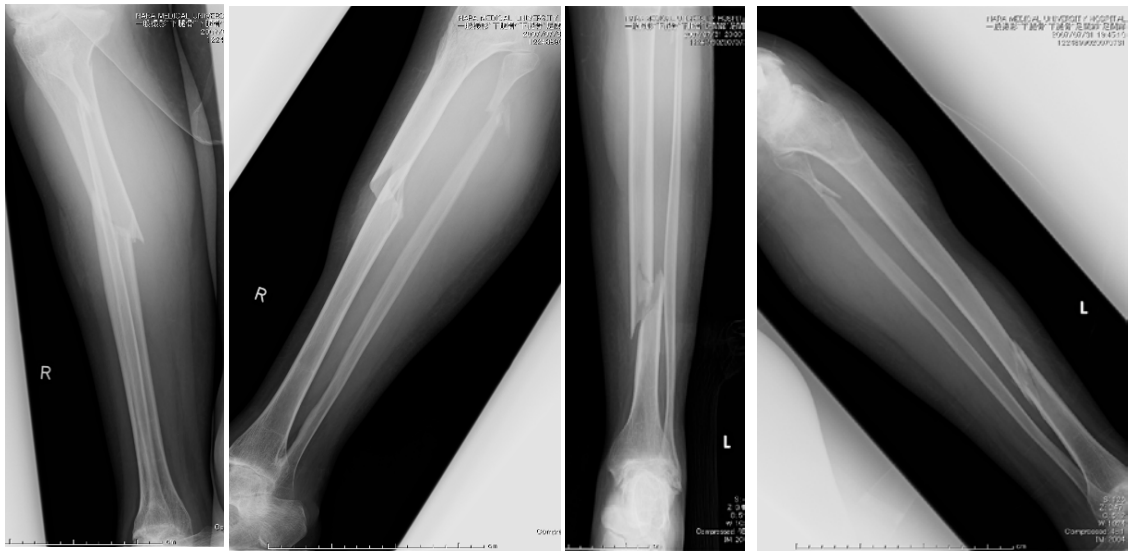
    3　injections / week：approx. 21 million yen / year

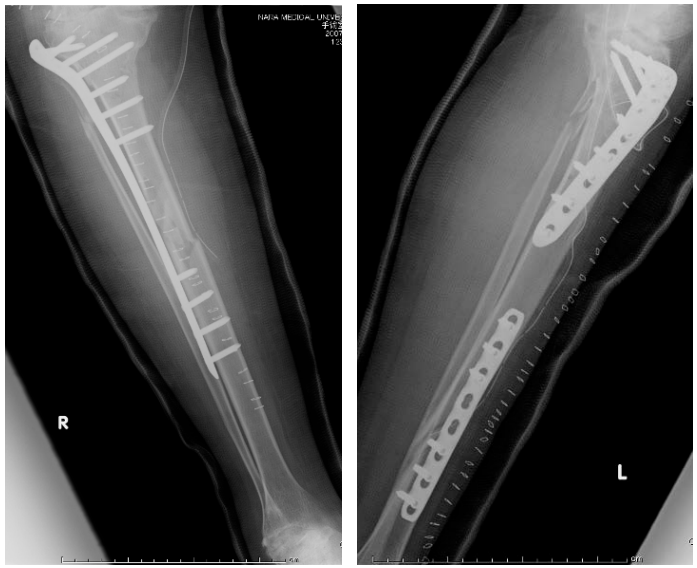
    3.5　injections / week：approx. 25 million yen / year

- With inhibitors

  approx. 60～100 million yen/year







Traumatic six bone fractures in a patient with high responding inhibitors

Source: Clinical case at Nara Medical University, Department of Pediatrics. This is an example of one clinical case. The clinical result does not apply to all cases.

