

CATALYST BIOSCIENCES

December 18th 2018

Research & Development Day



Forward looking statements

This presentation includes forward-looking statements that involve substantial risks and uncertainties. All statements, other than statement of historical facts, included in this presentation are forward-looking statements. Examples of such statements include, but are not limited to, the potential benefits of subcutaneous administration of dalcinonacog alfa (formerly CB 2679d/ISU304) and marzeptacog alfa (activated), the potential for long-term dosing of dalcinonacog alfa to maintain FIX activity in the high-mild hemophilia range, statements relating to Catalyst's clinical trial timelines, including plans for a Phase 2b clinical trial of dalcinonacog alfa, including initiation in the first quarter of 2019 and presentation of data at ISTH, plans for a Phase 3 trial of dalcinonacog alfa, plans for the completion of the ongoing clinical trial of marzeptacog alpha (activated) and presentation of data at EAHAD and ISTH and for a Phase 3 trial of marzeptacog alfa (activated), and the potential market opportunities for these products. Actual results or events could differ materially from the plans and expectations and projections disclosed in these forward-looking statements.

Various important factors could cause actual results or events to differ materially from the forward-looking statements that Catalyst makes, including, but not limited to, the risk that trial initiation or enrollment may be delayed and that ongoing or future trials may not achieve their endpoints, that subsequent clinical trials will not replicate the results from earlier clinical studies on small numbers of patients, that potential adverse effects may arise from the testing or use of Catalyst's products, including the generation of antibodies or inhibitors, the risk that costs required to develop or manufacture Catalyst's products will be higher than anticipated, the risk of competition from other hemophilia treatments, including those in development, Catalyst's ability not to infringe third party intellectual property rights, and other factors described in the "Risk Factors" section of Catalyst's Quarterly Report on Form 10-Q for the quarter ended September 31, 2018, which was filed with the Securities and Exchange Commission on November 1, 2018. Forward looking statements in this presentation speak only as of the date hereof. Catalyst does not assume any obligation to update any forward-looking statements, except as required by law.



We are working to establish a **new** standard of care in **hemophilia prophylaxis** by developing highly potent **subcutaneous treatments** that improve the quality of life for patients with hemophilia with inhibitors, acquired hemophilia & hemophilia B



Investment highlights



Novel subcutaneous compounds with orphan drug designation



Market: \$3.4B in annual sales



2018

FVIIa & FIX SQ efficacy clinically demonstrated



Experienced team



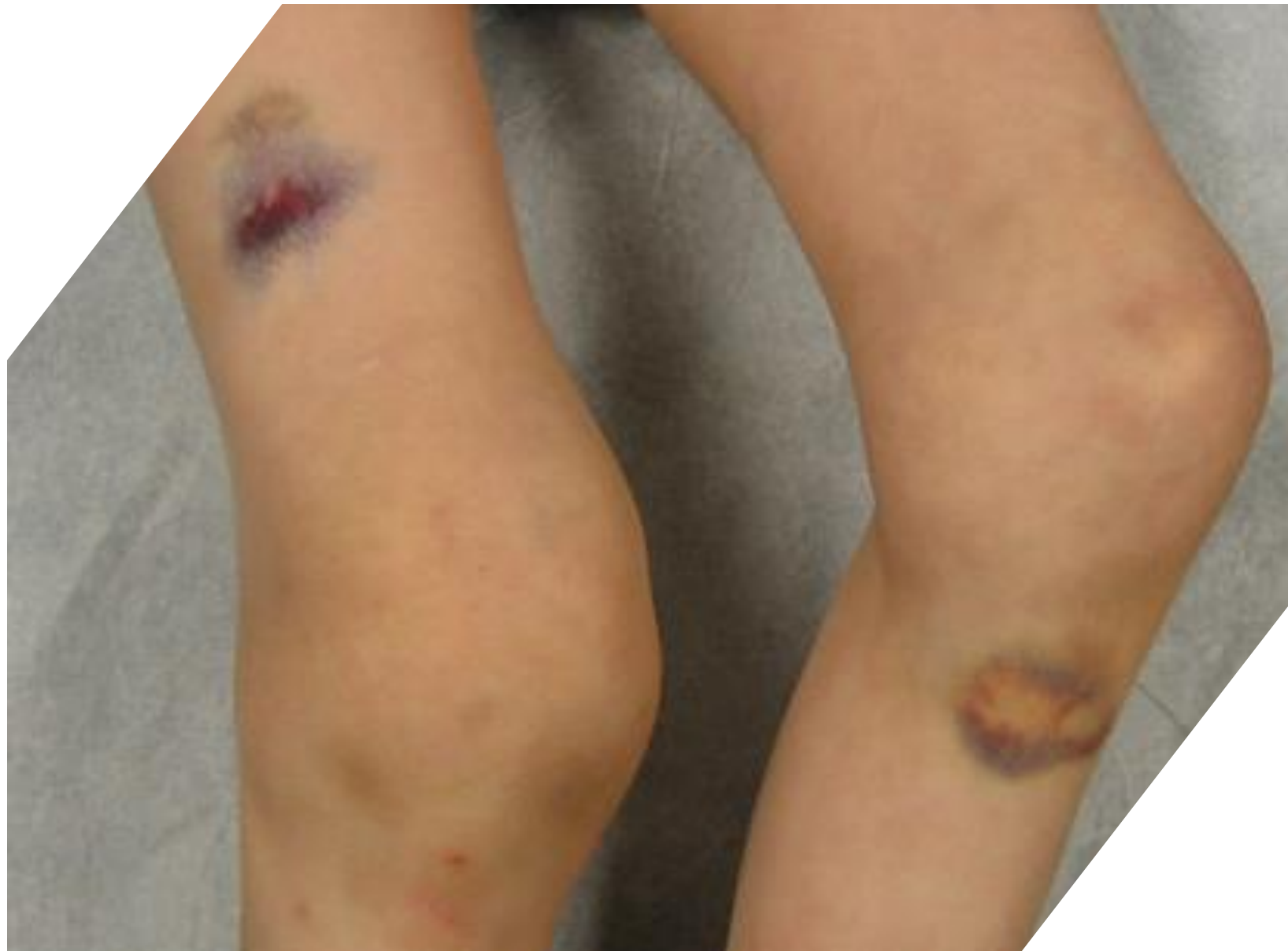
~134 worldwide patents – CBIO retains full ownership of all compounds



Well funded

\$129 M cash (Q3 2018)

Life with hemophilia



Hemophilia A or B – inhibitors

- A complication in factor replacement therapy that neutralizes the treatment
- 30% of Hem A (FVIII) patients and 5% of Hem B (FIX) patients develop inhibitors
- Patients are at high risk for hemorrhagic stroke and premature mortality

Hemophilia B

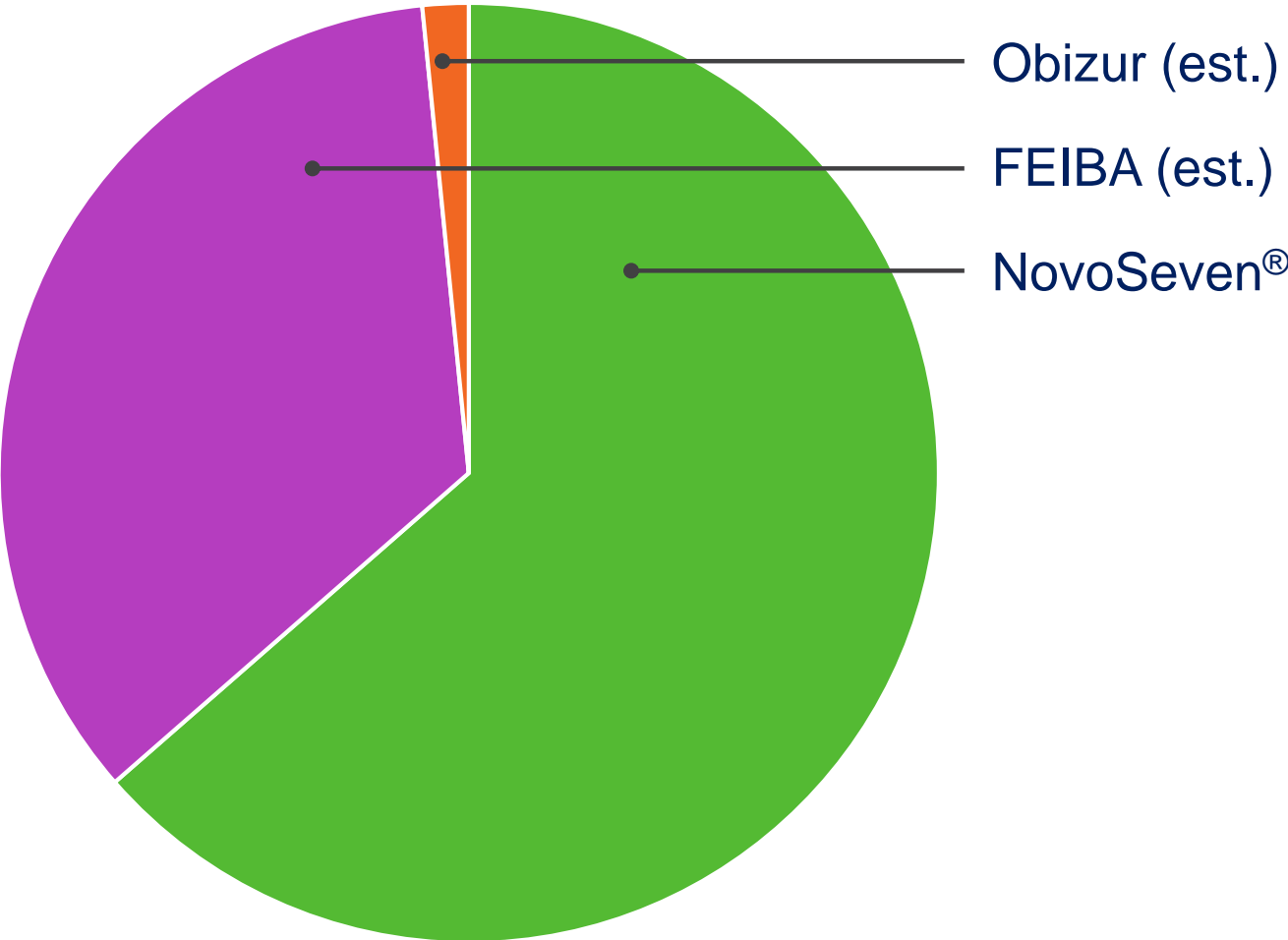
- Rare disorder, FIX deficient, mostly inherited but can be caused by a spontaneous mutation
- Causes spontaneous bleeding, mostly into joints, resulting in disabling joint damage

Acquired Hemophilia

- Rare disorder, occurs spontaneously, bleeding caused by anti-FVIII nAbs
- Currently treated with immunosuppressants + IV bypass agents (FVIIa, FEIBA® or Obizur®)
- Unmet need to adequately treat & prevent re-bleeds

FVIIa & Bypassing Agents: \$2.2B market

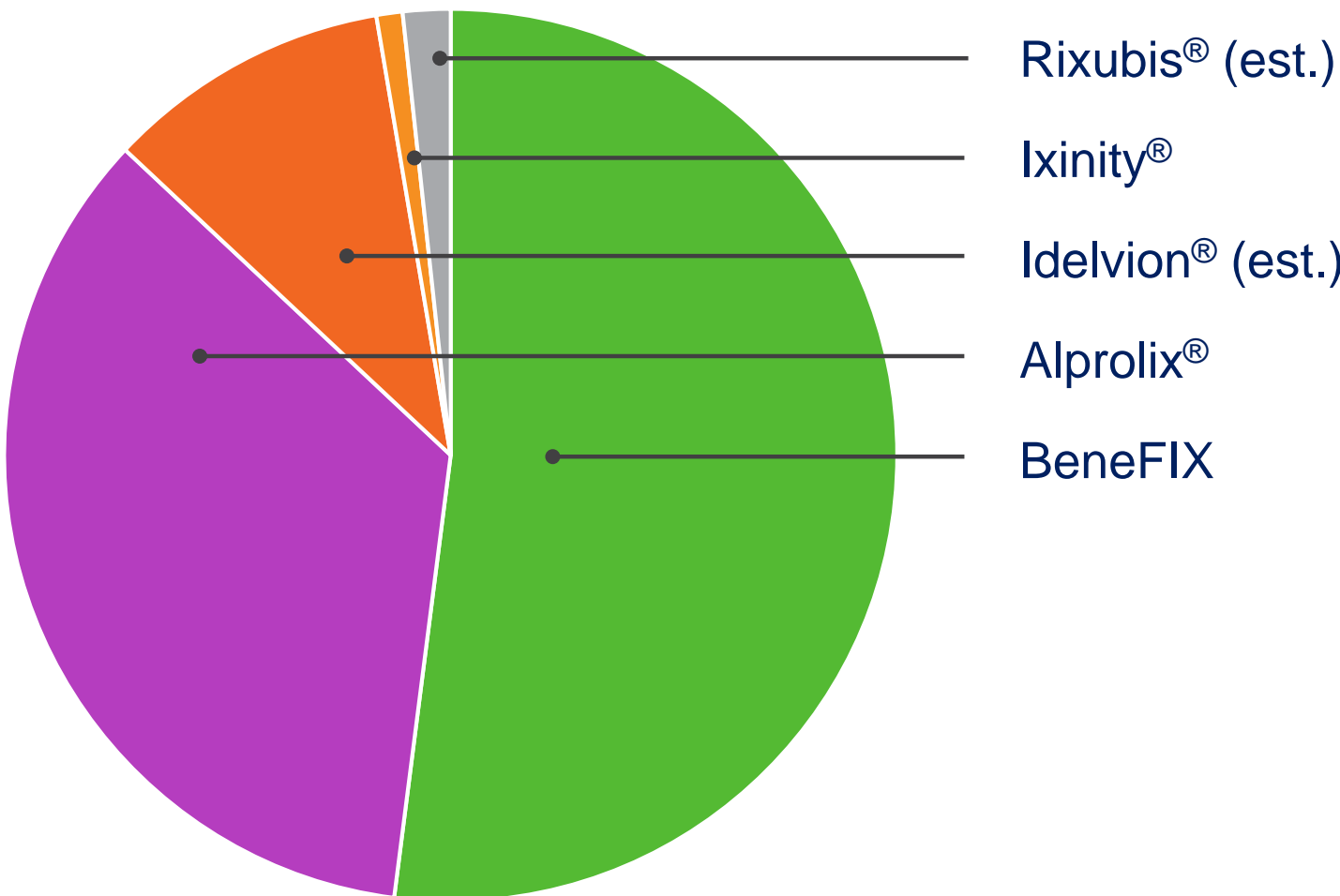
2017 Sales



In 2017 over 2,400 US and EU5 patients were treated with FVIIa and bypassing agents for hemophilia with inhibitors, acquired hemophilia and factor VII deficiency

Hemophilia B, FIX: \$1.2B market

2017 Sales



In 2017 over 6,000 US and EU5 hemophilia B patients were treated with recombinant FIX

Sources: WFH Annual Global Survey, GlobalData, Roche, Novo Nordisk, Aptevo, SOBI, Bioverativ. *Hemlibra® had global sales of \$58M in 1H 2018

Available treatments



- Regular intravenous (IV) infusions are necessary to maintain higher clotting levels
- IV treatments are very unpleasant and time-consuming
- Inconvenience affects compliance, outcomes and quality of life
- Especially difficult for pediatric patients & their families

The Catalyst Biosciences solution

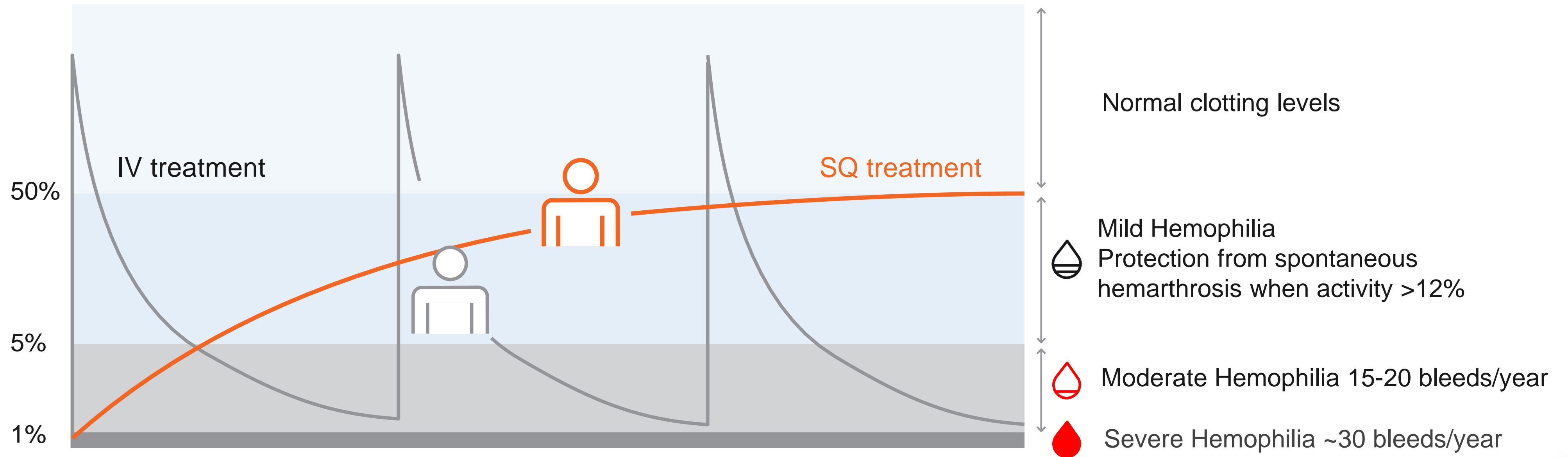


Our highly potent solution:

- + Quick & simple subcutaneous injection – allows for self-administration including in pediatric patients
- + Much higher & stable factor levels – keeps patients at safe levels for much longer

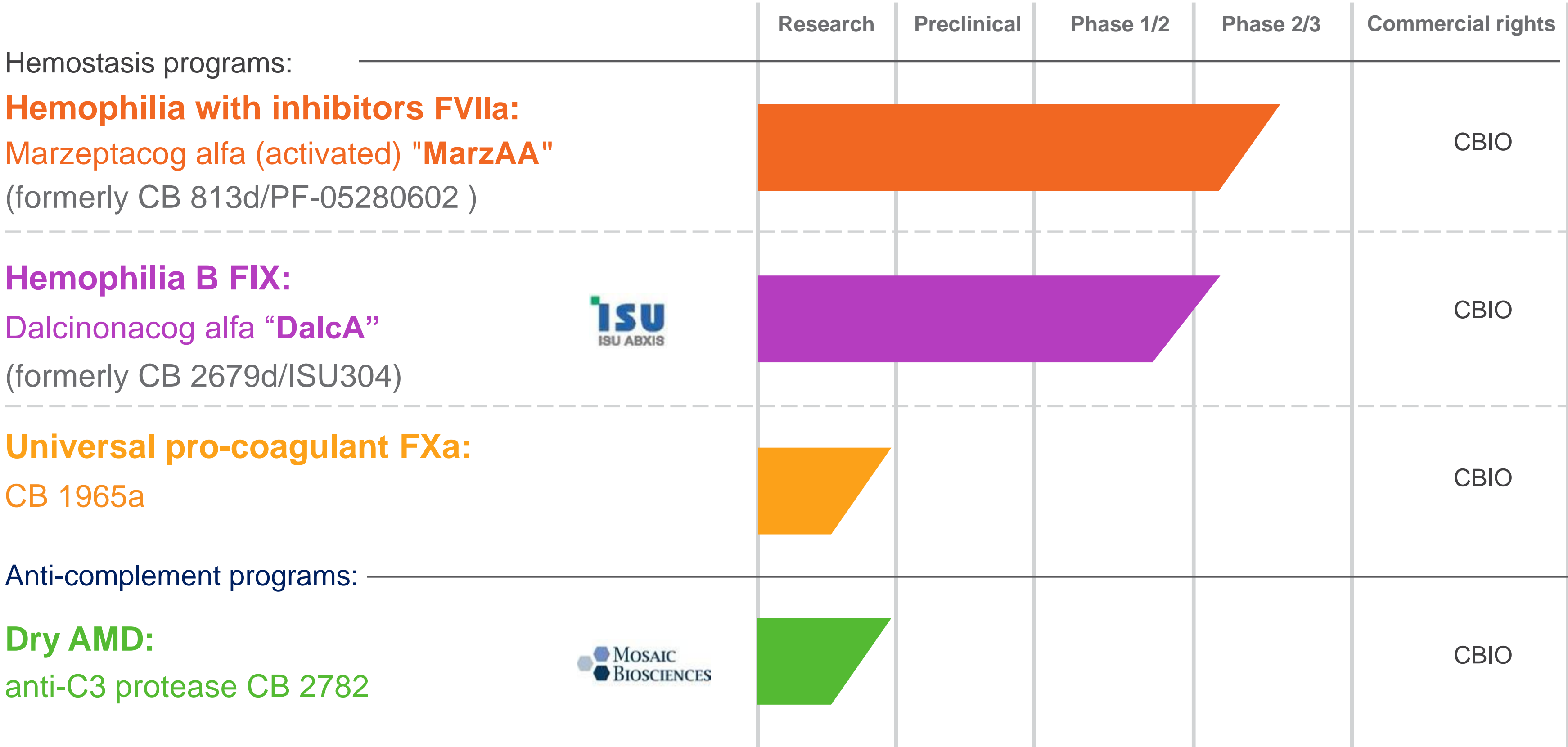
The new standard in hemophilia prophylaxis

Patients in high mild range are protected from spontaneous bleeds



- + The concept of prophylactic treatment is to keep severe & moderate hemophilia patients in the high mild range
- + Our subcutaneous treatment has the ability to build up over time, offering long-term stability in clotting levels

Pipeline



Team

President & CEO
Nassim Usman, Ph.D.