Top 10 High Cost Medical Care in 2016

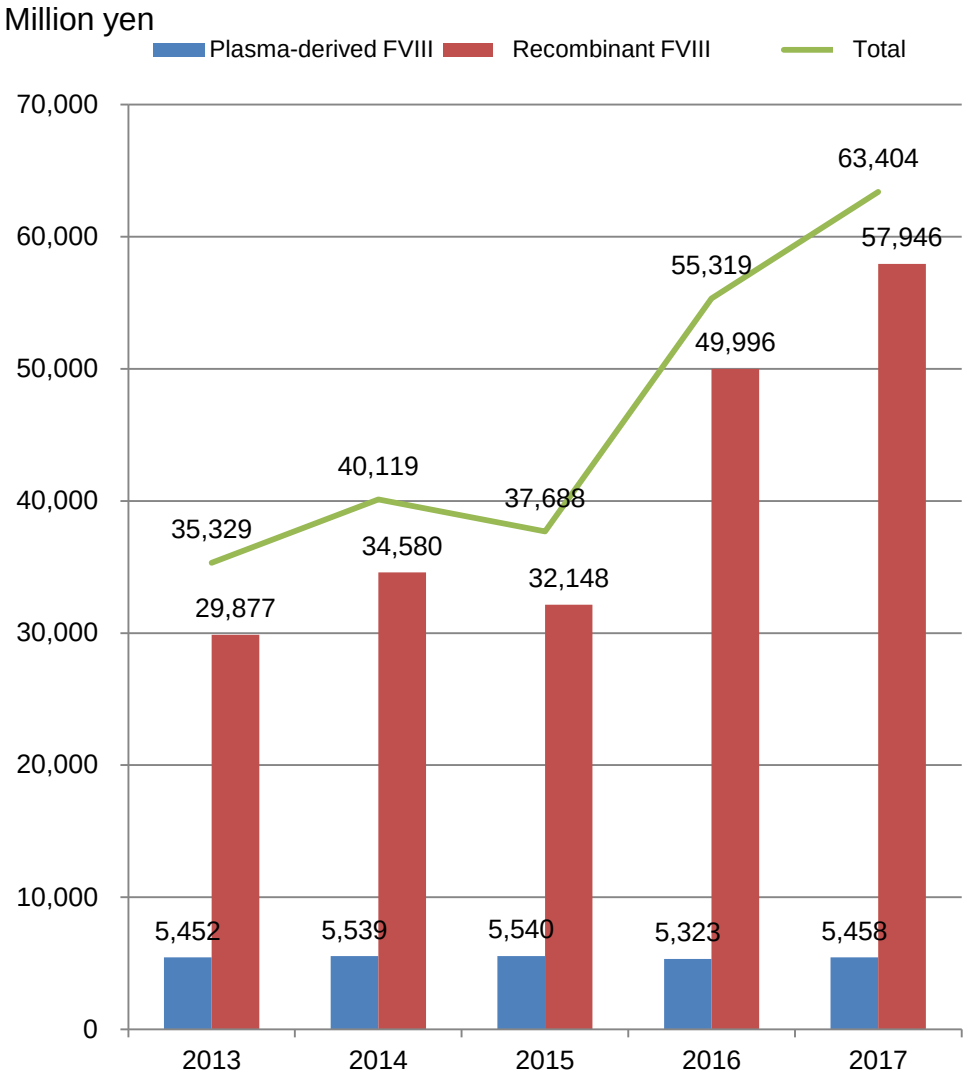
	Disease	Cost(Yen) / Month
1	Von Willebrand disease	106,941,690
2	Hemophilia A	102,379,460
3	Hemophilia A	70,229,710
4	Hemophilia A	50,427,470
5	Hemophilia A	49,941,080
6	Hemophilia A	45,902,330
7	Hemophilia A	41,049,330
8	Hemophilia A	41,049,330
9	Hemophilia A	40,780,090
10	Hemophilia A	37,268,590

Top100：

Hemophilia A: 23, Hemophilia B: 6, Heart disease： 47

Source: National Federation of Health Insurance Societies “H28 overview of expensive receipts for reimbursement”

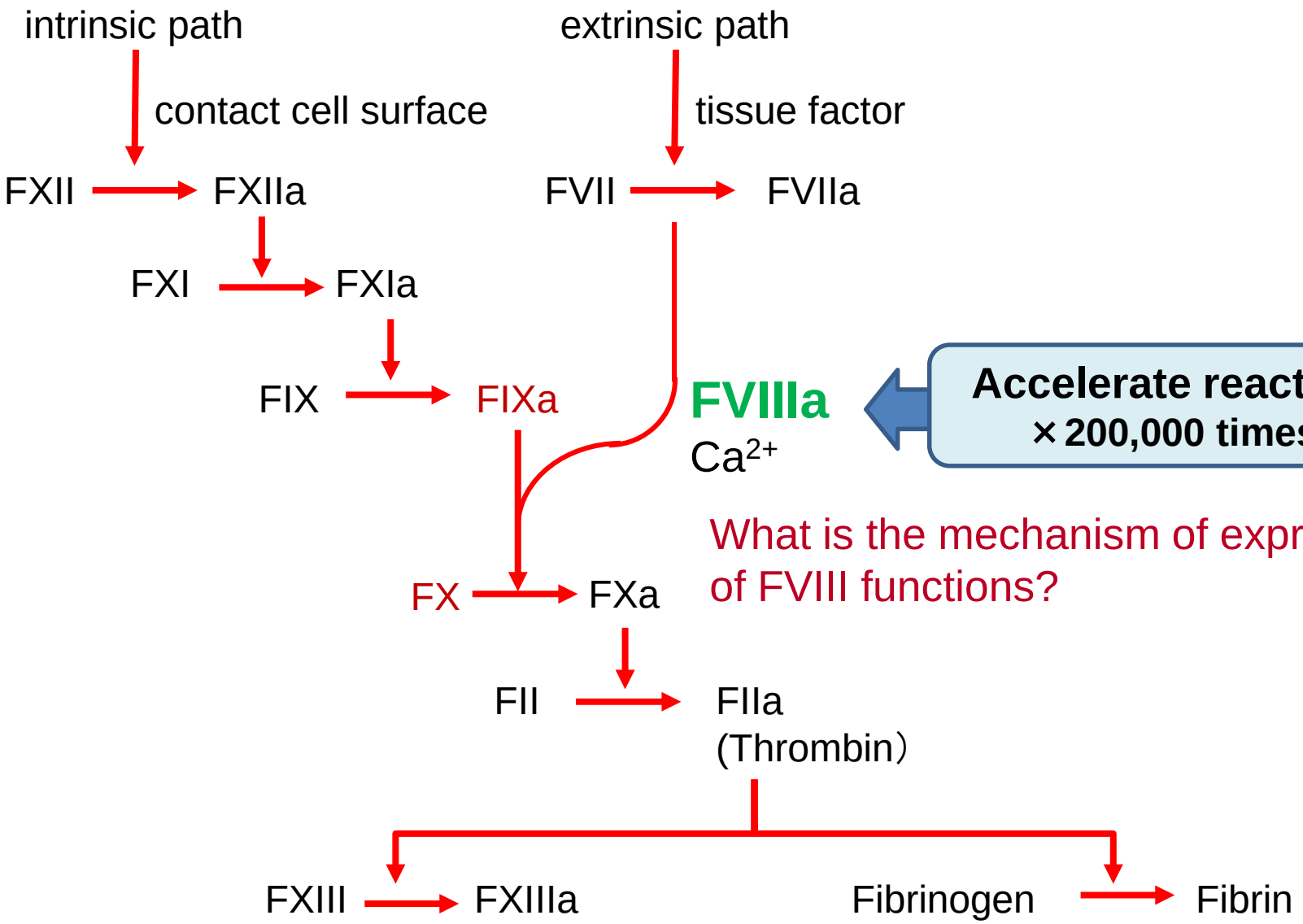
Total Costs of FVIII Agents (2013-2017)



63.4 billion yen + / year

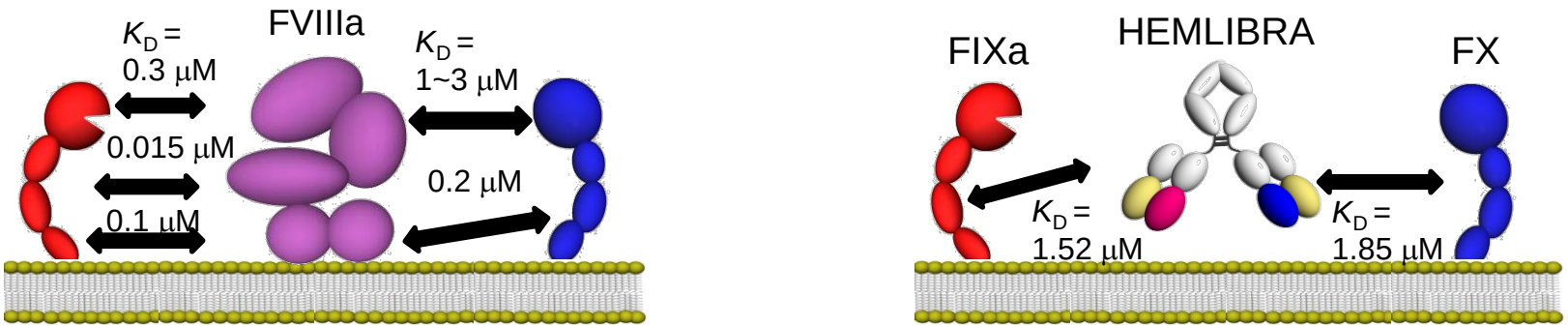
Created based upon data from "H24-28 Draft plans for stable supply of blood derivatives"

Coagulation Cascade



Source: Hideo Wada "Hemostatic mechanism, Seeing diseases, vol.5 Blood", 2nd edition, Medicmedia, Tokyo, 2017,pp.210-219, partially modified

FVIIIa Function and Concept of FVIIIa-Mimetic Bispecific Antibodies



[conceptual illustration]

Benefit of treatment with FVIII-mimetic bispecific antibody

- Subcutaneous injection is possible
- Long-acting (half-life, 30 days)
- Effective also in inhibitor patients
- Inhibitors against factor VIII not produced

Kitazawa T, Shima M et al. *Thromb Haemost* 2017; 117 (7): 1346-1357; Fay PJ, Koshibu K. *J Biol Chem* 1998; 273 (30): 19049-19054; Lenting P et al. *J Biol Chem* 1996; 271 (41): 25332-25337; Soeda T, Shima M et al. *J Biol Chem* 2009; 284 (6): 3379-3388; Lapan KA, Fay PJ. *J Biol Chem* 1997; 272 (4): 2082-2088; Takeyama M et al. *Biochemistry* 2012; 51 (3): 820-828.

Development of HEMLIBRA for Hemophilia A with Inhibitors

Chugai
Antibody engineering technology

2003

Dept. of pediatrics, NMU
FVIII mimicking function
Treatment of hemophilia
Experience of clinical studies