SVP, Technical Operations
Andrew Hetherington, M.B.A.









Chief Medical Officer
Howard Levy, M.B.B.Ch., Ph.D., M.M.M.

VP, Translational Research
Grant Blouse, Ph.D.









Chief Financial Officer
Fletcher Payne

VP, Business Development
Jeffrey Landau, M.B.A.









CATALYST BIOSCIENCES

December 18th 2018

Dalcinonacog alfa



Dalcinonacog alfa

Dalcinonacog alfa, a novel clinical stage SQ FIX product candidate differentiated from IV market leaders:

- + Simpler, less painful, small dose
- + SQ enhances pharmacokinetics
- + Potential to maintain continuous protective levels
- + Disruptive to all current intravenous products
- + Especially well suited for children

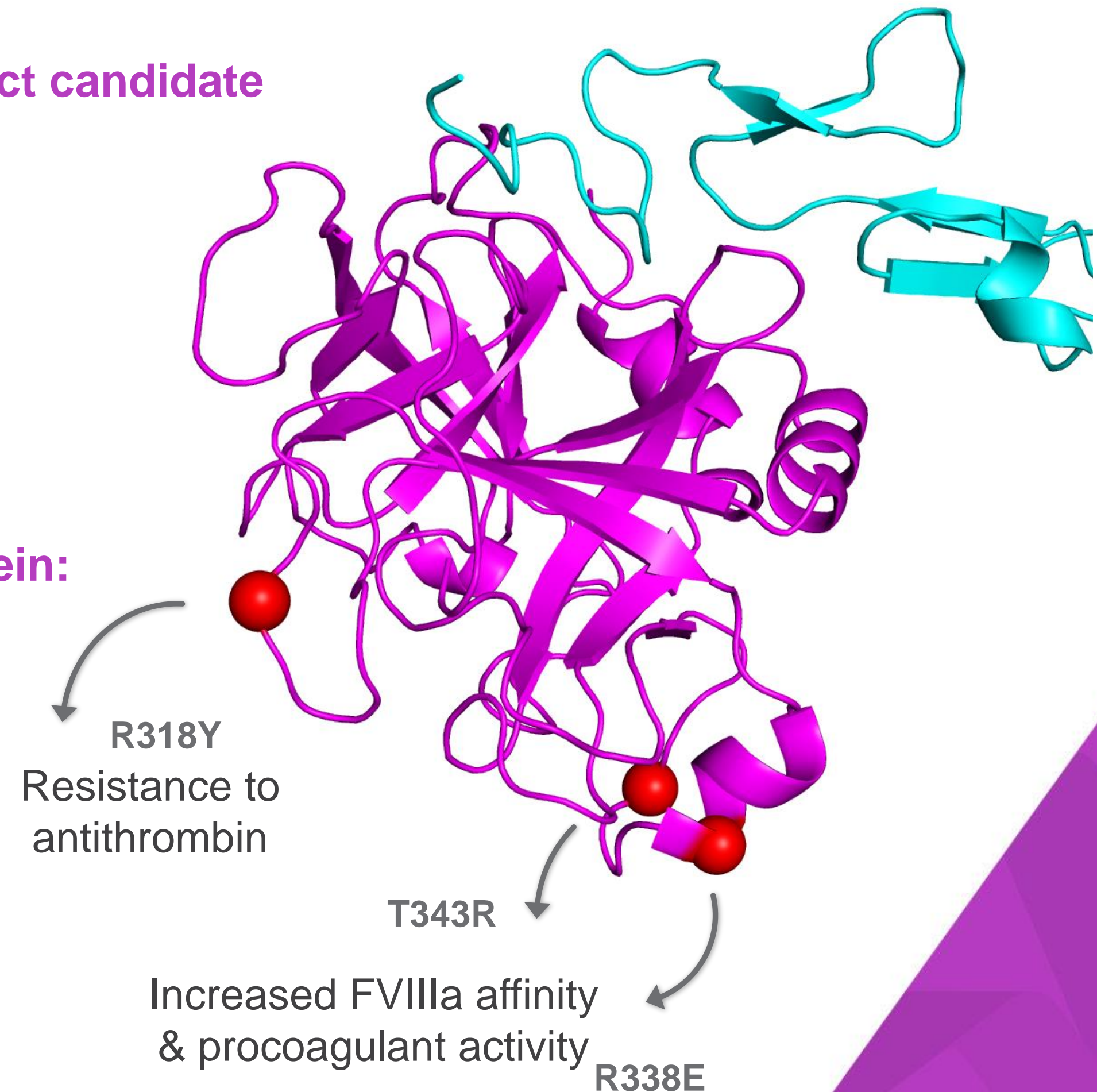
Three point mutations in two loops within the FIX protein:

- + Catalytic activity increased
- + Affinity for activated factor VIII increased
- + Resistance to inhibition by antithrombin improved

Best-in-class high-potency recombinant FIX product

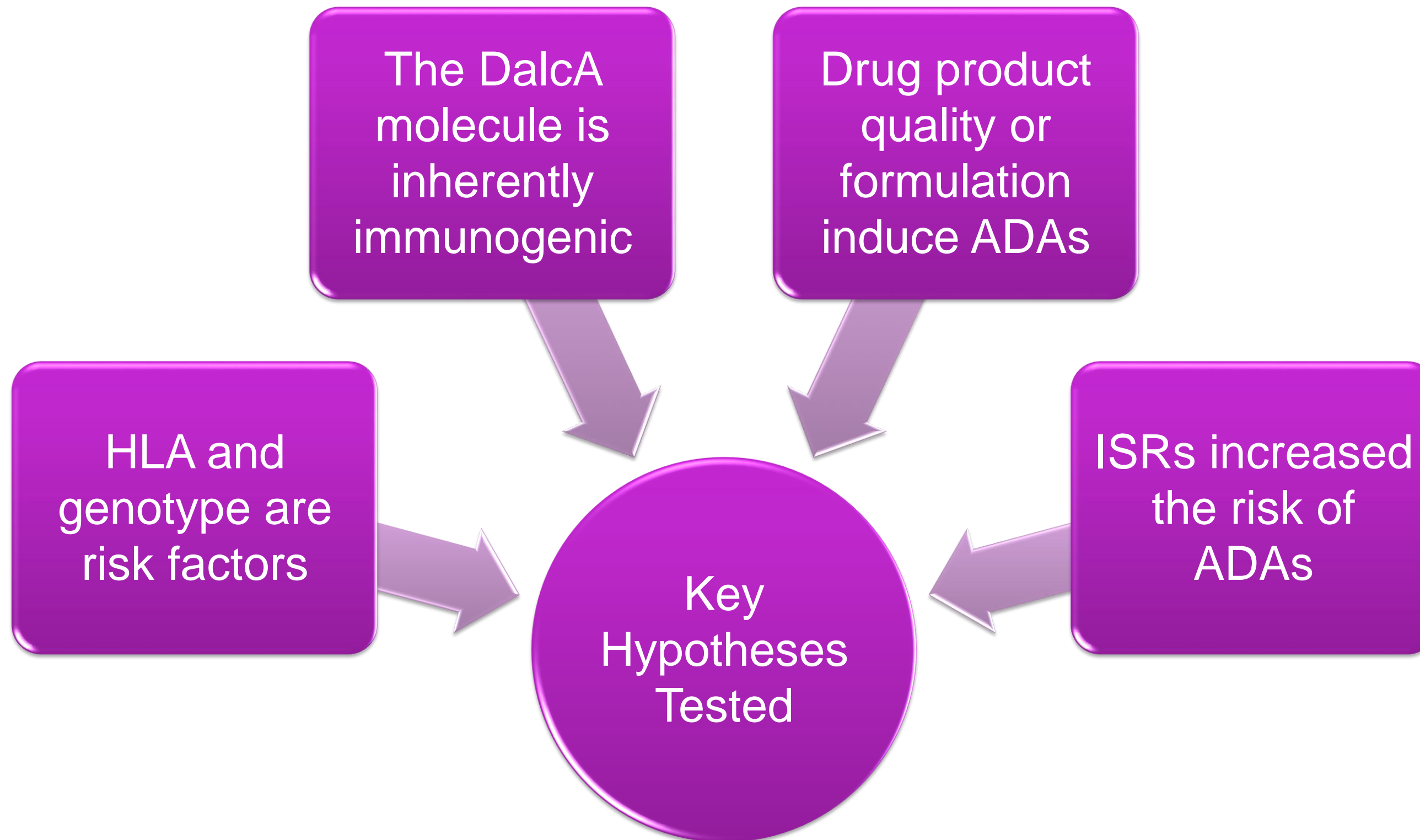
- + 22-fold more potent than BeneFIX in man

Orphan Drug Designation in US & EU



Retrospective immunogenicity assessment

A comprehensive assessment of immunogenicity addressed several key hypotheses



“Considering our global and regional *in silico* analysis alongside whole protein and peptide *in vitro* experiments ... we find the risk that wildtype FIX and therapeutic candidate DalcA will create or contribute to anti-therapeutic immune response to be minimal.”

EpiVax

DalcA has low immunogenicity & should proceed to P2b

Moving forward with dalcinonacog alfa after preclinical immunogenicity risk assessment



In Silico and *in vitro* risk is equivalent to that of competitors such as BeneFIX

Drug product characterization shows DalcA comparable to other rFIX products

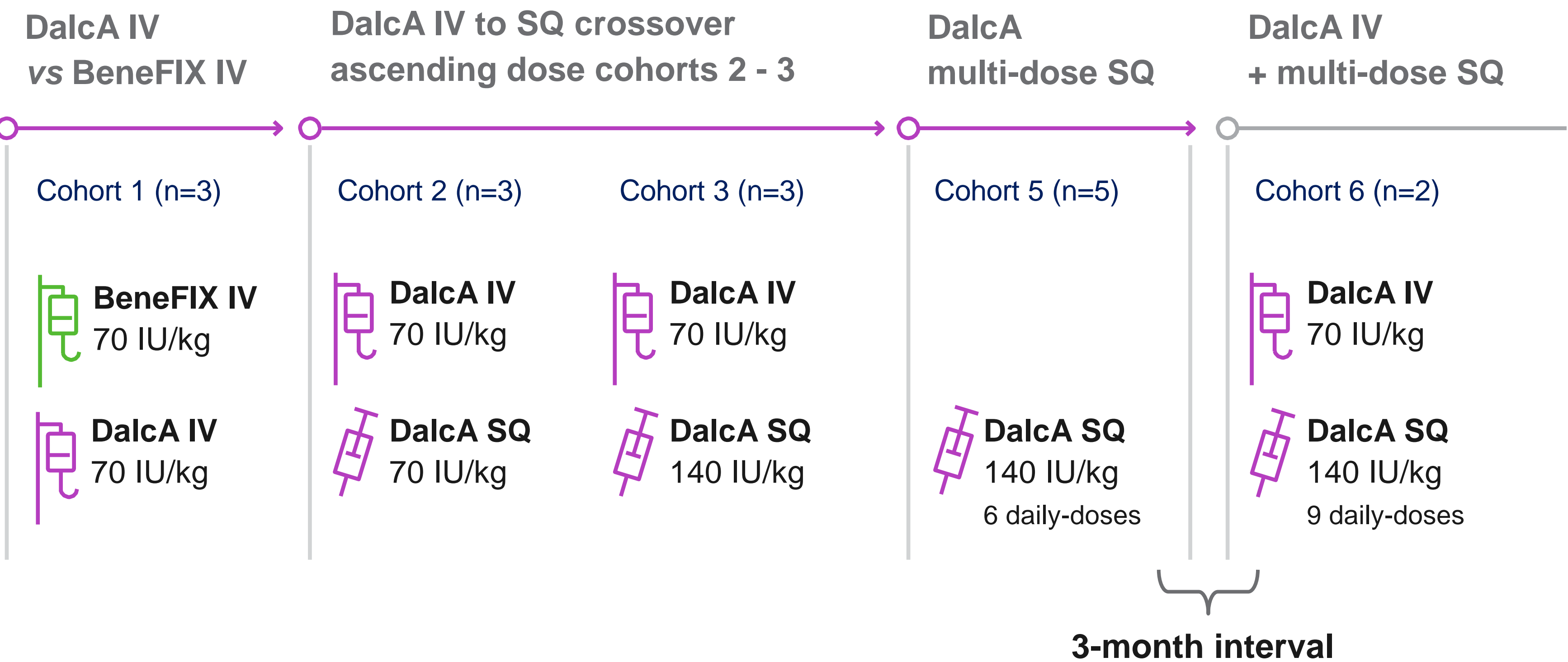
No significant ISRs were observed in a 7d monkey PK/tox study

Clinical, regulatory and immunology KOLs provided positive opinions

Back in the clinic: Preclinical immunogenicity profile is similar to commercial FIX products

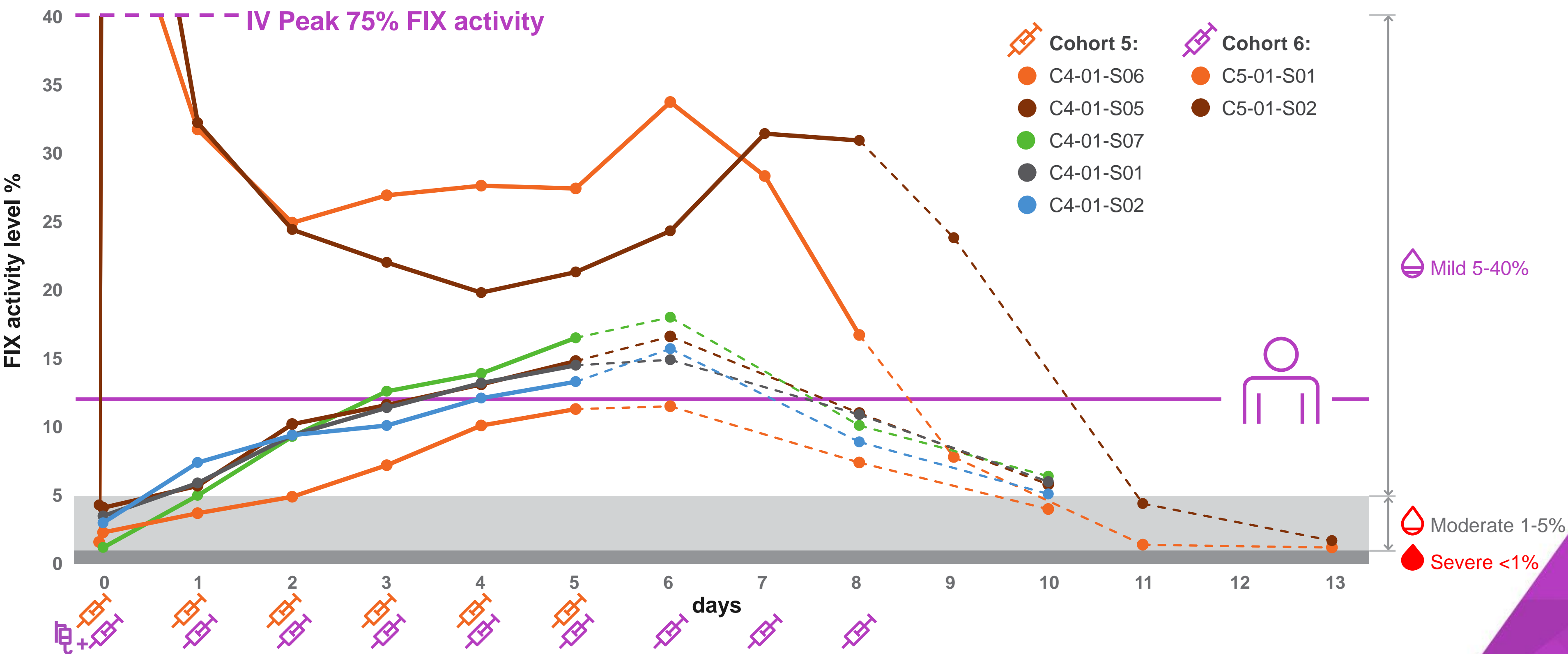
Dalcinonacog Phase 1/2 open label design

Subcutaneous treatment of hemophilia B



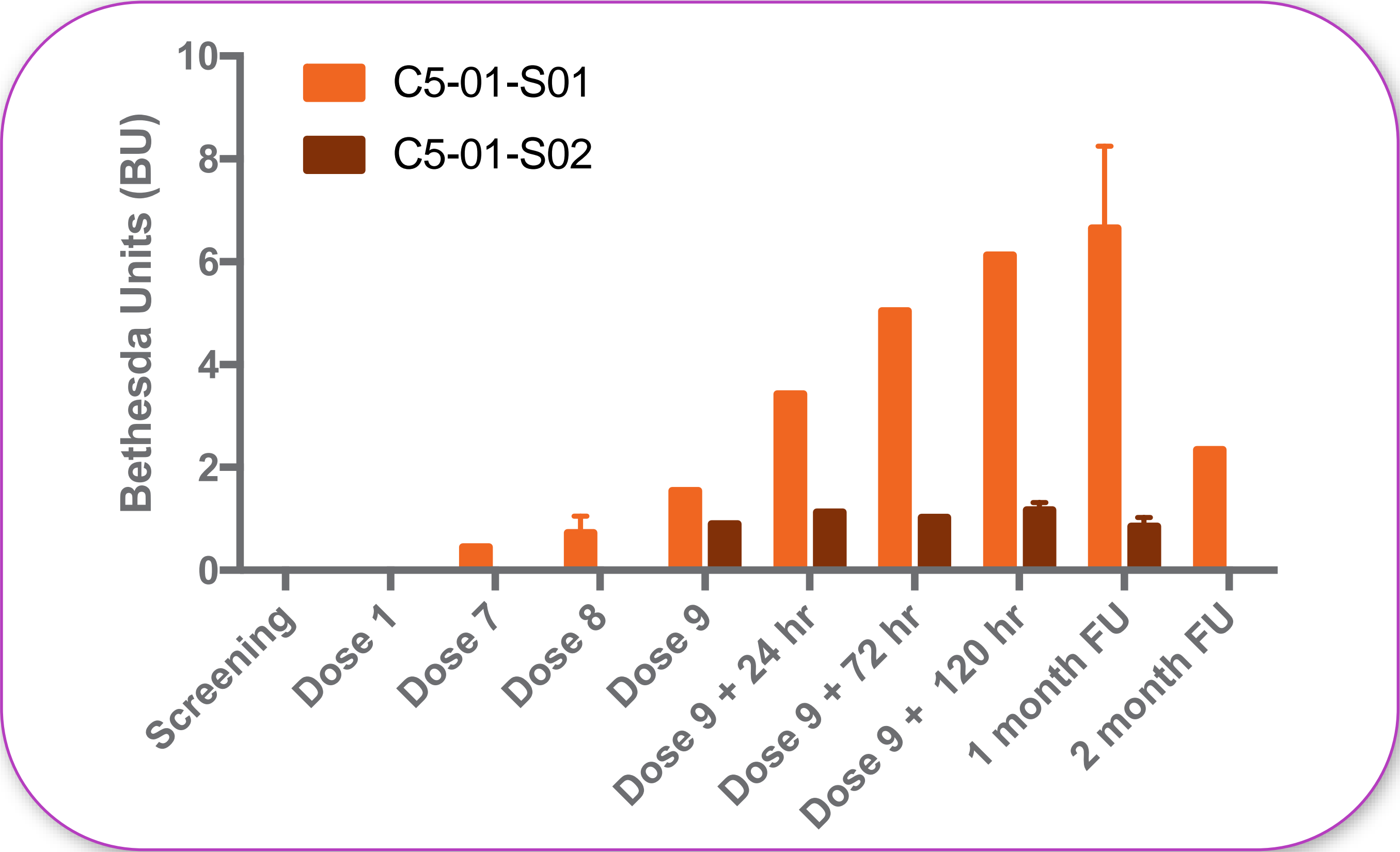
Phase 1/2: Cohort 5 & 6 FIX activity results