2012 Phase 1：Healthy adults (in Japan, Chugai)

2013 Phase1/2：Hemophilia A (in Japan, Chugai)

2015 Phase 3（international, Roche, Genentech, Chugai）

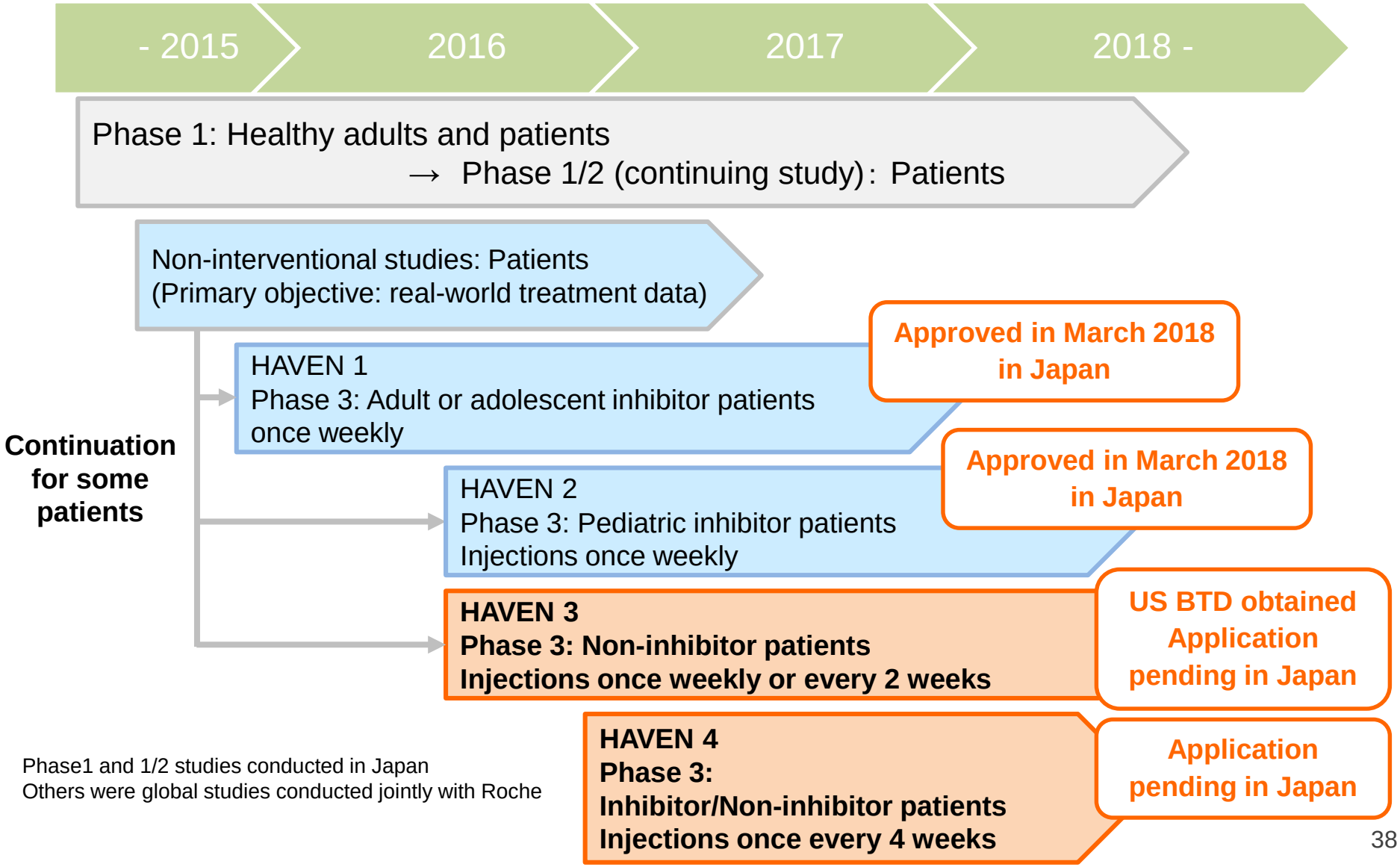
2015
Breakthrough therapy designation by FDA