6/7 patients had trough levels >12%, sufficient to protect against spontaneous joint bleeds



Phase 1/2: Cohort 6 FIX nAb development timeline

Time course of neutralizing antibody development after prior exposure in Cohort 5



The DalcA drug product is not inherently immunogenic

Investigation Hypothesis

In Silico & In vitro Immunogenicity
(Molecule is inherently immunogenic)

HLA Typing / Immunogenicity
(Certain HLA types increase risk of ADAs)

DP Quality Characterization
(Drug quality induces ADAs)

DP Formulation Characterization
(Formulation induces ADAs)

SQ Dosing
(Route of Administration induces ADAs)

Conclusion

Same profile as WT FIX & BeneFIX

Restrict genotype & potential at risk HLAs

Same as BeneFIX & RIXUBIS

No consistent ISRs in NHP 7-day SQ study

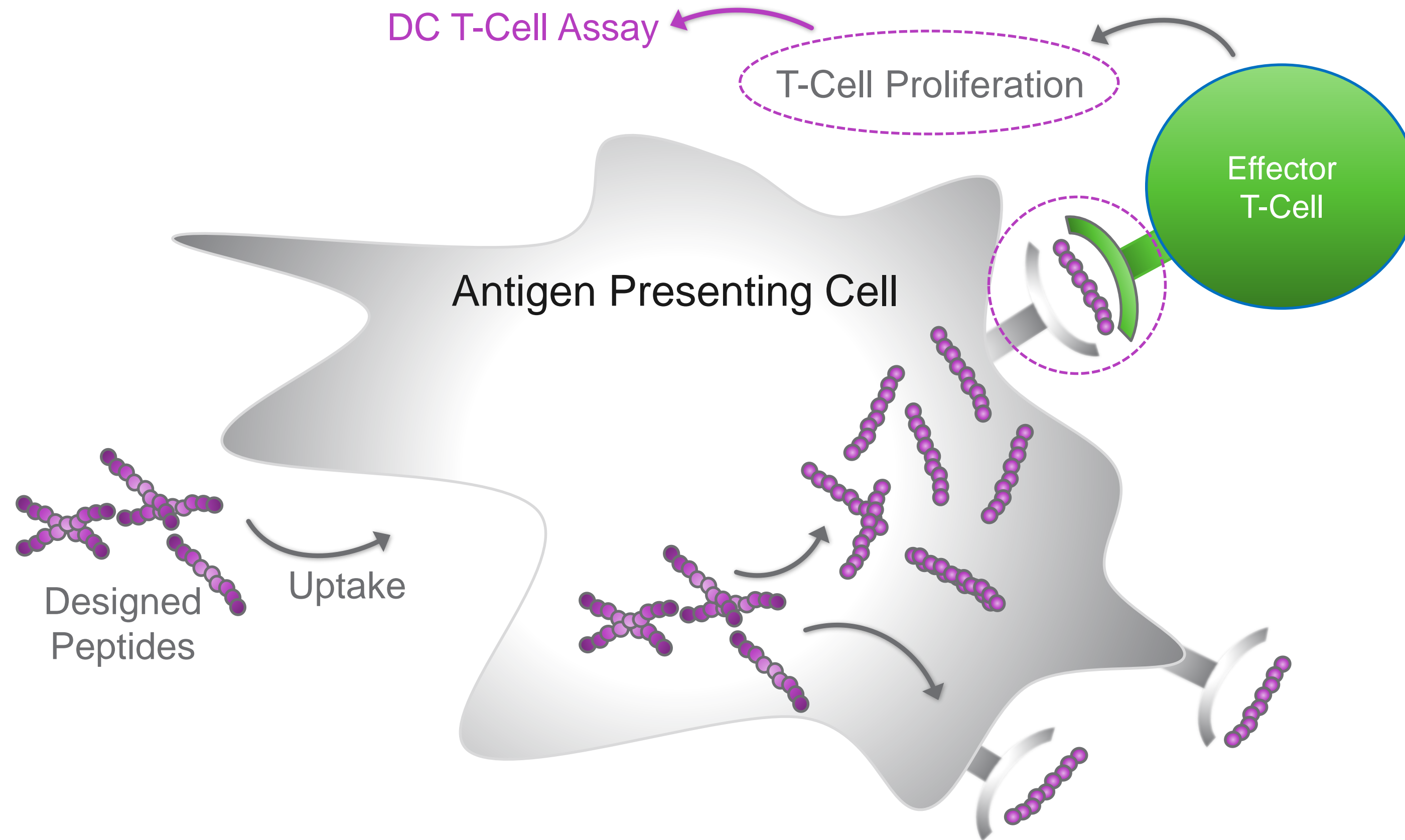
No issues with MarzAA with >325 days dosing & Idelvion with 15 exposure days

HLA and genotyping of 7/11 Korean subjects in the P1/2 trial

Subject ID	DRB1		DPB1		DQA1		DQB1		Genotype	Phenotype
C5-01-S01	03:01	04:01	02:01	02:01	03:01	05:01	02:01	03:01	128G>A	Arg43Gln: propeptide
C5-01-S02	01:01	13:01	02:01	04:01	01:01	01:01	05:01	06:01	128G>A	Arg43Gln: propeptide
C4-01-S02	01:01	08:01	02:01	05:01	01:01	01:01	05:01	06:01	1150C>T	Arg384Term: Truncation
C4-01-S07	08:01	12:01	02:01	05:01	03:01	05:01	03:01	03:01	1045G>T	Gly349Term: Truncation
C2-03-S01	04:01	13:01	04:01	05:01	01:01	03:01	03:01	06:01	880C>T	Arg294Term: Truncation
C3-02-S03	11:01	15:01	05:01	05:01	01:01	05:01	03:01	06:01	1219T>G	Cys407Gly: Protease
C3-02-S04	09:01	09:01	02:01	05:01	03:01	03:01	03:01	03:01	127C>T	Arg43Trp: propeptide

- + The two subjects in cohort 6 that developed the nAbs are cousins and have the same genotype
 - Genotype is an Arg to Gln mutation at amino acid -4 (defective propeptide cleavage site)
- + Only common HLA type is DPB1 02:01

Preclinical toolkit for evaluation of immunogenicity

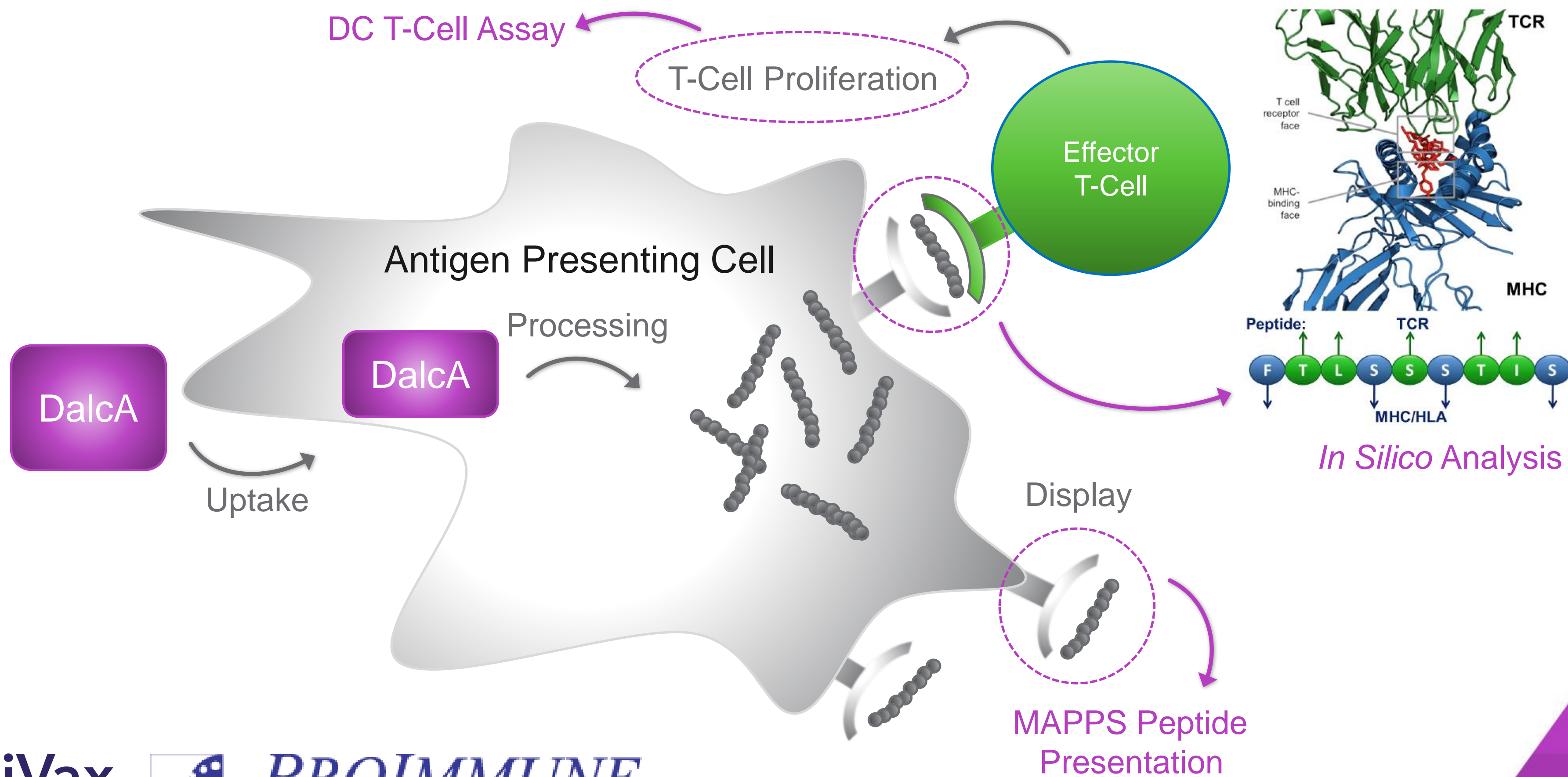


EpiVax

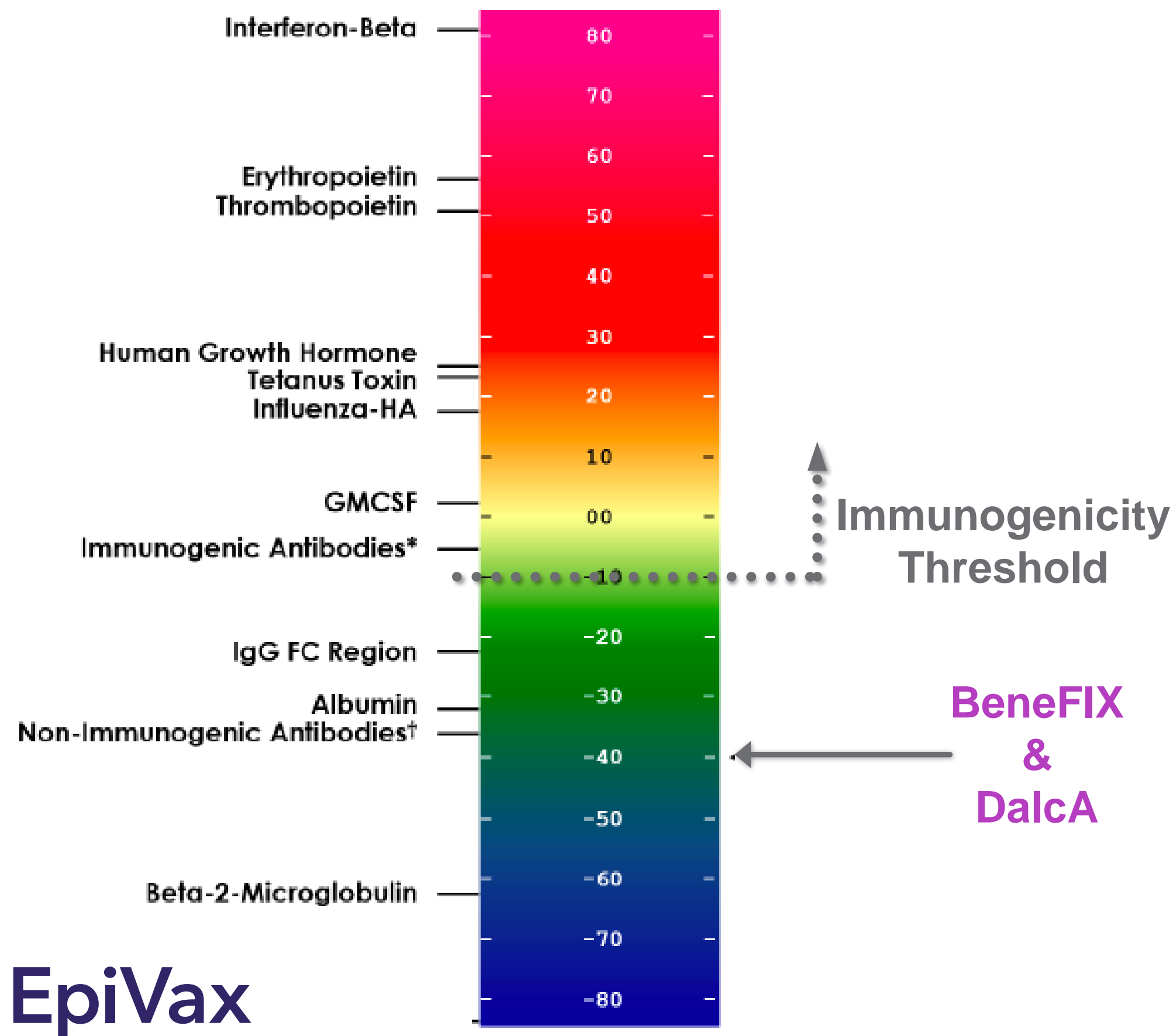


PROIMMUNE
www.proimmune.com

Preclinical toolkit for evaluation of immunogenicity



The *in silico* immunogenicity assessment shows low risk



In Silico immunogenicity risk assessment

- + Overall immunogenicity risk is low and on par with BeneFIX
- + Factor IX protein sequence contains fewer putative Class II T cell epitopes than would be expected in a randomly generated sequence of similar length of -42.54 (BeneFIX -41.65)
- + These scores fall in the lower range of the scale, indicating a weak potential for immunogenicity

DalcA shows a similar *in silico* risk as BeneFIX at R318Y

In Silico immunogenicity assessment at the R318Y site

BeneFIX

Frame Start	AA Sequence	Frame Stop	Hydro-phobicity	DRB1*0101 Z-Score	DRB1*0301 Z-Score	DRB1*0401 Z-Score	DRB1*0701 Z-Score	DRB1*0801 Z-Score	DRB1*1101 Z-Score	DRB1*1301 Z-Score	DRB1*1501 Z-Score	Hits
310	WGRVFHKGR	318	-1.2	0.99	0.51	0.61	1.26	1.63	1.39	0.92	0.67	0
311	GRVFHKGRS	319	-1.19	-0.35	0.22	-0.25	-1.09	1.00	1.04	0.36	1.24	0
312	RVFHKGRSA	320	-0.94	0.55	0.03	0.50	0.85	-0.87	0.18	1.09	0.32	0
313	VFHKGRSAL	321	-0.02	0.74	1.71	-0.63	1.41	1.67	1.00	2.03	0.79	3
314	FHKGRSALV	322	-0.02	2.73	2.29	2.67	2.59	1.74	2.32	2.01	2.48	8
315	HKGRSALVL	323	0.09	1.24	-0.06	0.30	1.33	0.69	0.54	1.15	1.12	0
316	KGRSALVLQ	324	0.06	-0.20	0.84	0.26	0.21	0.35	0.47	0.49	0.29	0
317	GRSALVLQY	325	0.34	0.37	1.27	0.87	0.23	-0.34	0.14	1.38	0.16	0
318	RSALVLQYL	326	0.81	0.04	0.72	-0.64	0.17	0.26	0.07	-0.26	1.16	0

DalcA

310	WGRVFHKGY	318	-0.84	0.93	0.59	0.53	1.02	0.58	1.31	1.00	0.61	0
311	GRVFHKGYS	319	-0.83	-0.54	0.03	-0.43	-1.28	0.80	0.84	0.17	1.05	0
312	RVFHKGYSA	320	-0.59	0.37	-0.11	0.71	0.88	-0.67	-0.12	1.28	0.80	0
313	VFHKGYSA	321	0.33	0.76	0.59	-0.63	1.42	0.51	-0.13	0.93	0.59	0
314	FHKGYSA	322	0.33	2.58	2.13	2.52	2.44	1.58	2.16	1.85	2.33	7
315	HKGYSALVL	323	0.44	0.61	-0.06	0.47	1.36	0.72	0.37	1.41	1.49	0
316	KGYSALVLQ	324	0.41	-0.49	0.55	-0.02	-0.07	0.04	0.18	0.20	0.01	0
317	GYSALVLQY	325	0.7	0.01	0.90	0.52	-0.13	-0.72	-0.24	1.02	-0.19	0
318	YSALVLQYL	326	1.17	1.45	1.30	0.73	1.56	1.74	1.51	0.31	1.72	2

DalcA shows a similar risk as BeneFIX at R338E

In Silico immunogenicity assessment at the R338E site

BeneFIX

Frame Start	AA Sequence	Frame Stop	Hydro-phobicity	DRB1*0101 Z-Score	DRB1*0301 Z-Score	DRB1*0401 Z-Score	DRB1*0701 Z-Score	DRB1*0801 Z-Score	DRB1*1101 Z-Score	DRB1*1301 Z-Score	DRB1*1501 Z-Score	Hits
330	LVDRATCLR	338	0.32	0.41	-0.46	-0.64	0.26	0.16	0.15	0.50	-0.07	0
331	VDRATCLRS	339	-0.19	0.47	1.26	1.99	0.42	0.71	0.98	1.37	1.13	1
332	DRATCLRST	340	-0.73	-0.11	-0.93	-0.47	0.32	0.14	0.34	-0.56	0.40	0
333	RATCLRSTK	341	-0.78	-1.52	-0.63	-1.28	-1.76	0.34	-0.96	-0.57	-0.92	0
334	ATCLRSTKF	342	0.03	0.71	0.43	0.91	1.02	0.49	-0.03	0.65	0.43	0
335	TCLRSTKFT	343	-0.24	0.46	-2.06	-0.18	0.54	0.27	-0.06	-0.74	-0.32	0
336	CLRSTKFTI	344	0.33	0.67	1.45	-1.15	0.53	0.26	0.98	1.03	1.19	0
337	LRSTKFTIY	345	-0.09	0.58	1.21	0.37	0.78	0.23	-0.51	2.00	0.59	1
338	RSTKFTIYN	346	-0.9	-0.90	-0.66	-0.70	-0.56	0.26	-0.75	-0.22	-0.73	0