2017（16th November） Approval from FDA

2018 （27th February） Approval from EMA

2018 （23rd March） Approval from MHLW

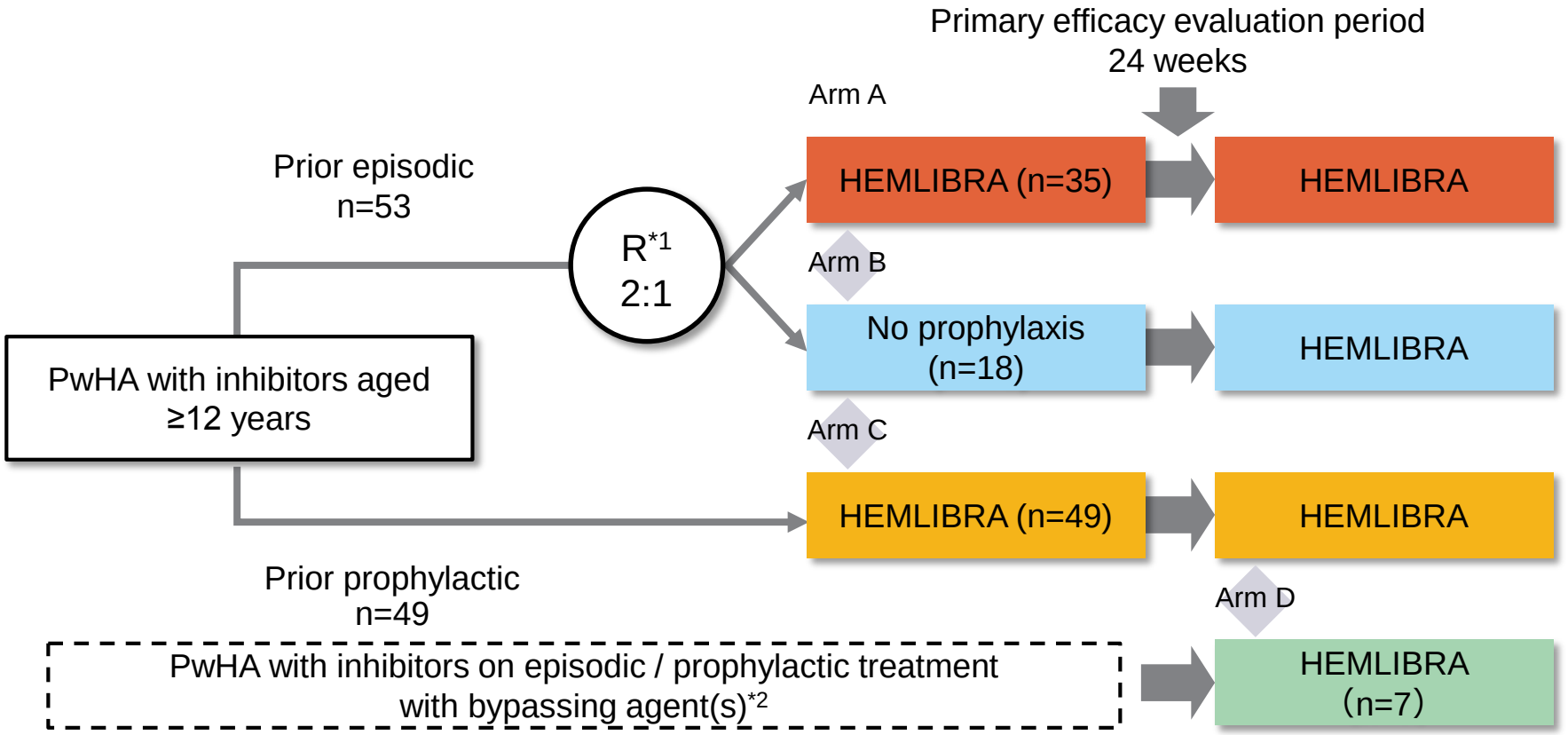
Clinical Development of HEMLIBRA



Phase1 and 1/2 studies conducted in Japan
Others were global studies conducted jointly with Roche

HAVEN 1: Study Design

Patients were enrolled from Arm A to C in accordance with how bypass agents were used prior to the study. Arm D enrolled those patients who were unable to register prior to the closure of the three arms.



. Bypassing agents (BPAs) were used to treat bleeds regardless of the use of HEMLIBRA

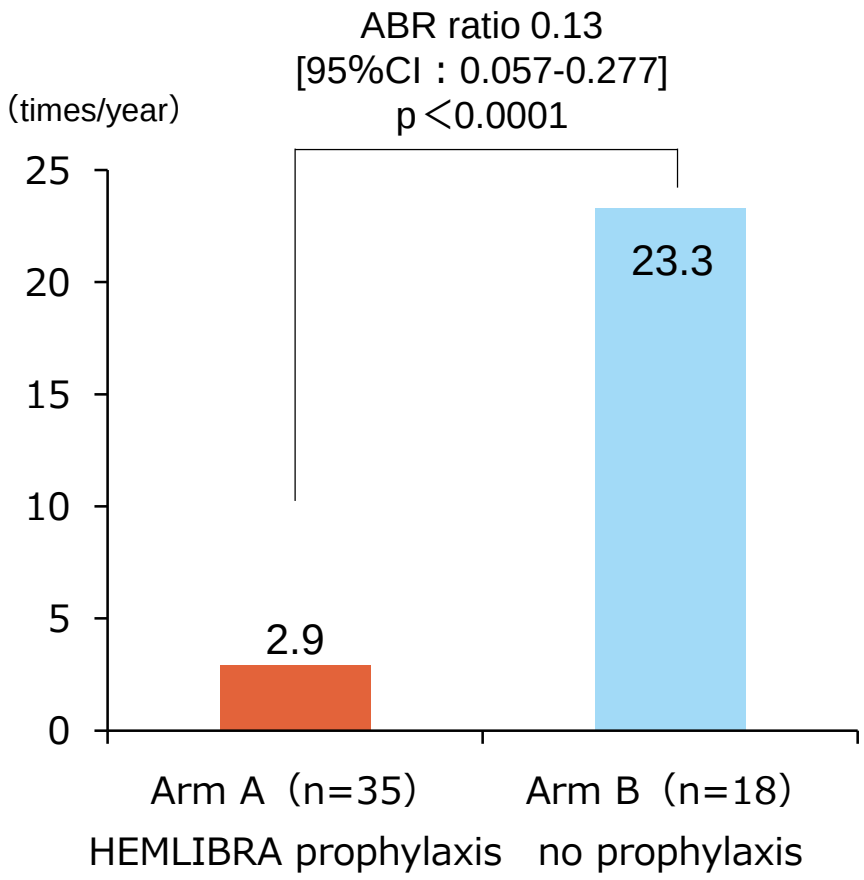
※1 Randomization factor（bleedings in 24 weeks prior to registration: less than nine, nine and more)
※2 Patients who were unable to enroll in the three arms before their closure were registered in Arm D to obtain additional efficacy, safety, PK and pharmacodynamics data.
PwHA: patients with Hemophilia A