DalcA

330	LVDRATCLE	338	0.43	-0.21	-0.86	-0.99	0.03	0.31	-0.22	0.10	-0.66	0
331	VDRATCLES	339	-0.08	0.23	1.02	1.76	0.18	0.46	0.74	1.13	0.90	1
332	DRATCLEST	340	-0.62	-0.43	-1.01	-0.51	0.17	0.11	-0.38	-0.64	0.13	0
333	RATCLESTK	341	-0.67	-2.31	-1.39	-1.28	-1.89	-0.45	-1.72	-1.32	-1.49	0
334	ATCLESTKF	342	0.14	0.43	0.15	0.64	0.74	0.20	-0.32	0.37	0.16	0
335	TCLESTKFT	343	-0.13	0.78	-1.21	0.84	0.65	-0.77	-0.01	-1.18	-0.94	0
336	CLESTKFTI	344	0.44	0.21	0.99	-1.59	0.08	-0.22	0.52	0.58	0.76	0
337	LESTKFTIY	345	0.02	0.07	0.69	-0.13	0.27	-0.31	-1.04	1.49	0.09	0
338	ESTKFTIYN	346	-0.79	-0.82	-1.30	-0.62	-0.48	0.34	-0.67	-0.85	-1.34	0

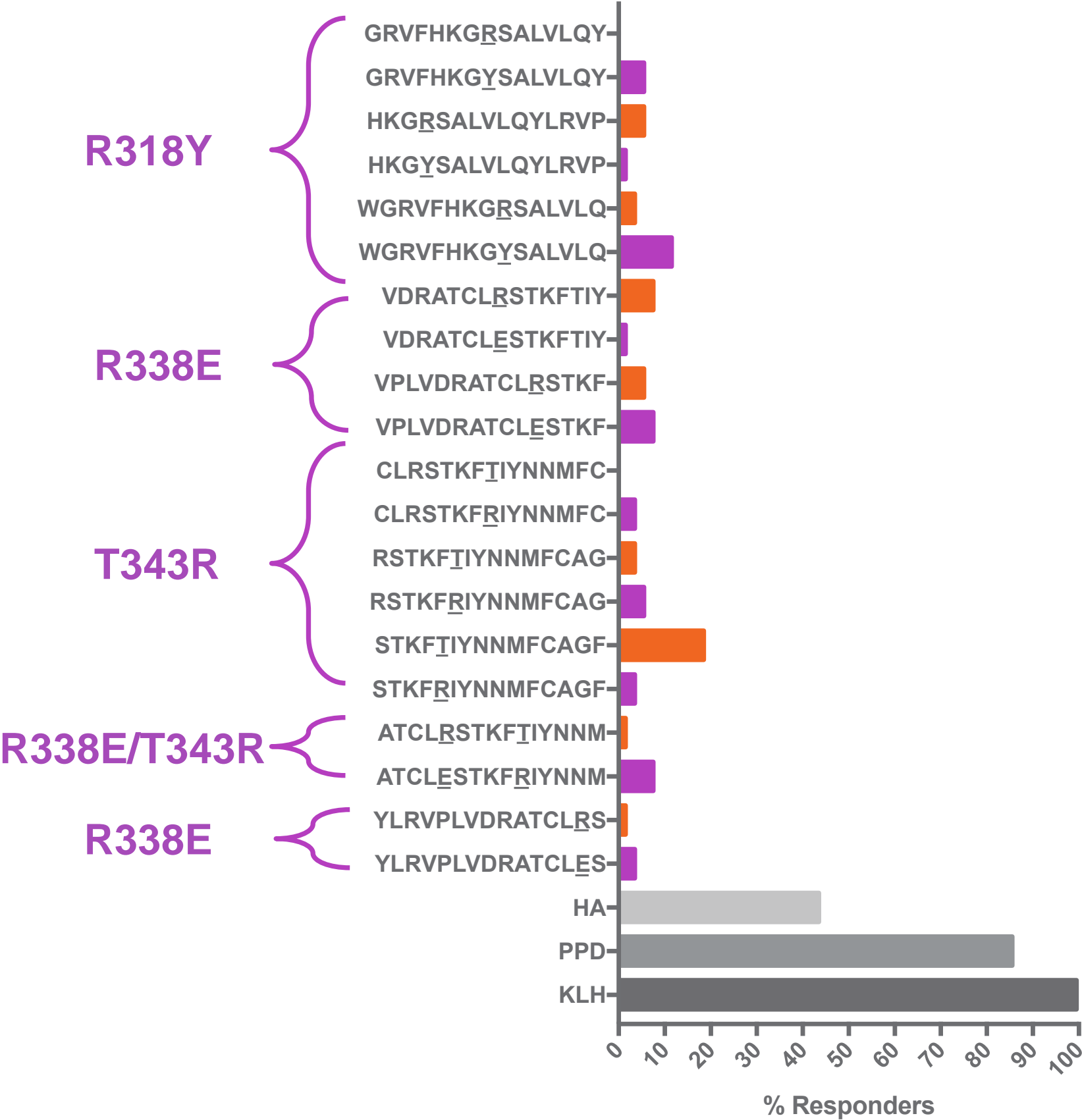
DalcA shows a similar risk as BeneFIX at T343R

In Silico immunogenicity assessment at the T343R site

BeneFIX	Frame	AA	Frame	Hydro-	DRB1*0101	DRB1*0301	DRB1*0401	DRB1*0701	DRB1*0801	DRB1*1101	DRB1*1301	DRB1*1501	Hits	
	Start	Sequence	Stop	phobicity	Z-Score	Z-Score	Z-Score	Z-Score	Z-Score	Z-Score	Z-Score	Z-Score		
	335	TCLRSTKFT	343	-0.24	0.46	-2.06	-0.18	0.54	0.27	-0.06	-0.74	-0.32		0
	336	CLRSTKFTI	344	0.33	0.67	1.45	-1.15	0.53	0.26	0.98	1.03	1.19		0
	337	LRSTKFTIY	345	-0.09	0.58	1.21	0.37	0.78	0.23	-0.51	2.00	0.59		1
	338	RSTKFTIYN	346	-0.9	-0.90	-0.66	-0.70	-0.56	0.26	-0.75	-0.22	-0.73		0
	339	STKFTIYNN	347	-0.79	-0.98	-1.59	-0.09	-0.20	0.10	-0.18	-0.48	0.53		0
	340	TKFTIYNNM	348	-0.49	0.53	-0.35	-0.47	1.00	-0.97	-0.84	-0.31	0.31		0
	341	KFTIYNNMF	349	-0.1	0.50	0.57	1.19	1.15	-0.03	0.95	0.13	0.55		0
	342	FTIYNNMFC	350	0.61	1.21	0.24	1.37	1.14	2.25	1.44	0.62	2.53		2
343	TIYNNMFCA	351	0.5	-0.19	-0.66	-0.87	-0.72	-0.82	0.20	-0.69	-0.40	0		
Dalca	335	TCLRSTKFR	343	-0.67	0.10	-0.91	-0.47	-0.12	0.64	-0.38	0.39	-0.67	0	
	336	CLRSTKFRI	344	-0.09	0.80	1.58	-1.02	0.66	0.40	1.12	1.16	1.32	0	
	337	LRSTKFRIY	345	-0.51	0.72	1.28	0.34	0.98	0.35	0.80	1.61	0.50	0	
	338	RSTKFRIYN	346	-1.32	-1.16	-0.40	-2.08	-0.83	0.53	-0.49	0.03	-0.70	0	
	339	STKFRIYNN	347	-1.21	-0.76	-1.38	0.12	0.01	0.33	0.04	-0.26	0.74	0	
	340	TKFRIYNNM	348	-0.91	0.52	-0.48	-1.03	0.52	-0.69	-0.44	-0.18	0.19	0	
	341	KFRIYNNMF	349	-0.52	0.98	1.05	1.66	1.62	0.47	1.44	0.61	1.01	1	
	342	FRIYNNMFC	350	0.19	1.46	0.51	1.62	1.39	2.52	1.70	0.88	2.78	3	
	343	RIYNNMFCA	351	0.08	-0.30	-0.02	-0.97	-0.82	-0.93	0.09	-0.07	0.21	0	

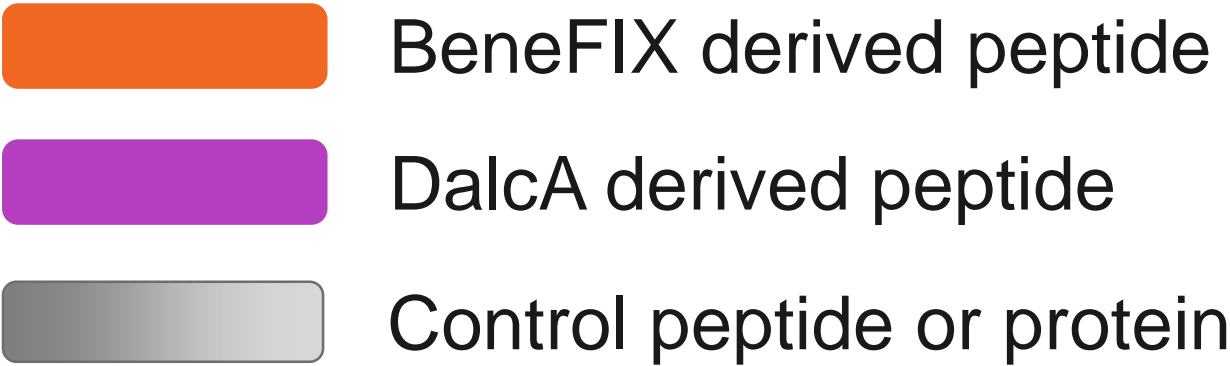
Peptides from DalcA show low immunogenicity risk

% Responding Donors



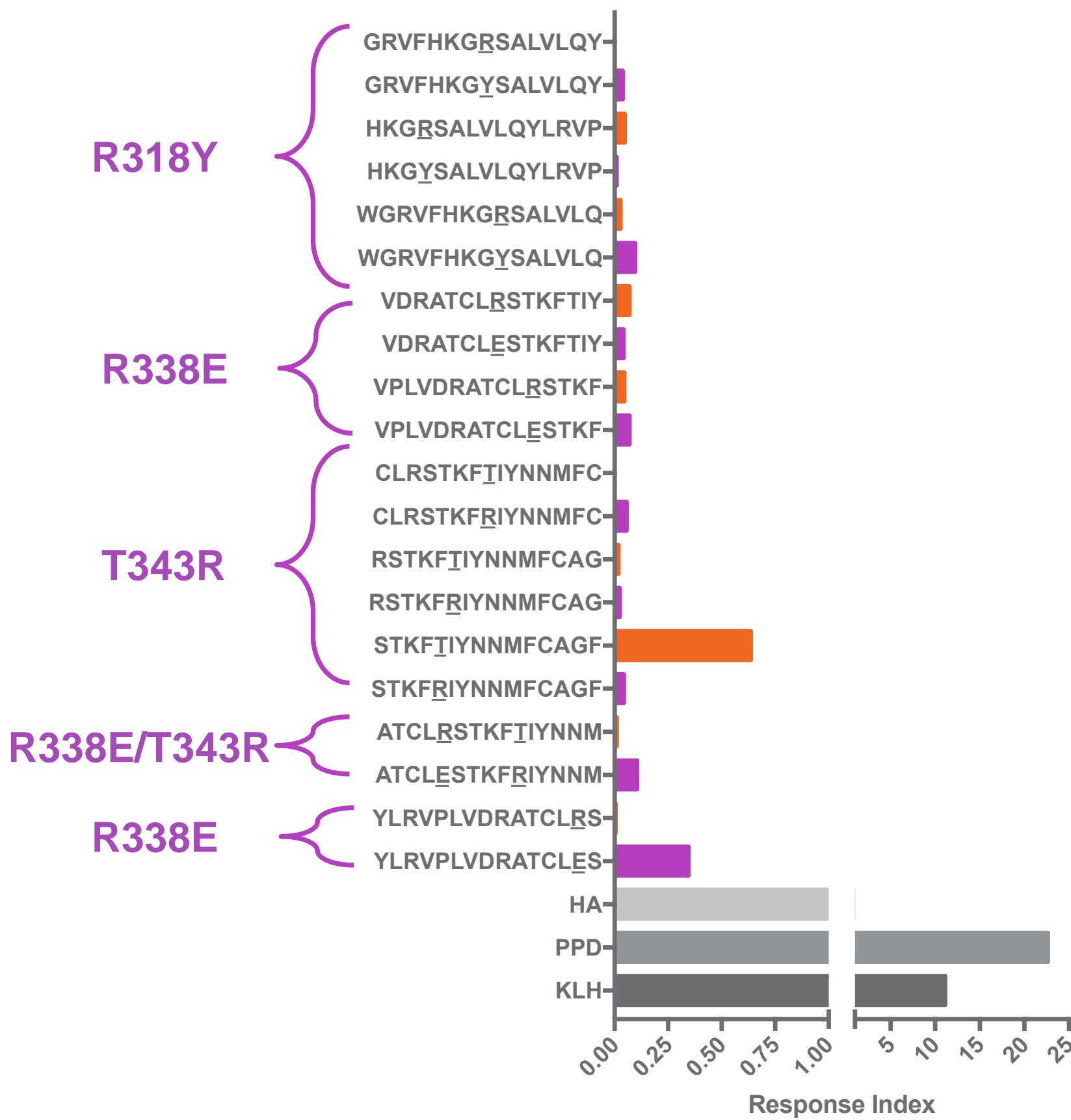
DC-T cell stimulation: Peptides

- + Overall immunogenicity risk profile for the individual peptides is low and on par with BeneFIX
- + Peptides covered all three amino acid substitutions and selected from *in silico* data
- + Peptides identified in MAPPS experiment have partial or full overlap with tested peptides




Peptides from DalcA show low immunogenicity risk


Response Index




DC-T cell stimulation: Peptides

- + Overall immunogenicity risk profile for the individual peptides is low and on par with BeneFIX
- + Peptides covered all three amino acid substitutions and selected from *in silico* data
- + Peptides identified in MAPPS experiment have partial or full overlap with tested peptides

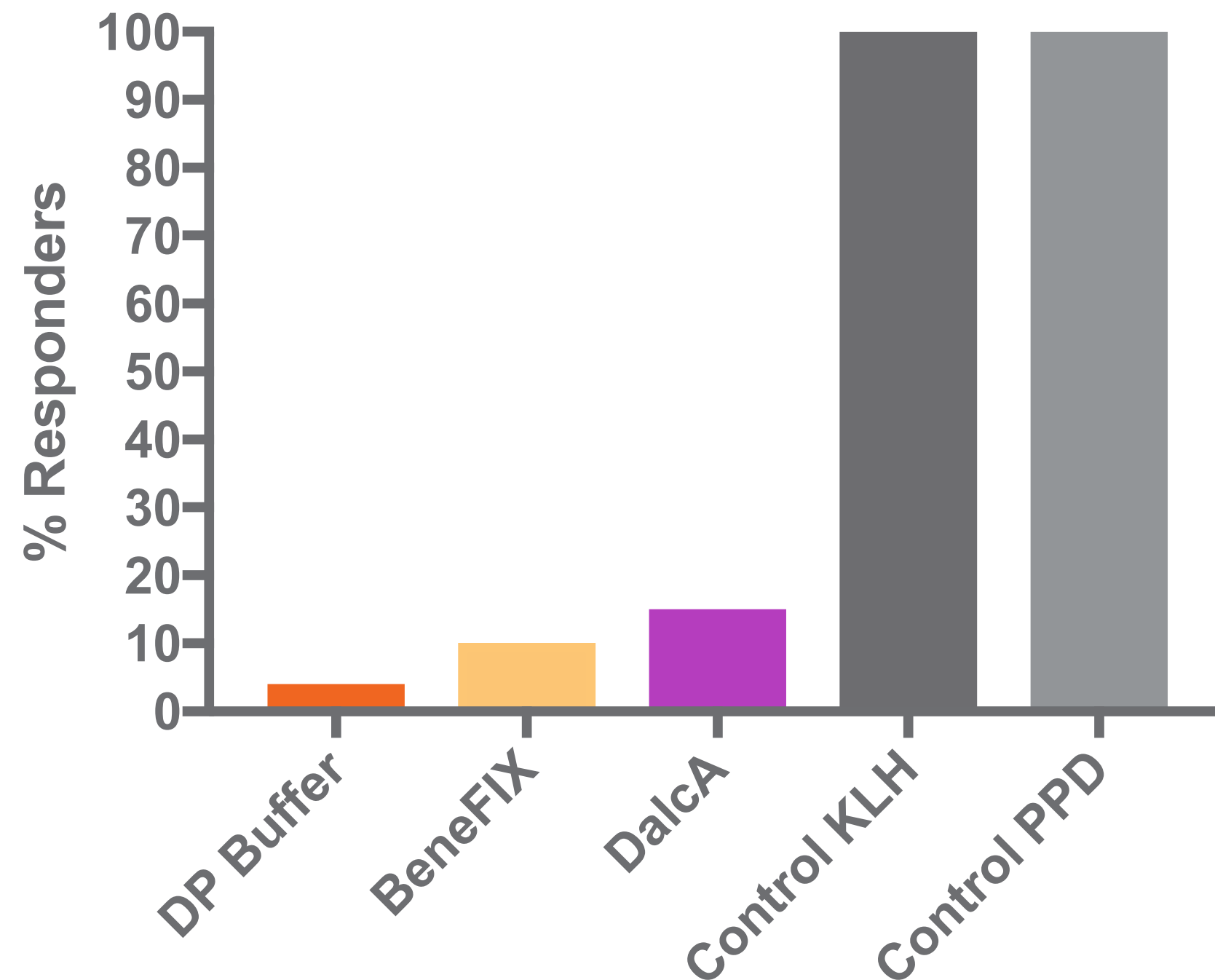
 BeneFIX derived peptide

 DalcA derived peptide

 Control peptide or protein

The DalcA drug product shows low immunogenicity risk

Responding Donors

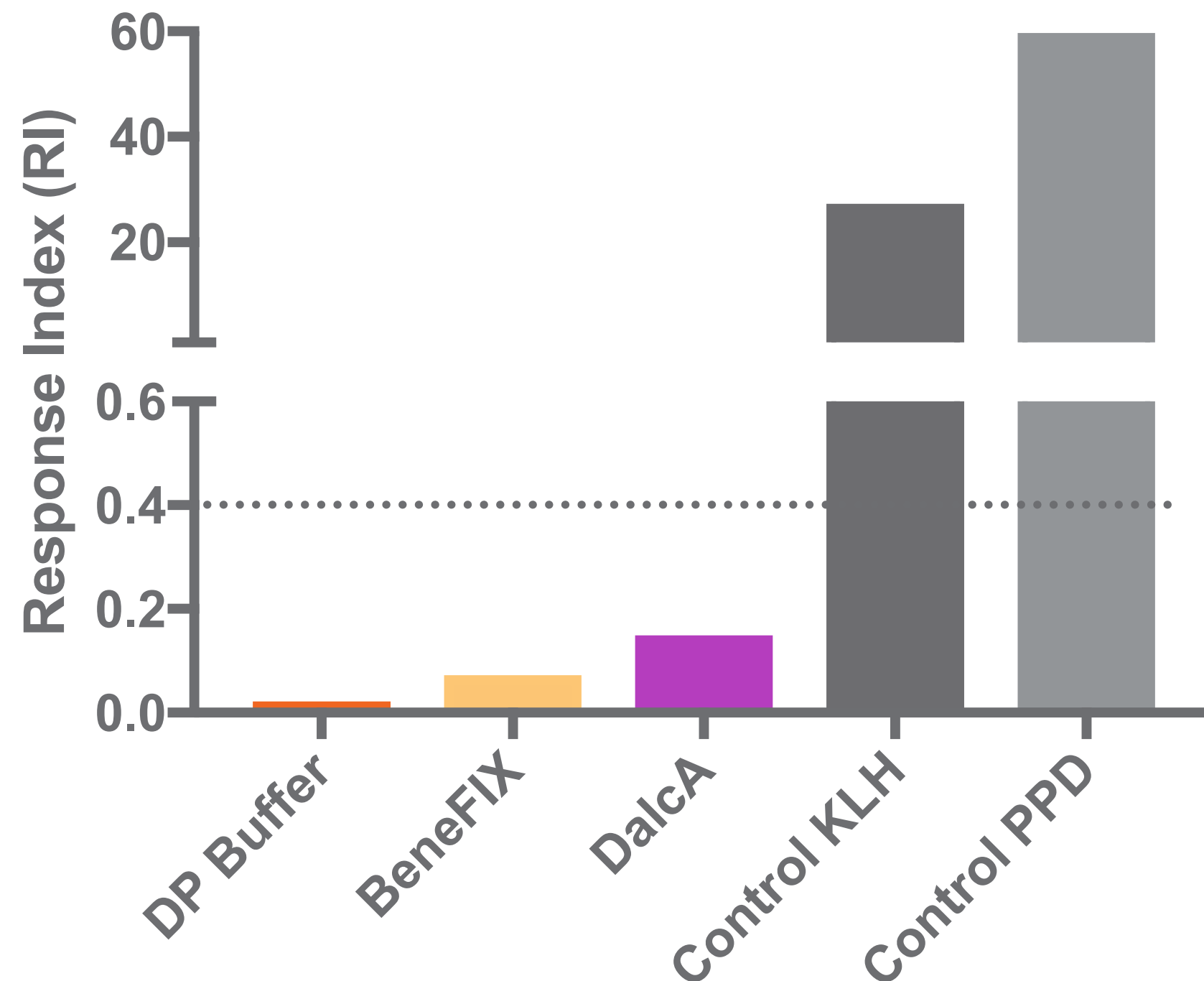


DC-T cell stimulation: Drug Product

- + Overall immunogenicity risk profile risk is low and on par with BeneFIX
 - Formulation buffer was at background
- + 8/52 responders to DalcA and 5/52 responders to BeneFIX (52/52 responders for both controls)
- + No significant HLA association was evident