Source：Evaluation dossier for new drug approval, phase 3 global study（BH29884）

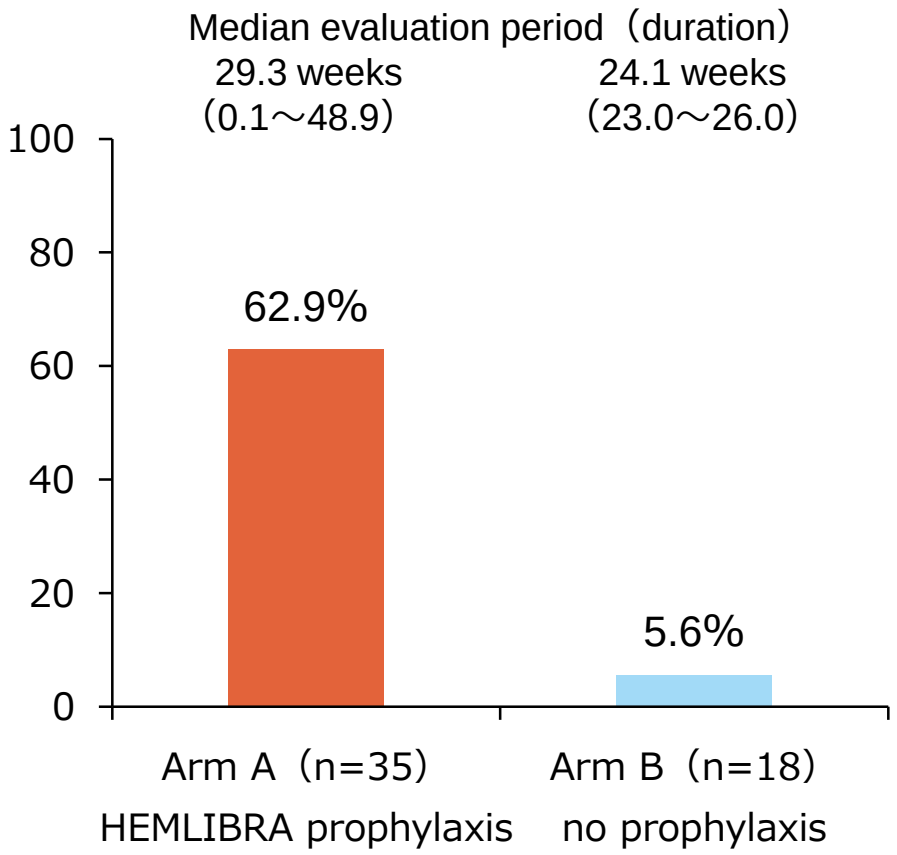
HAVEN 1：Treated Bleeds

HEMLIBRA prophylaxis（Arm A）vs no prophylaxis（Arm B）

Annual Bleeding Rate (ABR) of Treated Bleeds



Percentage of Treated Zero Bleeds

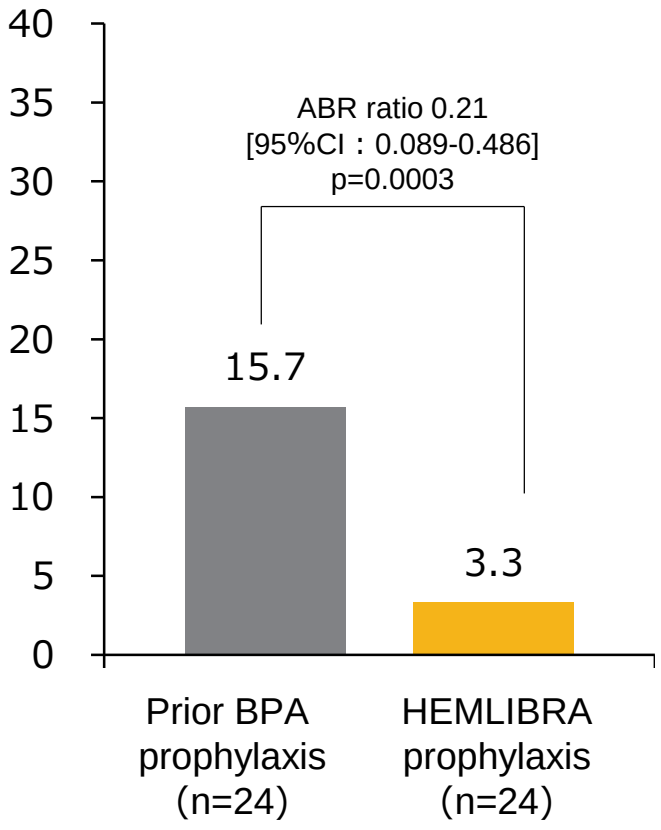


Source：Evaluation dossier for new drug approval, phase 3 global study（BH29884）

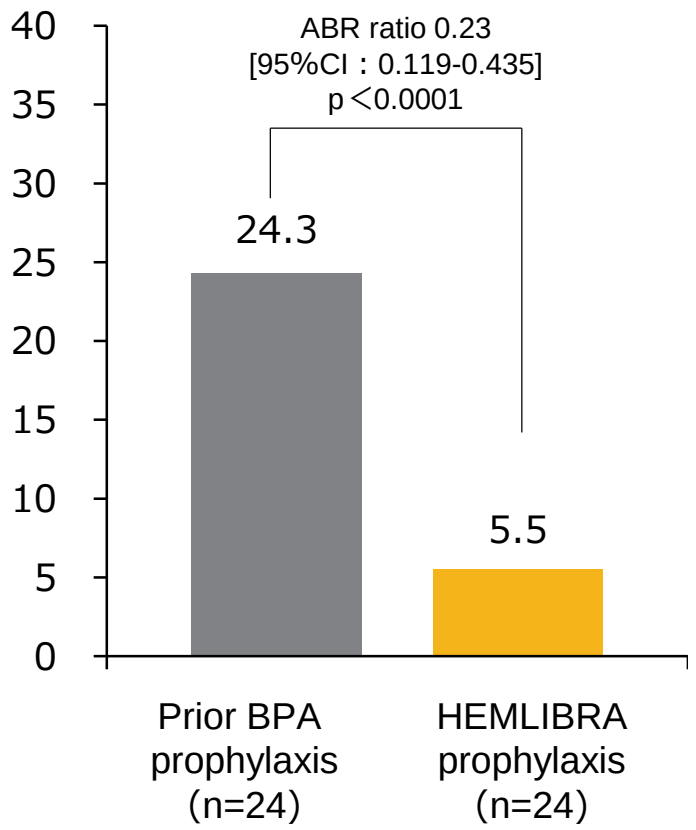
HAVEN 1：Treated Bleeds

Intra-individual comparison vs prior BPA prophylaxis（Arm C）

ABR of Treated Bleeds



ABR of All Bleeds



Source：Evaluation dossier for new drug approval, phase 3 global study（BH29884）

HAVEN 1: Safety Summary

Patients who received HEMLIBRA

	Total (N=103)
Total number of adverse events (AEs), n	198
Total patients ≥1 AE, n (%)	73 (70.9)
Serious AE*	9 (8.7)
Thrombotic microangiopathy (TMA)**	3 (2.9)
Thrombotic event	2 (1.9)
Death**	1 (<1)
AEs leading to withdrawal	2 (1.9)
Grade ≥3 AE	8 (7.8)
Related AE	23 (22.3)
Local injection-site reaction	15 (14.6)

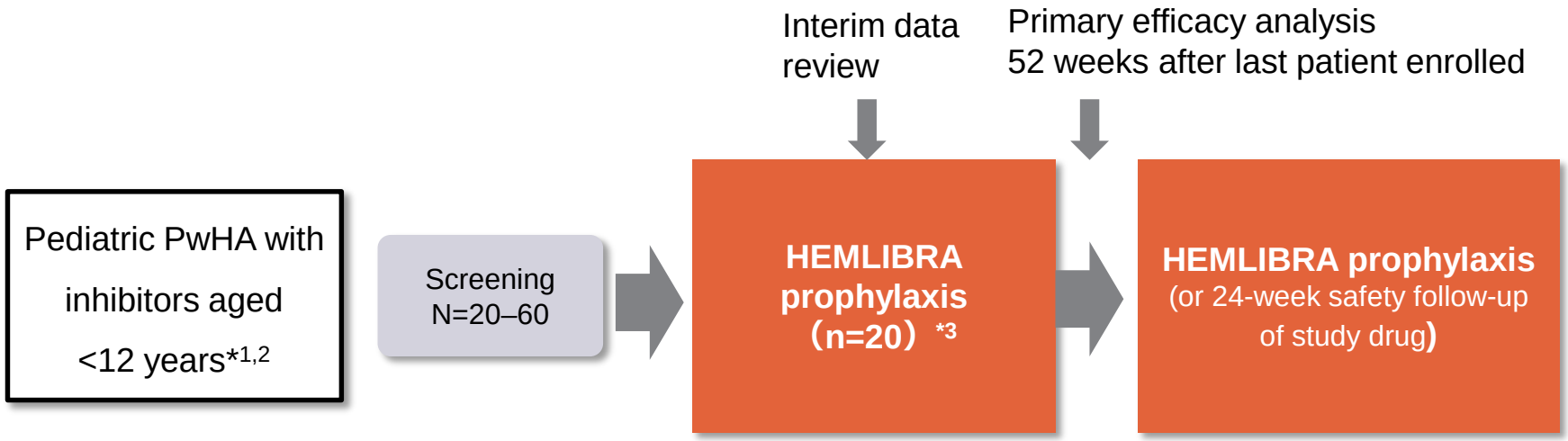
- **Third TMA event occurred after primary data cut-off; patient also experienced fatal rectal hemorrhage
- Thrombotic events were skin necrosis/superficial thrombophlebitis in one patient, and cavernous sinus thrombosis in a second patient
- No patients tested positive for anti-drug antibodies

*Additional serious AEs included one event each of: iron deficiency anemia, sepsis, hemarthrosis, muscle hemorrhage, gastric ulcer hemorrhage, headache and hematuria.Two additional withdrawals not related to AEs; one withdrawal by patient, one withdrawal due to physician decision.

Source：Johannes Oldenburg et al. ISTH 2017

HAVEN 2: Study Design

The target number of patients was 20 to 60.
Primary efficacy evaluation period is 52 weeks.
This interim analysis reviewed 20 patients.