The DalcA drug product shows low immunogenicity risk

Response Index



DC-T cell stimulation: Drug Product

- + Overall immunogenicity risk profile risk is low and on par with BeneFIX
 - Formulation buffer was at background
- + Clinical therapeutics with low risk have Response Index values (RI) between 0.1 and 0.4
 - Consistent with range of responses observed for other clinical grade therapeutics with low risk (less than an RI of 0.4)
- + No significant HLA association was evident

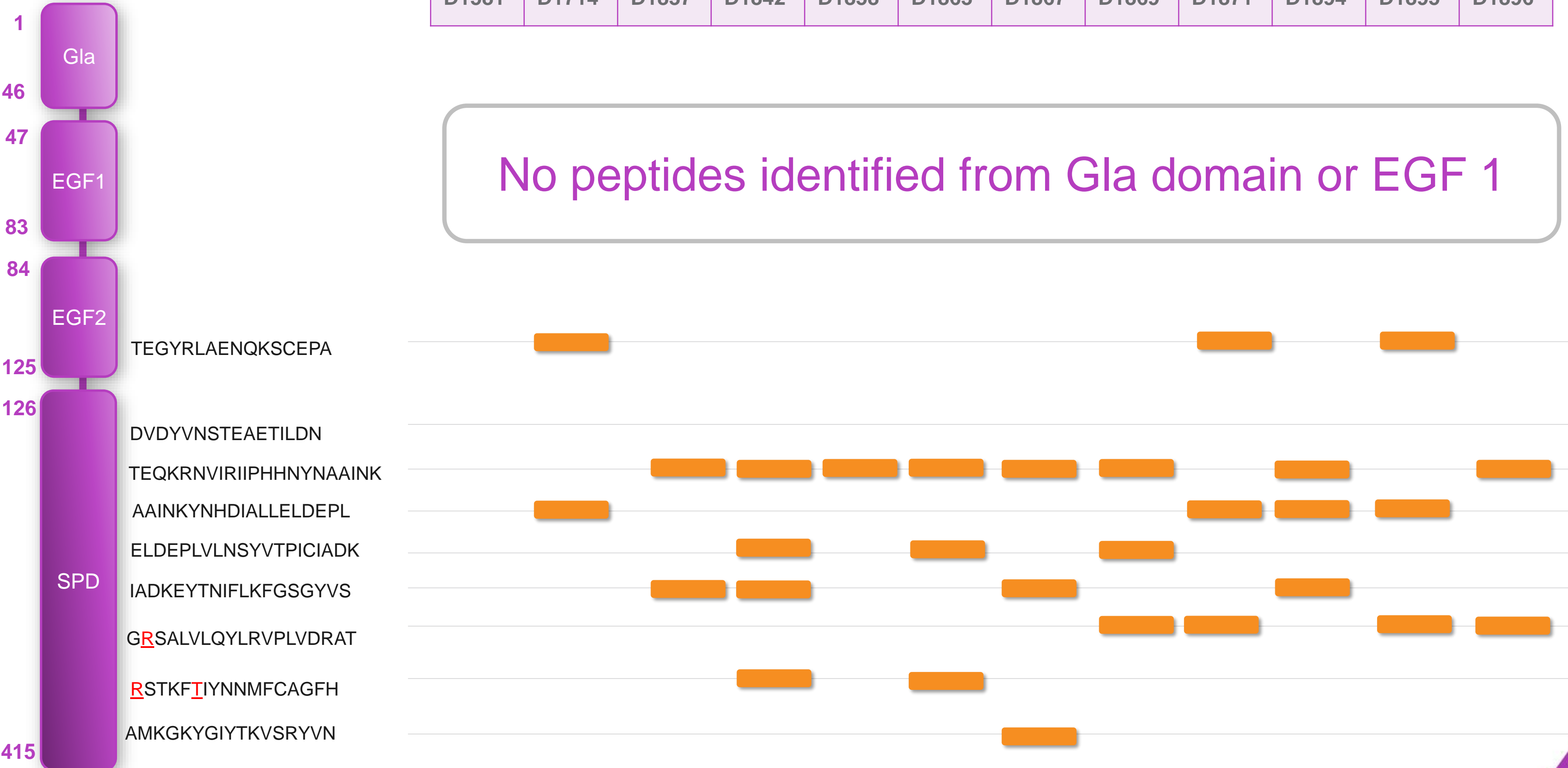
Presented peptides are comparable for DalcA & BeneFIX

BeneFIX HLA-DR

Donors

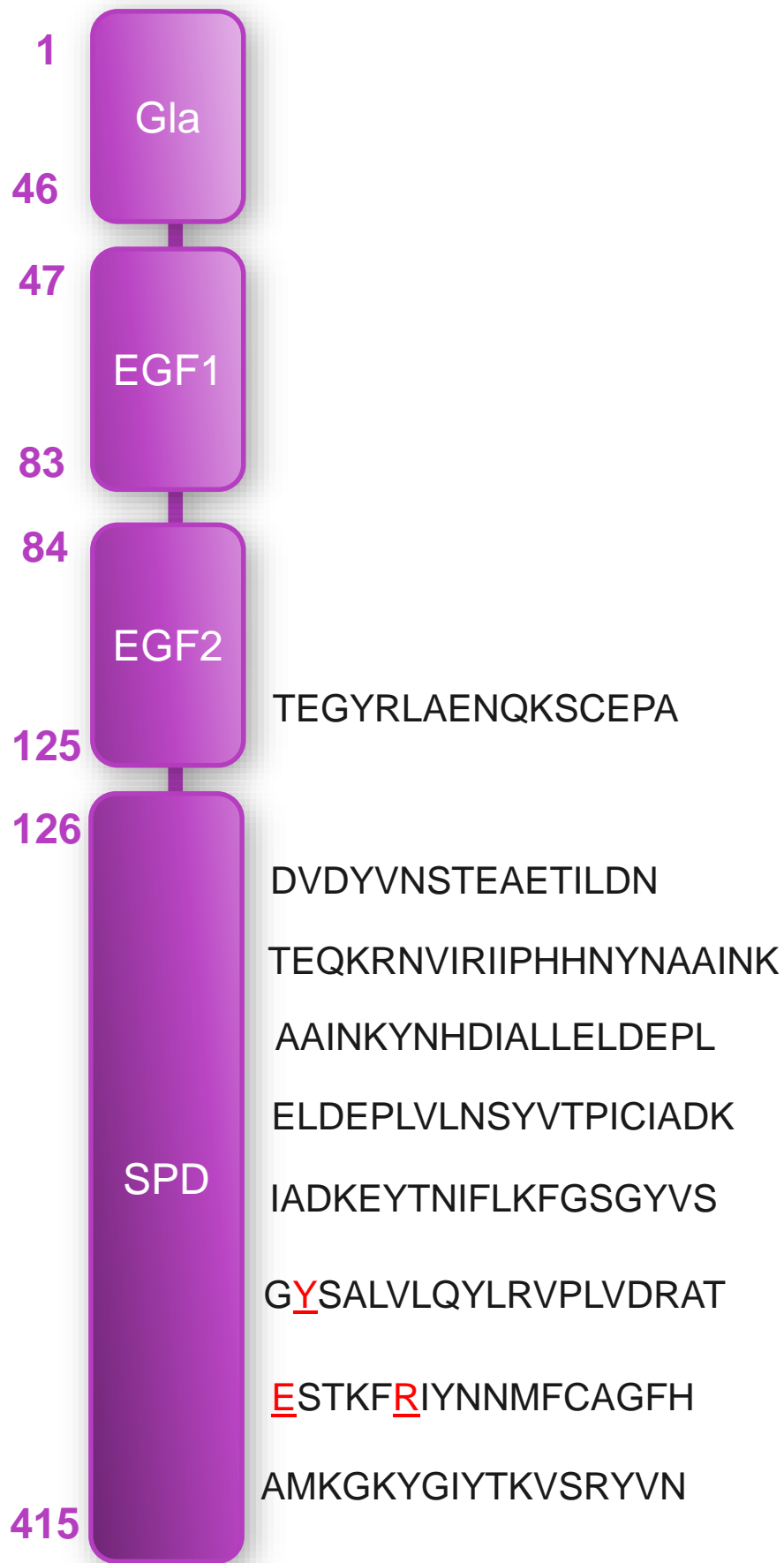
D1581	D1714	D1837	D1842	D1858	D1863	D1867	D1869	D1871	D1894	D1895	D1896
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No peptides identified from Gla domain or EGF 1



Presented peptides are comparable for DalcA & BeneFIX

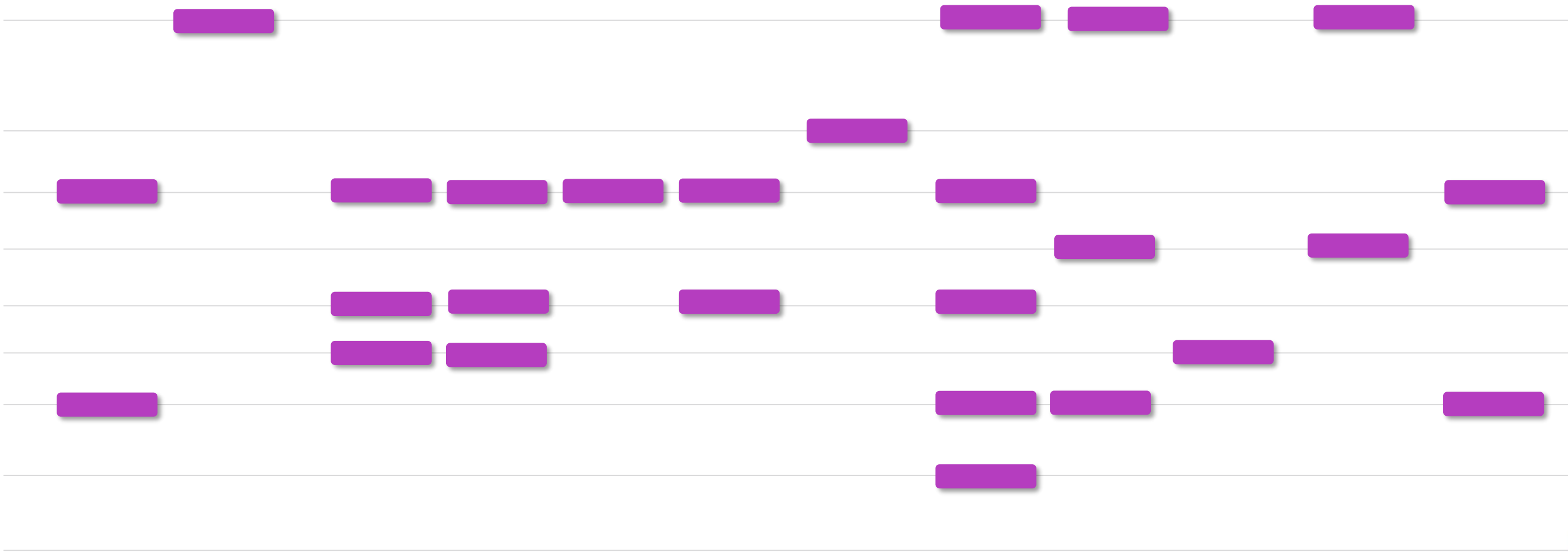
DalcA HLA-DR



Donors

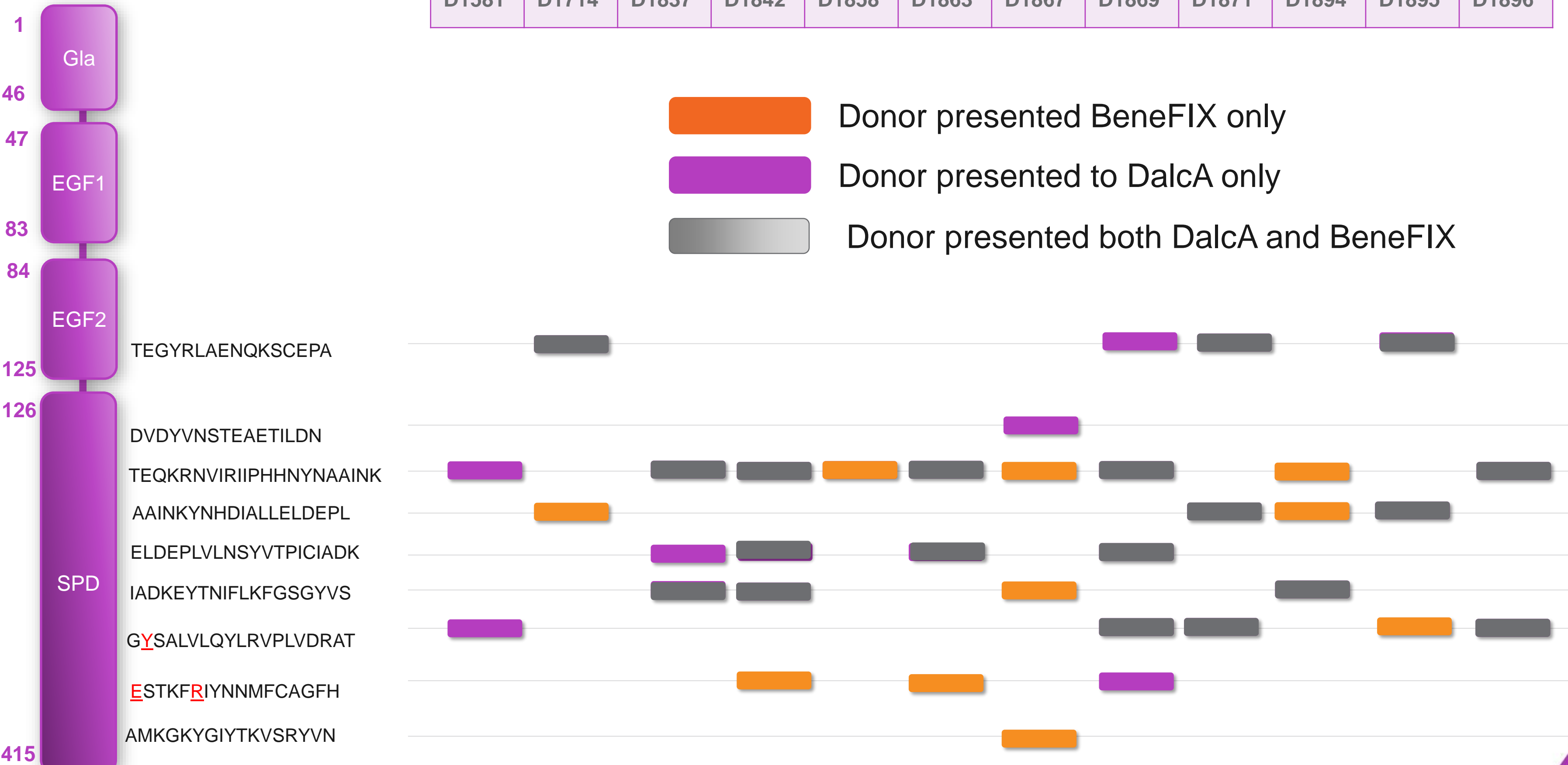
D1581	D1714	D1837	D1842	D1858	D1863	D1867	D1869	D1871	D1894	D1895	D1896
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No peptides identified from Gla domain or EGF 1



Presented peptides are comparable for DalcA & BeneFIX

Overlap HLA-DR



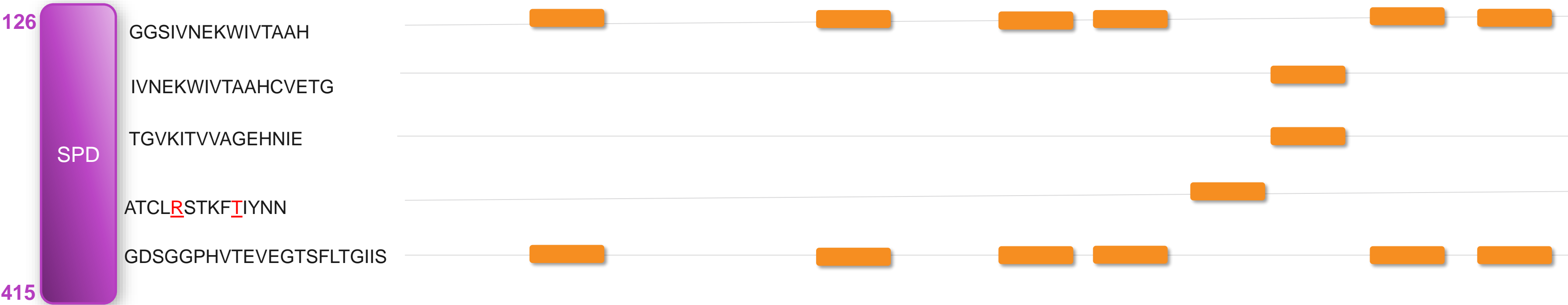
Presented peptides are comparable for DalcA & BeneFIX

HLA-DP profile

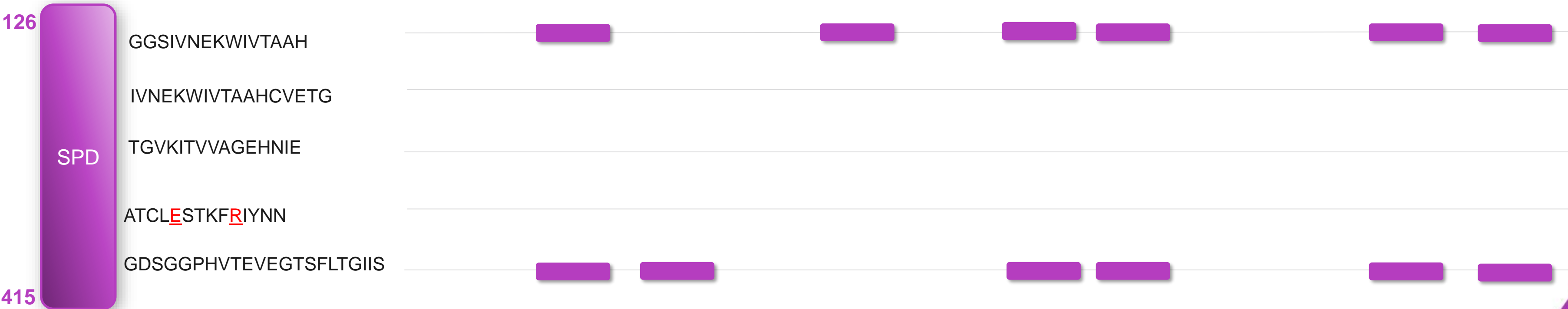
Donors

D1581	D1714	D1837	D1842	D1858	D1863	D1867	D1869	D1871	D1894	D1895	D1896
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BeneFIX

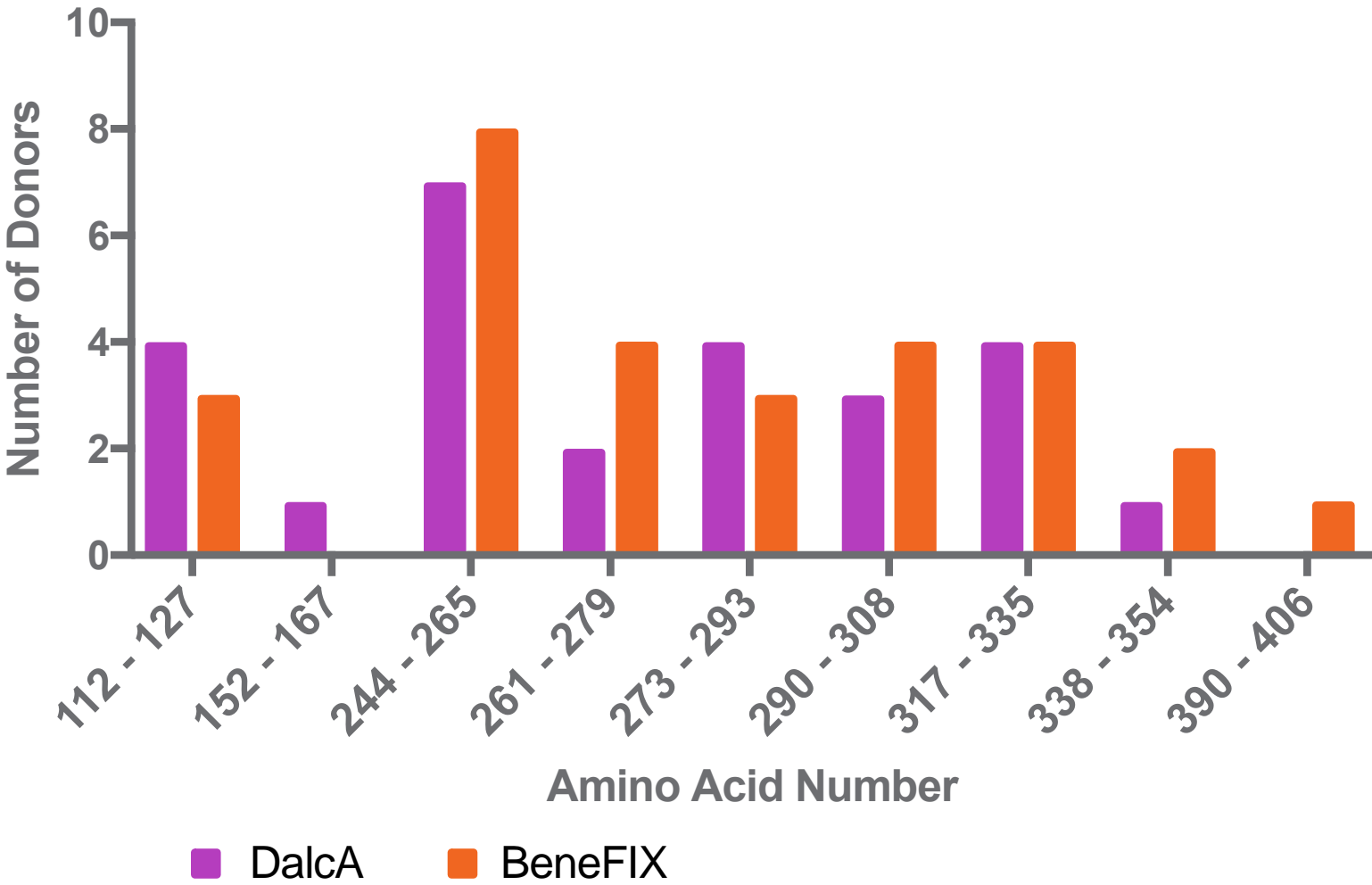


DalcA

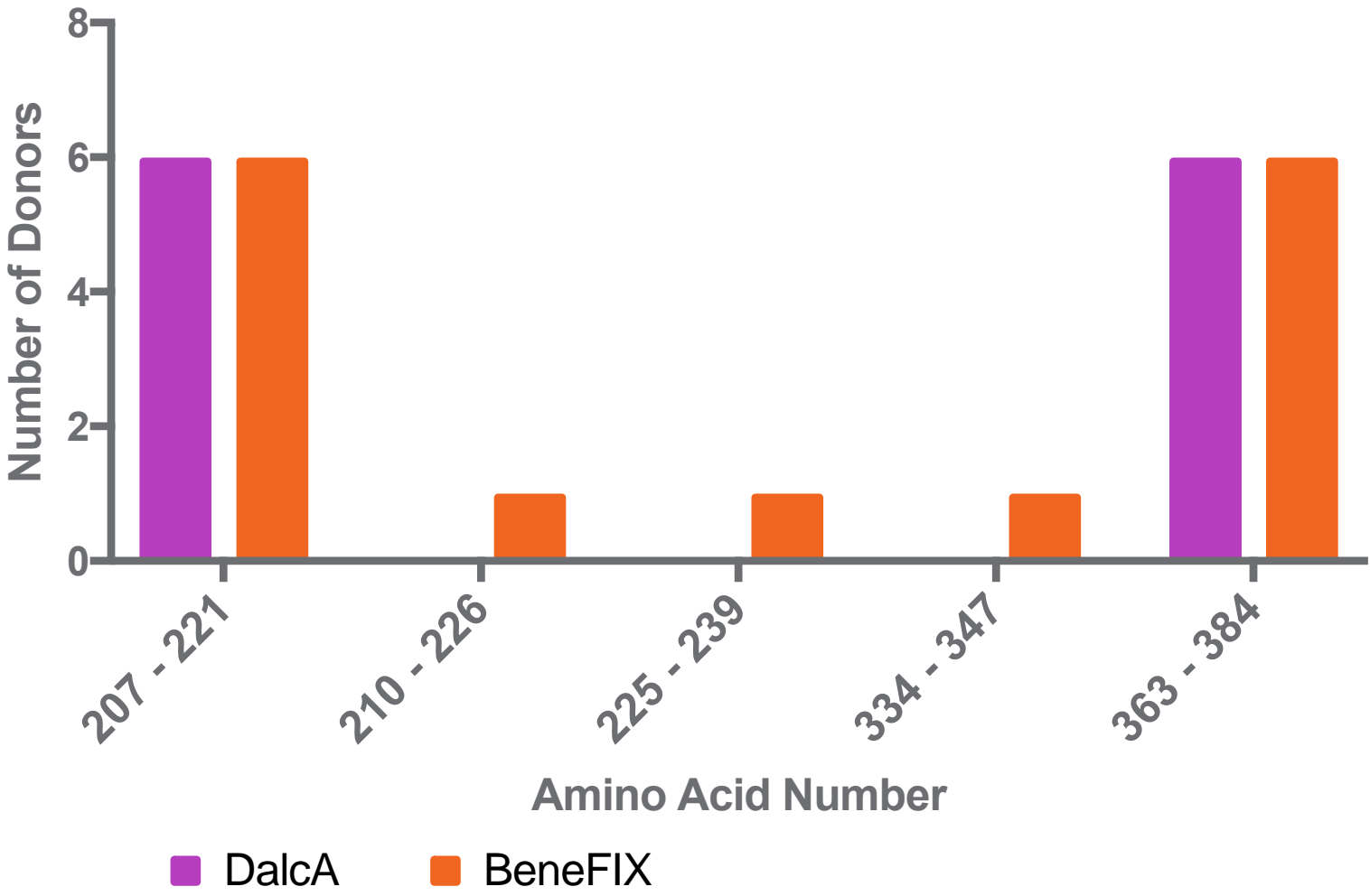


Comparable peptide presentation by HLA-DR and HLA-DP

Peptide presentation by HLA-DR

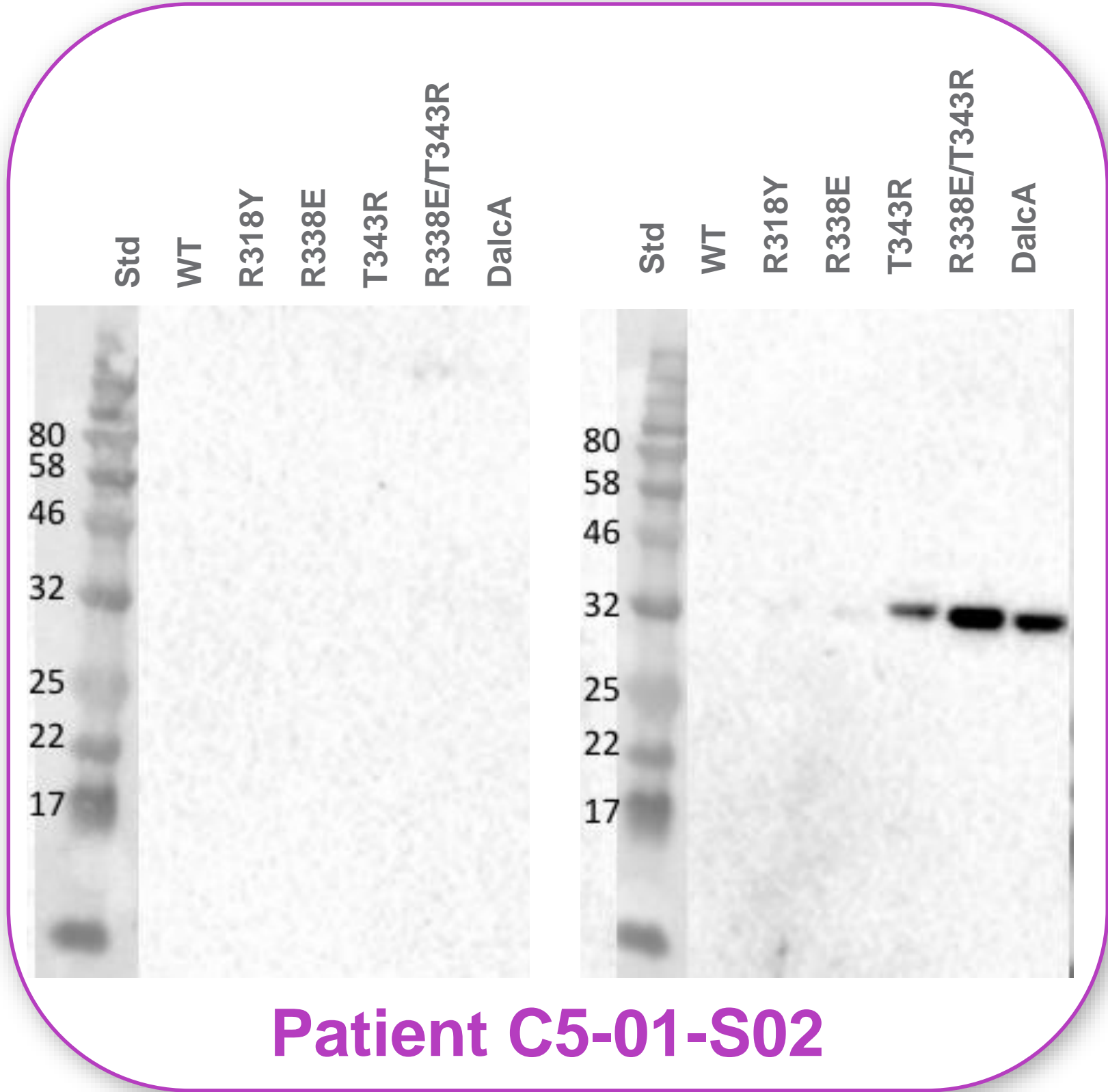
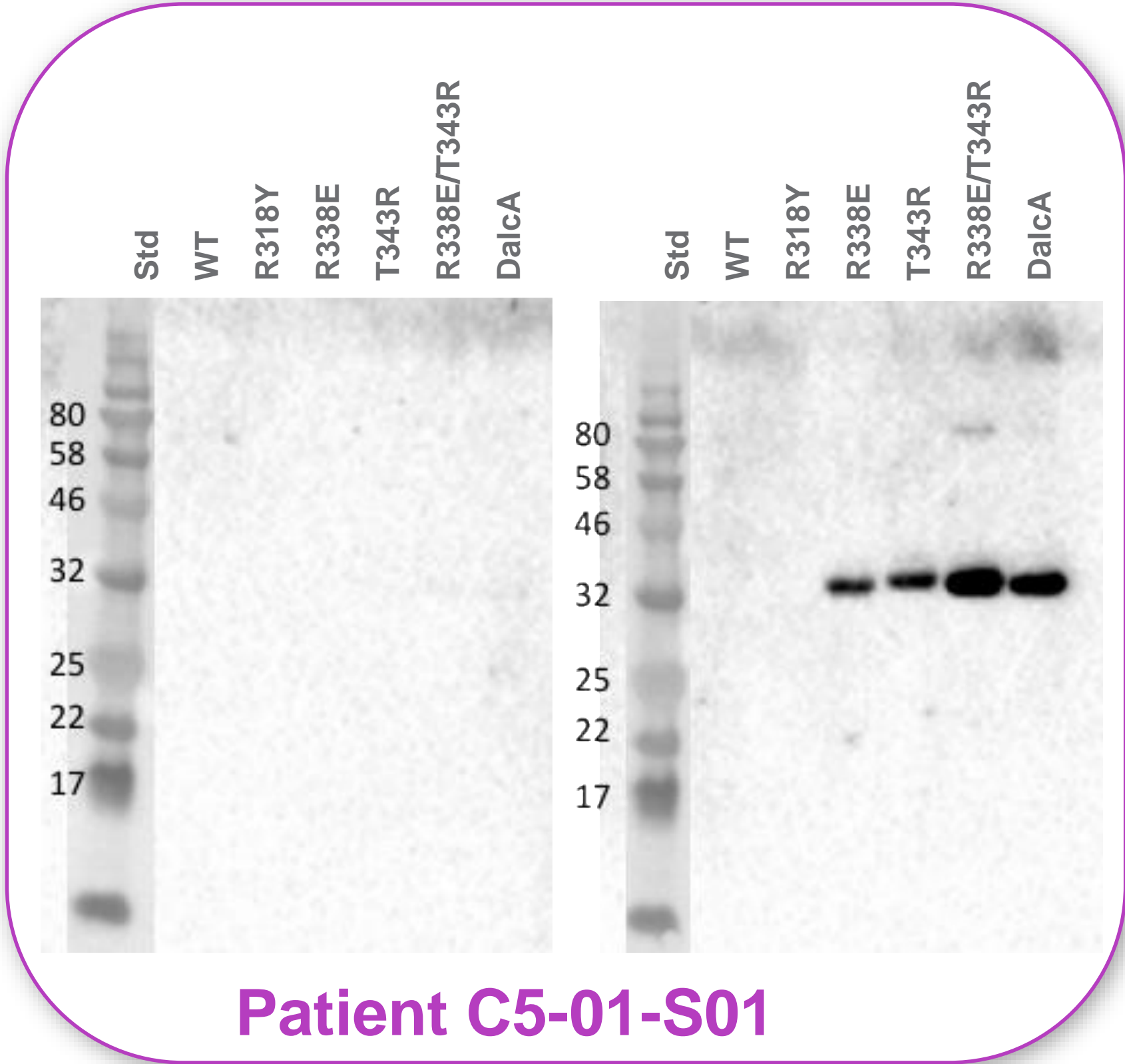


Peptide presentation by HLA-DP



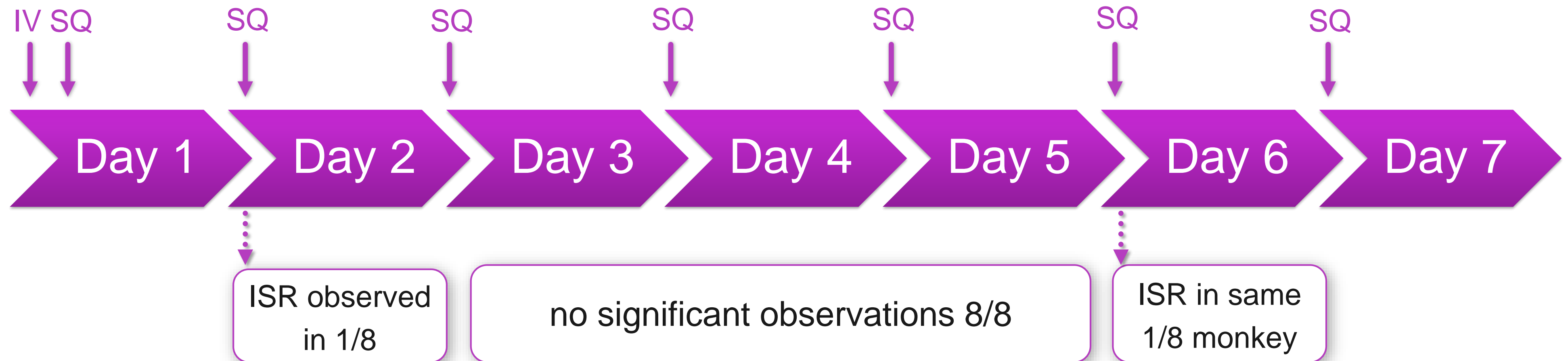
Epitope mapping identified nAb binding to the T343R region Nasdaq: CBIO

Overview of native western blot analysis



+ Neutralizing antibody epitopes are centered on R338E and T343R

Consistent ISRs were not observed in the 7-day tox study



- + Lack of consistent response across sites within an animal and between animals indicate that the **monkey model does not show ISRs** as recorded in ISU 304 P1/2 trial
- + No ISRs were observed in a previous minipig SQ multidose study
- + One observed mild ISR in >325 doses of MarzAA in man and no ISRs in a similar NHP study

DalcA is comparable to BeneFIX & RIXUBIS

Multiple industry standard characterizations performed

Potency

Biological Activity

Product Purity

Biophysical and Structural Properties

Chemical Modifications

Post Translational Modifications

Host Cell Impurities

Product and Process Related Impurities

Thermal Stability upon Reconstitution

Product quality &
stability attributes are
comparable to
marketed rFIX
products

What may have led to the development of nAbs?