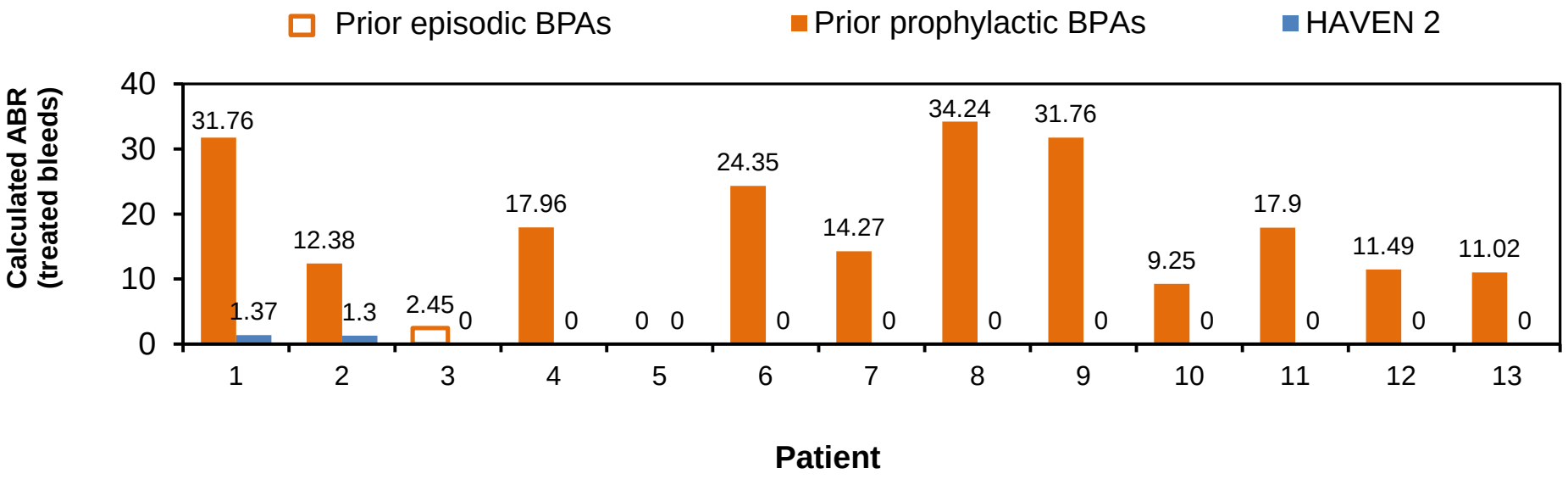
BPA were used to treat bleeds regardless of the use of HEMLIBRA

*1：Patients aged 2< were not included in the interim analysis as the patient registration was conducted in stages depending on the age category.
*2：Patients aged 12-17 were enrolled if body weight< 40 kg
*3：Number of patients registered at the time of the interim analysis

Source：Evaluation dossier for new drug approval, phase 3 global study（BH29992）

HAVEN 2: Intra-individual Comparison

vs prior BPA prophylaxis



Treated bleeds: 2 (2 patients, 1 per each) / 13 patients (observation period: 106 – 291 days)

Treated bleeds ABR reduced by 99%

Data sorted by HEMLIBRA ABR in descending order and then by descending efficacy period duration. Intraindividual comparison performed for 13 NIS patients on HAVEN 2 study for ≥12 weeks.

Source: Young et al. ASH 2017

HAVEN 2: Safety Summary

Adverse events, n (%)	HEMLIBRA 1.5 mg/kg QW (N=20)
Total number of AEs	43
Total patients experiencing ≥1 AE, n (%)	14 (70.0)
Serious AE	3 (15.0)
Grade ≥3 AE	3 (15.0)
Related AE	**3 (15.0)**
Local injection-site reaction	3 (15.0)

- Serious AEs: mouth hemorrhage, appendicitis, catheter-site infection
- **All related AEs were mild injection-site reactions (3 patients; 9 events)**
- No thromboembolic or thrombotic microangiopathy events observed
- No patients tested positive for anti-drug antibodies

Source：Guy Young et al. ISTH 2017

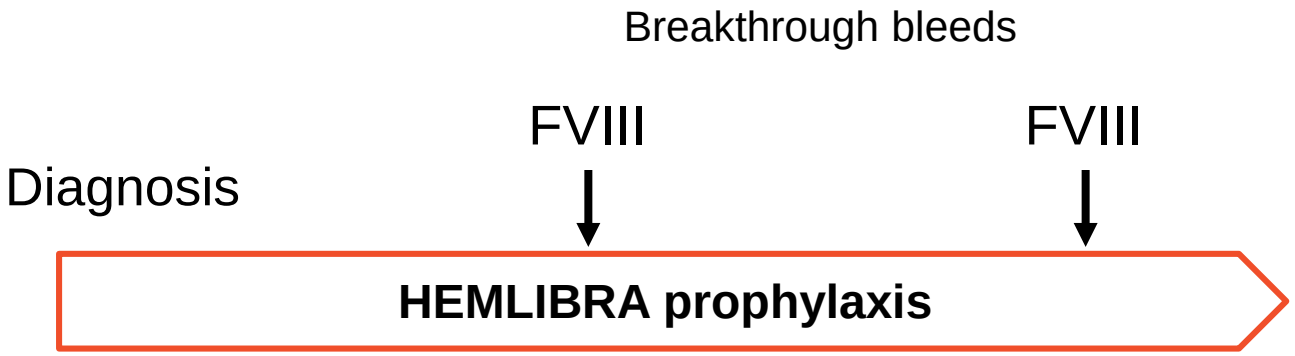
Phase III Studies of HEMLIBRA for Hemophilia A without Inhibitors

	Subjects	Interval	Initiation	Number of patients
HAVEN3	≧ 12 years, Non-inhibitor	Weekly Every 2 wks	Sep, 2016	152
HAVEN4	≧ 12 years, inhibitor, Non-inhibitor	Every 4 wks	Jan, 2017	48
HOHOEMI	<12 years Including PUPs Non-inhibitor	Every 2 wks Every 4 wks	Oct, 2017	13

PUPs: previously untreated patients

Source: NCT02847637, NCT03020160, JapicCTI-173710

Concept of Early Use of HEMLIBRA for Prophylaxis



Maintain Higher Trough Levels

- Zero bleeding
- Higher activity
- Intact joints
- Protect from subclinical bleeds
- Prevent intracerebral hemorrhage
- No induction of FVIII inhibitors
- No need of ITI

Paradigm Shift of Hemophilia A Treatment

- Zero Joint Bleeding
- Intact Joint
- Maintain Higher Trough Levels

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