The DalcA molecule is not inherently immunogenic – What now to consider in the clinic

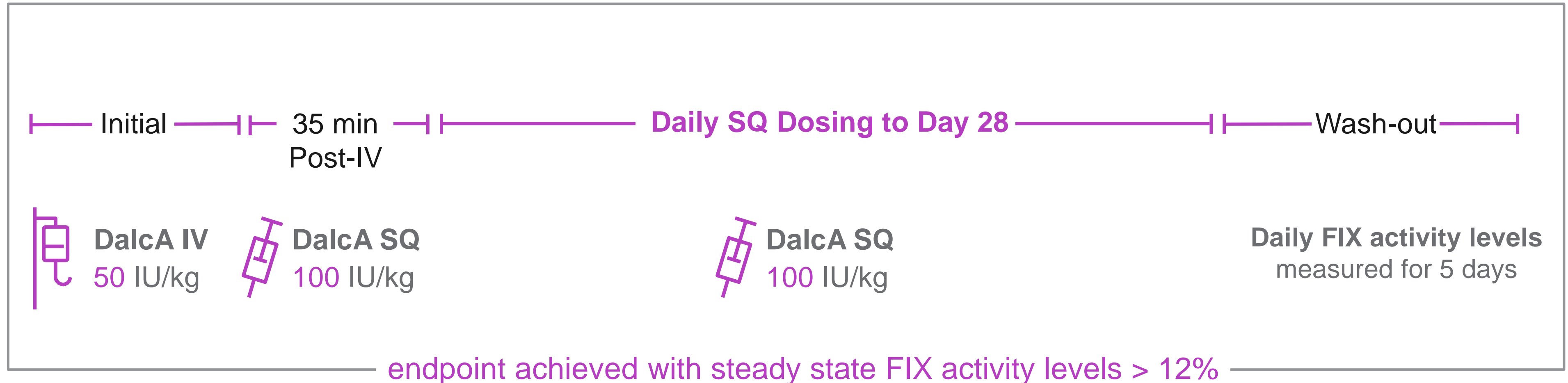
- The nAbs were associated with the rare genotype and/or certain HLA types
- The nAbs did not cross-react with BeneFIX or RIXUBIS so do not present a safety risk
- The nAbs were a rare event observed early in the trial within a restricted population

Conclusion – Evaluate further safety & efficacy in a Phase 2b trial

- + Broaden the subject population to have a diverse ethnic and genotypic background
- + Exclude the rare genotype of the two subjects who developed nAbs in the P1/2 trial
- + Consider HLA profile and exclude those with HLA types that may be deemed at risk
- + Execute the P2b trial (28 days of dosing) with careful monitoring for development of nAbs

DalcA Phase 2b SQ clinical trial design: DLZ-201

Moving forward with the phase 2b study: DLZ-201



- + Enrollment: 6 patients
- + Single IV dose followed by 28 day SQ dosing
- + Primary endpoint: Steady state FIX activity level above 12% with daily dosing
- + Secondary endpoints: no inhibitor formation, pharmacokinetics, pharmacodynamics

DalcA regulatory next steps

Next steps to Phase 3 & agency approvals

CBIO has obtained the perspective of ex-FDA experts on nAb

- + Proceed with care with Phase 2b in 6 patients
- + Preclinical immunogenicity assessment was comprehensive – no issues identified
 - Complementary on the completeness of CBIO's investigation of nAb

CBIO received scientific advice from MHRA

- + Additional data (Phase 2b) is needed to assess nAb
- + Global Phase 3 clinical study design:
 - 20 adult patients with Hemophilia B
 - 6 months prophylactic dosing
- + Toxicology package is sufficient

Pre-IND meeting with FDA will be scheduled after completion of the Phase 2b study

Final Phase 3 clinical study design will incorporate EMA, MHRA and FDA guidance

Conclusions on the dalcinonacog alfa program

Moving forward in clinical development after an extensive immunogenicity risk assessment

Preclinical immunogenicity assessment shows that dalcinonacog alfa is equivalent to that of competitors such as BeneFIX

A comprehensive evaluation of the drug product shows comparable quality to marketed rFIX products

KOLs and subject experts agree with the immunogenicity risk assessment and proceeding with the P2b to evaluate the safety and efficacy of dalcinonacog alfa

CATALYST BIOSCIENCES

December 18th 2018

Marzeptacog alfa (activated)



Marzeptacog alfa (activated)

Marzeptacog alfa (activated), a novel clinical stage SQ FVIIa product candidate differentiated from IV market leaders:

- + Simpler, less painful, small dose
- + SQ enhances pharmacokinetics
- + Potential to maintain continuous protective levels
- + Disruptive to current intravenous bypass products
- + Especially well suited for children

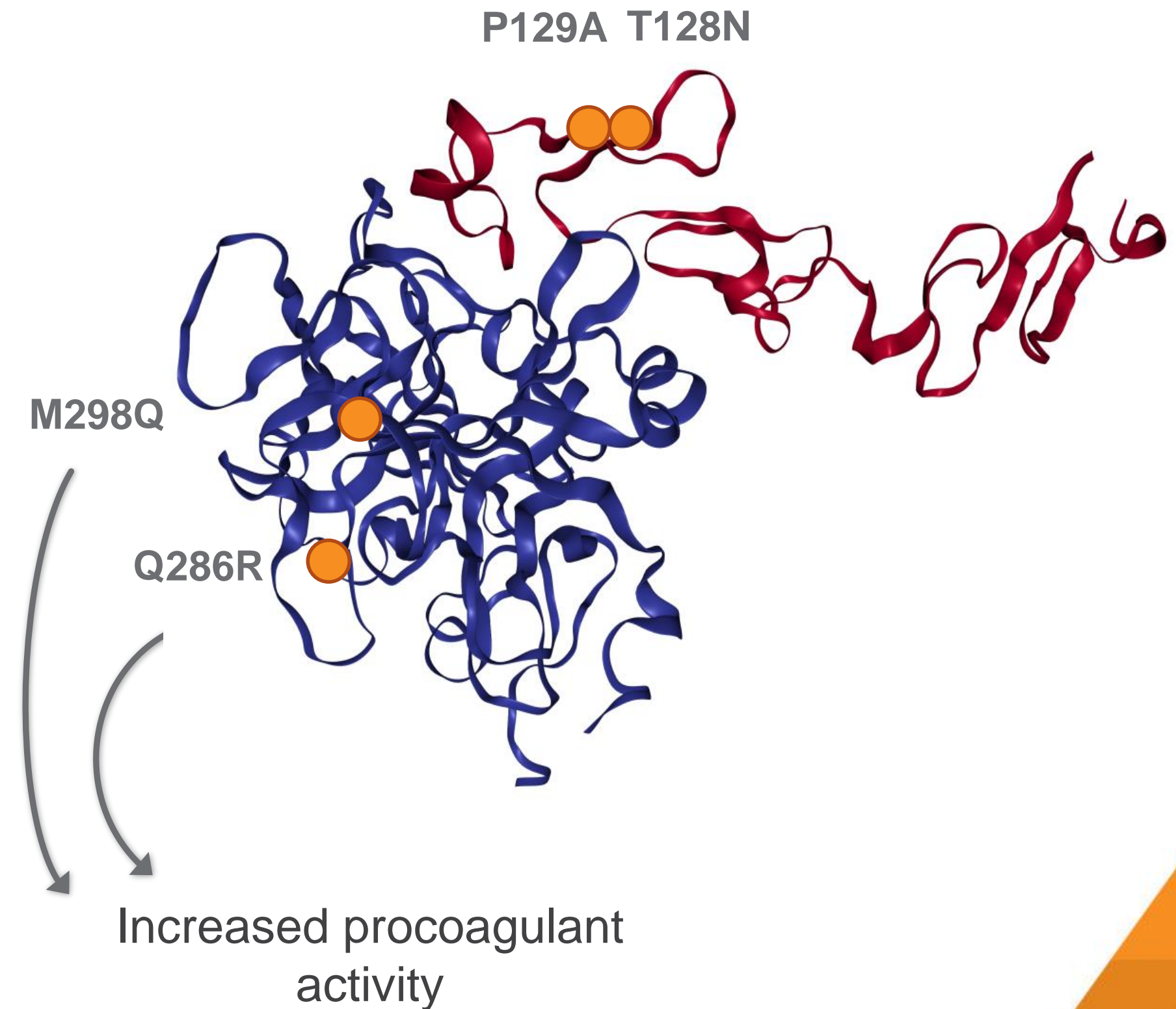
Four point mutations within the FVIIa protein

- + Catalytic activity increased

Best-in-class high-potency rFVIIa product

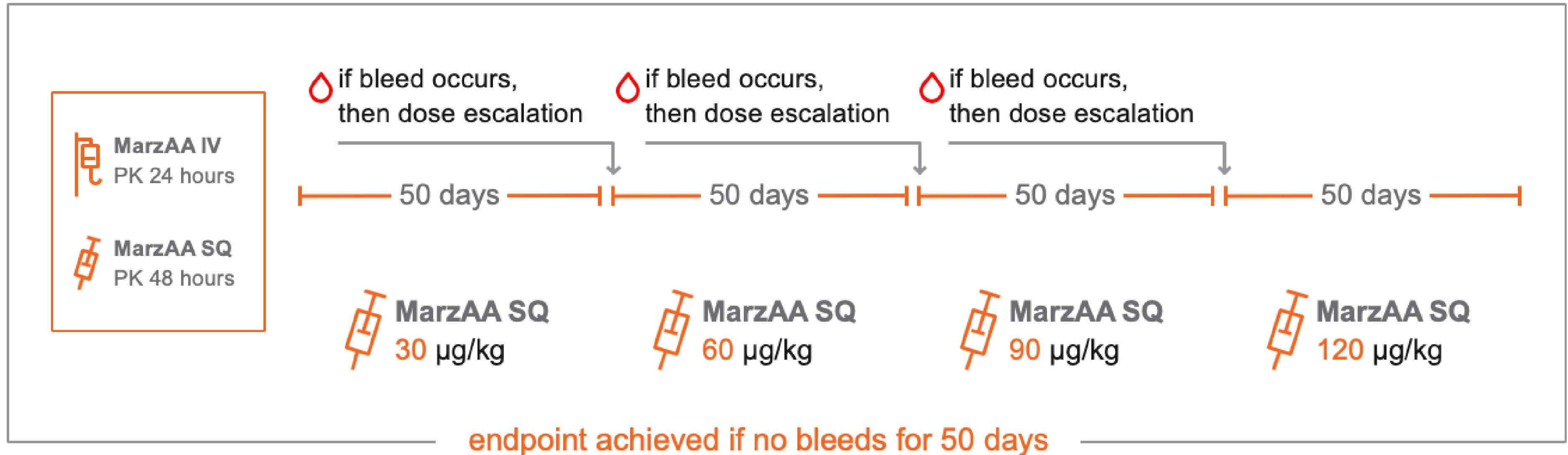
- + 9-fold more potent than NovoSeven RT

Orphan Drug Designation in US



MarzAA phase 2 SQ clinical trial design

Hemophilia with inhibitors: FVIIa



- + Open label SQ study with individual dose escalation if needed
- + Hemophilia A or B with inhibitors
- + Up to 12 adult patients with documented annual bleeding rate (ABR) >12
- + Primary endpoint: reduction in annual bleed rate
- + Secondary endpoints: safety and tolerability, no inhibitor formation

Subject demographics & disposition

High pre-treatment ABRs reduced to a median of 0

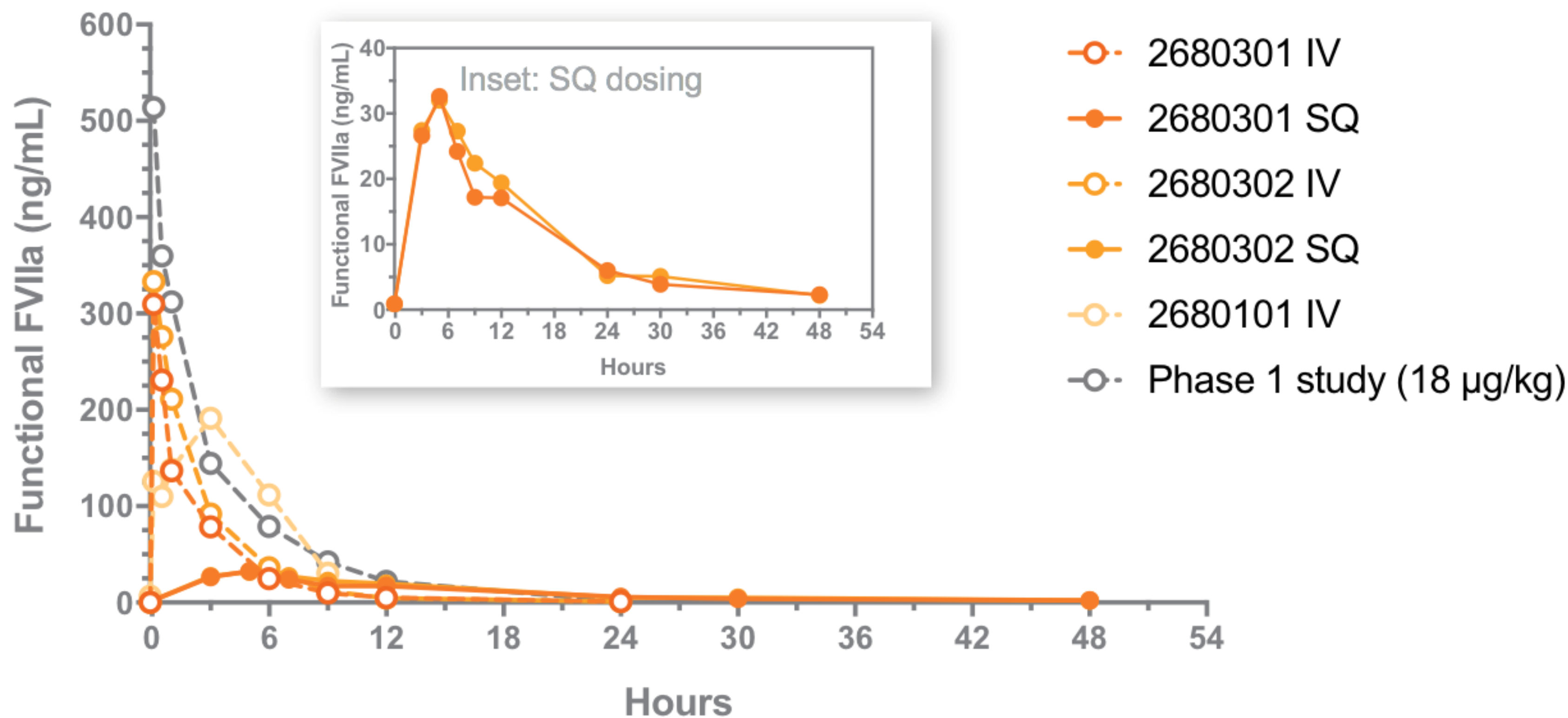
- + 13 subjects have been consented and 9 enrolled (Median ABR 16.25; Range 12.2-27.7)
- + 5 subjects have completed dosing with clinically significant reduction in ABR
- + 4 subjects had no bleeds at their final dose level
- + IV half-life of 3.9 hours was increased to SQ half-life of 13.1 hours
- + No anti-drug antibodies have been detected to date
- + After more than 325 SQ injections, only one injection site reaction of swelling that resolved without sequelae

Subject demographics & disposition

Subject ID	Age	Highest Inhibitor level BU	Age when inhibitor diagnosed	Hemophilia A or B	ABR	ABR on treatment	Proportion of days with bleeding	Proportion of days with bleeding on treatment
2680101	36	16	15	A	12.2	Revoked consent	Revoked consent	Revoked consent
2680301	18	5	14	A	26.7	Zero at 60 µg/kg 3.8 overall	18%	Zero at 60 µg/kg 1% overall
2680302	30	2.7	26	A	18.3	Fatal unrelated SAE	11%	Fatal unrelated SAE
6430201	29	4.2	27	A	15.9	Zero	12%	Zero
6430202	35	4.7	35	A	16.6	Zero	11%	Zero
0510101	43	5.5	39	A	22.2	Untreated traumatic hematoma Day 4. ABR 7.3	22%	2%
0510104	31	1.73	31	B	27.7	Dosing		Dosing
6430204	18	56	6	A	15.9	Dosing		Dosing
6430203	23	4.5	21	A	15.2	Zero	4%	Zero
7100101	23	2.94	19	A		In screening		In screening

MarzAA Phase 2 study interim PK results

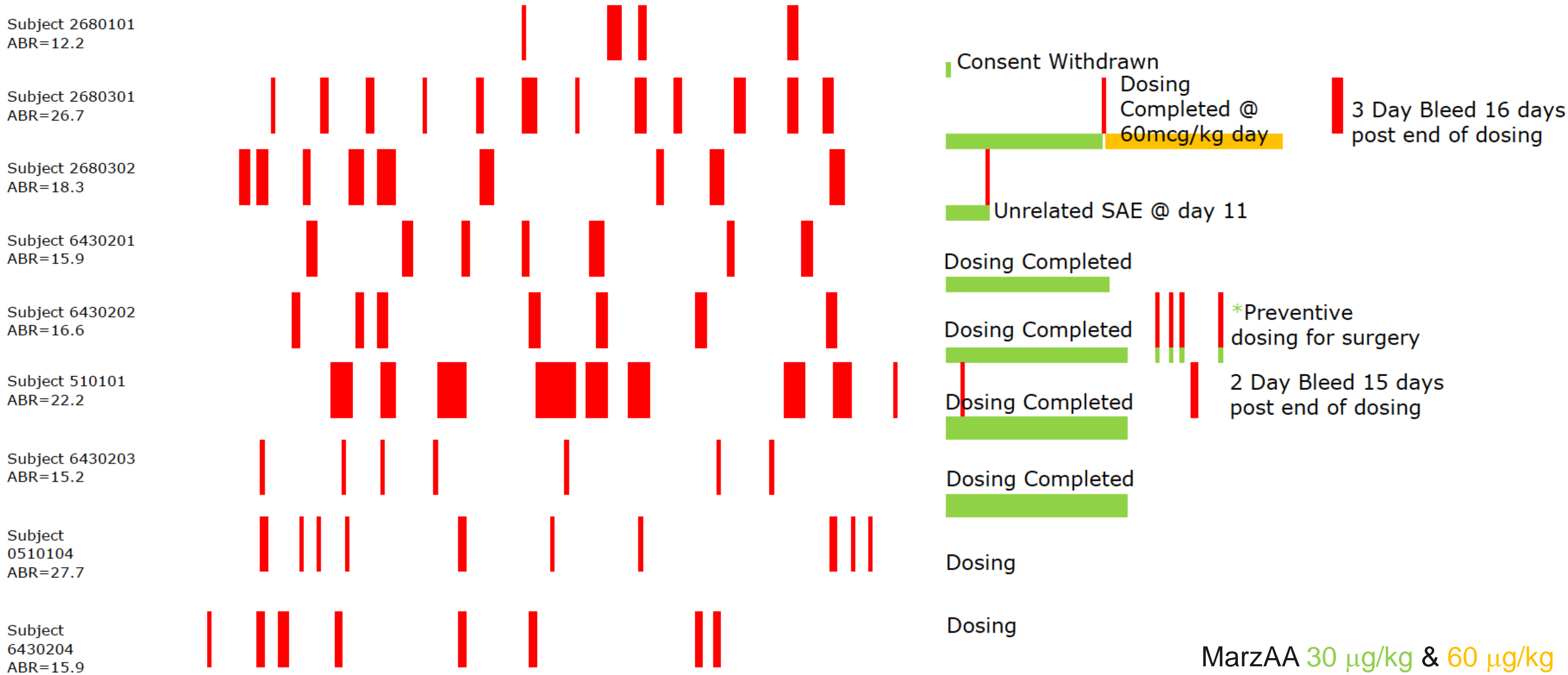
FVIIa functional activity after IV or SQ administration



MarzAA pharmacokinetics

Route	Half-life alpha (hr)	Half-life beta (hr)	Mean Residence Time (hr)	Cmax (ng/mL)	Tmax (hr)	AUC _{0-t} (ng/mL*hr)	AUC _{0-inf} (ng/mL*hr)	Bioavailability (%)
IV Median ± Interquartile Range	1.1 ± 1.2	3.9 ± 1.4	4.5 ± 2.5	309.5 ± 267.0	0.083 ± 1.5	1042.0 ± 410.4	1048.3 ± 497.8	22 ± 25
SQ Median ± Interquartile Range		13.1 ± 12.2	20.6 ± 16.5	22.0 ± 20.3	6 ± 3.5	332.5 ± 253.6	411.1 ± 179.5	

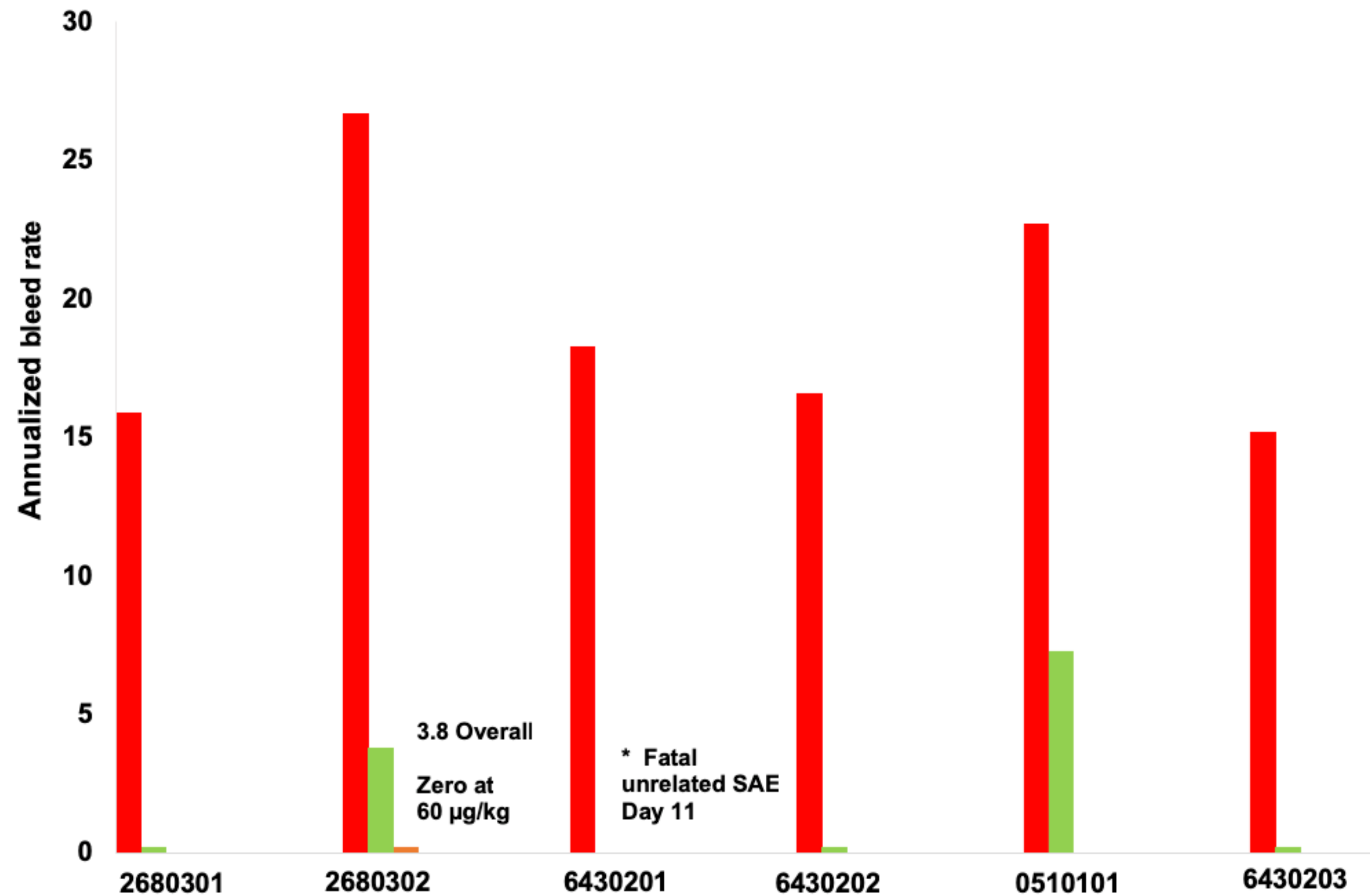
MarzAA reduces annualized bleed rate (ABR)



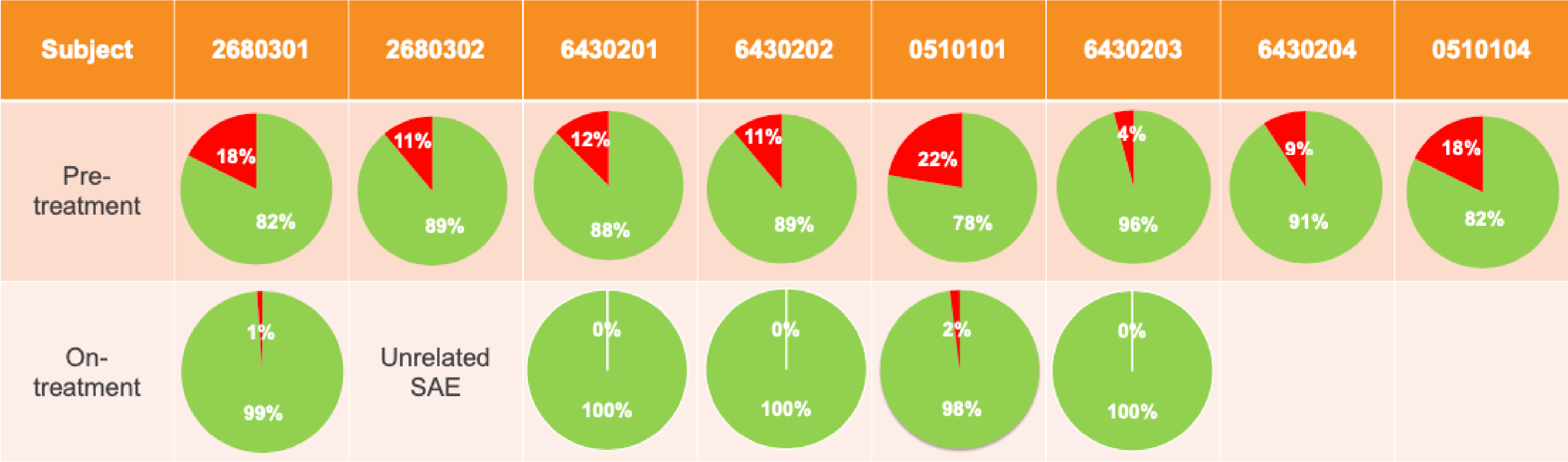
The width of the red bar represents bleed duration: 1 to 9 days



Pre-treatment ABR & ABR during treatment



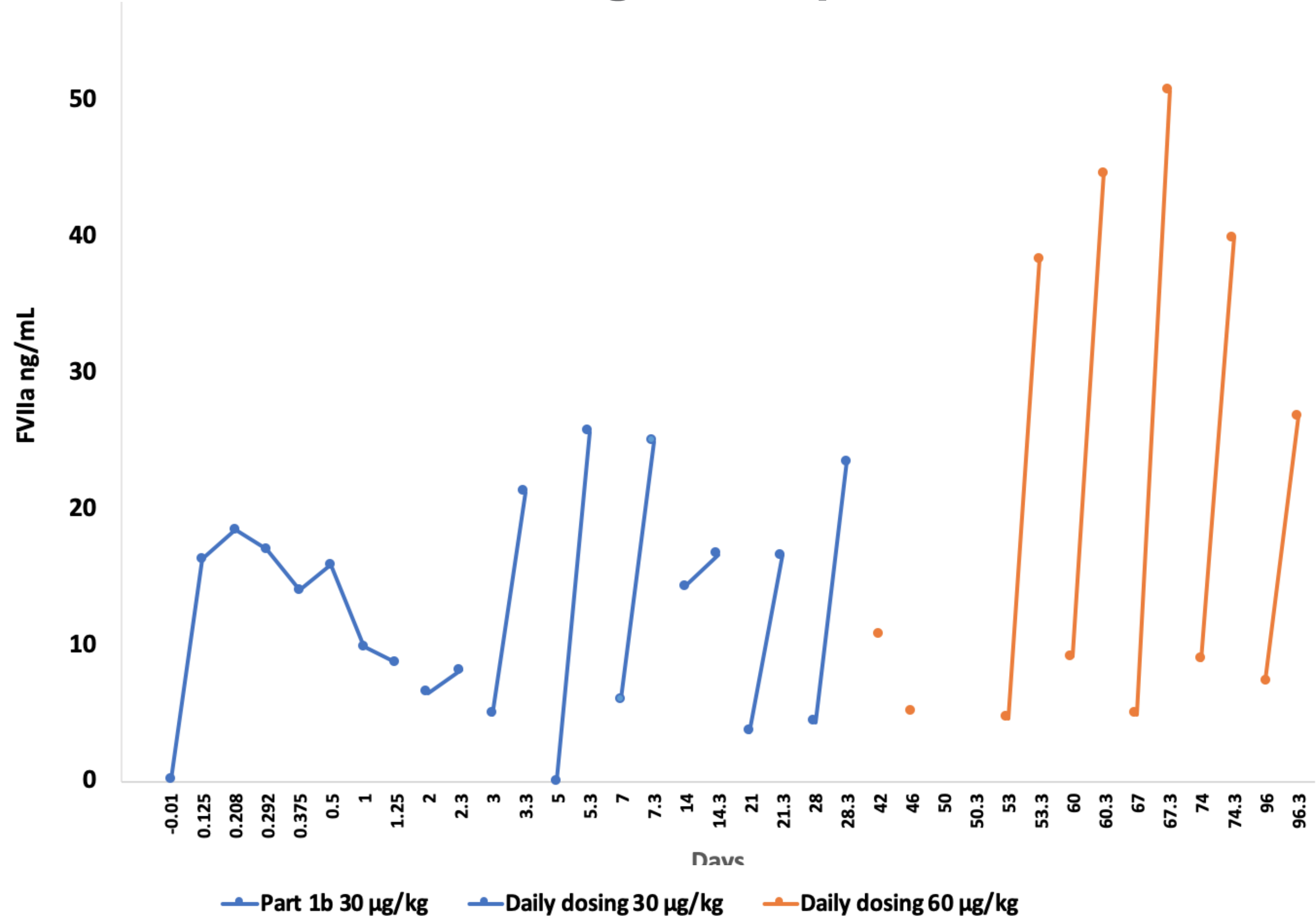
Pre- and on-treatment proportion of bleeding days efficacy



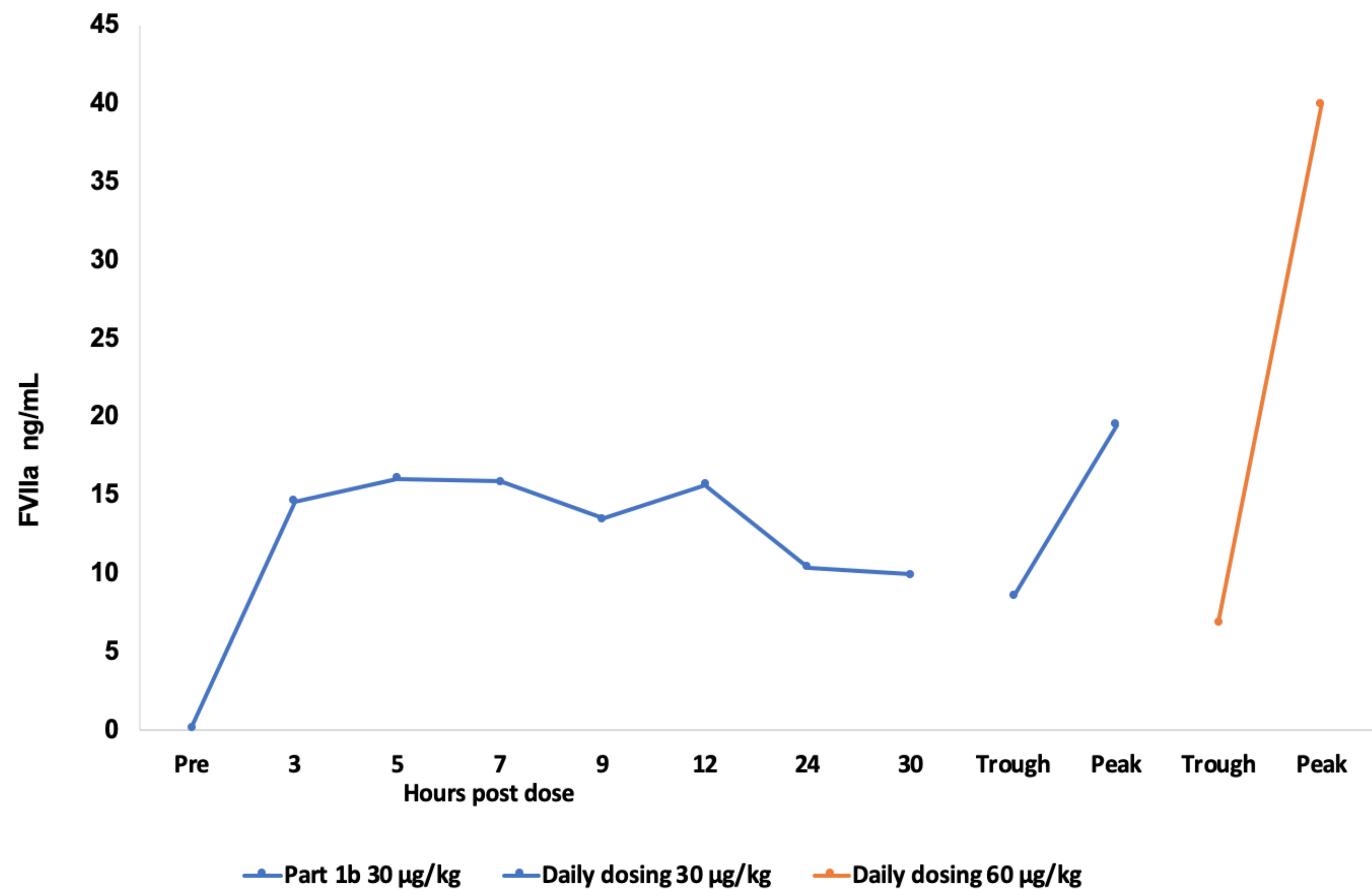
Red denotes the proportion of days with bleeding during observation period

- + The average percentage of days of bleeding in the pre-treatment period was 13.2% (standard deviation 6.3%) [median 11.9%]
- + In the treatment period, these percentages were reduced to 1.9% (standard deviation 3.2%) [median 0.5%]
- + The analysis of these pairwise differences by a randomization paired t-test yields $p=0.03$ (and $p=0.036$ by Wilcoxon signed-rank test)

Mean First SQ dose PK and trough & 7h post-dose FVIIa



Mean First SQ dose PK and trough & 7h post-dose FVIIa level by dose



Next Steps to Phase 3 & Agency Approvals

MarzAA Phase 3 trial design based on EMA and MHRA feedback

- + An end of Phase 2 meeting with FDA to be scheduled after completing clinical study report

Global Phase 3 clinical study:

- + 20-40 adult patients with Hemophilia
- + 6 Hemophilia B patients
- + 6 months lead in and 6 months treatment
- + The primary end point - significant reduction in ABR and population of patients with zero bleeds

Non-clinical strategy developed with four experts ex CBER reviewers

A PK/PD clinical study will start in 2019 – based on MHRA feedback

Conclusions on the marzeptacog alfa (activated) program

Moving forward in clinical development after clinical proof of concept

Clinical efficacy and tolerability demonstrated

Additional clinical data at EAHAD 2019 and ISTH 2019

Trial guidance obtained from EMA & MHRA, will confirm at FDA end-of-phase 2 in late 2019

CATALYST BIOSCIENCES

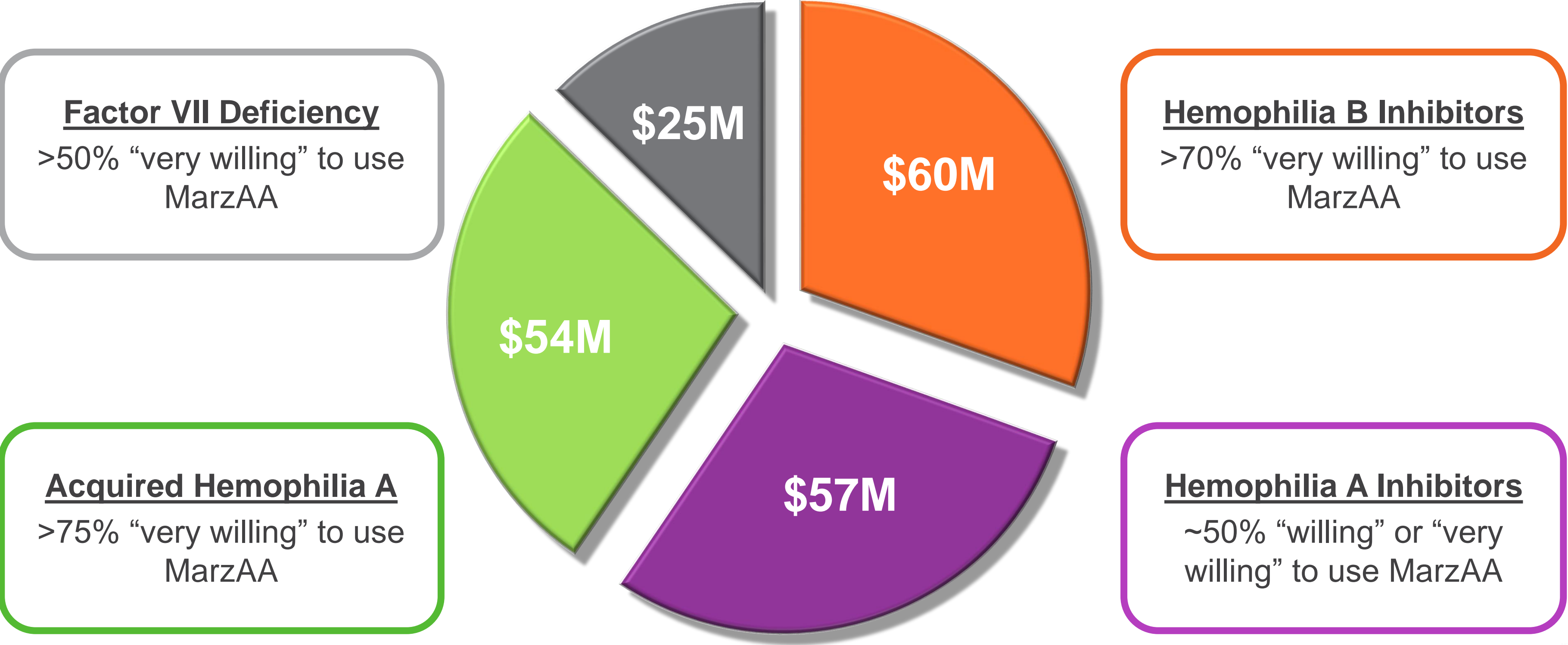
December 18th 2018

Financial Information



MarzAA US Revenue Forecast \$196M (~\$400M Worldwide)

Target Product Profile Strongly Resonates Across Multiple Indications



Financial information

Selected data

Operating Results	Q3 2018	Q3 YTD	2018 Forecast	2019 Est.
Operating Expense	\$8.3 M	\$22.1 M	OpEx >\$30M	OpEx ~\$56M
Net Loss	(\$7.7 M)	(\$19.2 M)	Cash ~\$120M	Cash Burn ~ \$50M
Net Loss per share	(\$0.64)	(\$1.75)		

Share Data

Common Stock Outstanding.....	11,942,729
Fully Diluted Shares.....	14,623,688
Average Volume.....	166,084
Market Capitalization as of 17 December 2018.....	..\$111 M

Financial Strength

Cash & Cash Equivalents Q3/2018.....	\$129.2 M
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Catalyst / ISU DalcA Collaboration

ISU gains Korean commercial rights, CBIO to pay ISU a fixed low-single-digit royalty

Prior Agreement

- + ISU had a option for first right of refusal on Korean commercial rights and a profit share
- + Catalyst responsible for worldwide development, regulatory and commercialization

Restructured Agreement

- + Catalyst maintains global development, regulatory and ex-Korea commercialization rights
- + ISU granted:
 - Korean commercial rights
 - Up to \$19.5M in development, regulatory and sales based milestones
 - Single digit net-sales royalty
 - Option for profit share removed

Milestones

	2018				2019			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
<div>MarzAA</div> <div>(FVIIa)</div>	<div>P2 Initiated</div> <div>✓</div>		<div>ISTH</div> <div>Interim P2 data</div> <div>✓</div>	<div>ASH</div> <div>P2 data</div> <div>✓</div>	<div>EAHAD</div> <div>P2 data</div>		<div>ISTH</div> <div>P2 Data</div>	<div>EoP2</div> <div>A/B Inhibitors</div>
<div>DalcA</div> <div>(FIX)</div>	<div>EAHAD</div> <div>Top-line multidose clinical data (oral)</div> <div>✓</div>	<div>WFH</div> <div>Final Cohort 5 data</div> <div>Initiate Cohort 6</div> <div>✓</div>	<div>ISTH</div> <div>Phase 1/2 Cohort 6 data</div> <div>✓</div>		<div>Initiate P2b</div> <div>EAHAD</div>		<div>P2b data</div> <div>ISTH nAb Analysis</div>	
<div>Anti-C3</div> <div>(dAMD)</div>					<div>PK/PD</div>	<div>ARVO</div> <div>PK/PD</div>		

Summary

- ✓ **Disruptive approach to a \$3.5 billion market**
Subcutaneous prophylactic dosing designed to be less painful and much more convenient, especially for children
 - + Clinical proof of efficacy demonstrated for both Marzeptacog alfa (activated) & Dalcinonacog alfa

- ✓ **FVIIa: Marzeptacog alfa (activated)**
~\$2.2 Billion market
Phase 2 of a Phase 2/3 program enrolling 90% reduction in ABR on treatment
No ADAs or nAbs observed to date
 - + Phase 2 data at EAHAD & ISTH 2019
 - + EoP2 in 2019

- ✓ **FIX: Dalcinonacog alfa**
~\$1.2 billion market
>30% activity levels achieved with daily SQ dosing
Potential to maintain long-term FIX activity in the mild hemophilia range to be explored in P2b
 - + Initiate Phase 2b in Q1 2019

- ✓ **Anti-C3 for Dry AMD:**
multi-billion market opportunity
C3 is a clinically validated target, potential to generate a best-in-class molecule
 - + Pre-clinical proof-of-concept in 2018

- ✓ **Strong financial position, ~2.5 years cash**

THANK YOU

Nasdaq: CBIO

catalystbiosciences.com

