
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 8-K

**CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): December 13, 2018

CATALYST BIOSCIENCES, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-51173
(Commission
File Number)

56-2020050
(IRS Employer
Identification No.)

**611 Gateway Blvd., Suite 710
South San Francisco, California**
(Address of principal executive offices)

94080
(Zip Code)

(650) 871-0761
Registrant's telephone number, including area code

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 1.01 Entry into a Material Definitive Agreement

On December 13, 2018, Catalyst Biosciences, Inc., a Delaware corporation (the “Company”), entered into an Amended and Restated License Agreement (the “A&R License Agreement”), effective as of December 17, 2018, with ISU Abxis (“ISU”). The A&R License Agreement amends and restates in full the Company’s License and Collaboration Agreement with ISU, dated as of September 16, 2013, as amended (the “Original Agreement”), to, among other things, revise the rights granted and financial obligations of the parties thereunder.

Pursuant to the A&R License Agreement, ISU will receive commercialization rights in South Korea to Dalcinacog alfa (“DalcA”) (formerly CB 2679d/ISU304), Catalyst’s next-generation engineered coagulation Factor IX being developed for the treatment of severe hemophilia B, and the Company will receive clinical development and commercialization rights in the rest of world (excluding South Korea) and manufacturing development and manufacturing rights worldwide (including South Korea). The A&R License Agreement eliminates the profit sharing arrangement in the Original Agreement and provides for a low single-digit royalty payment to ISU, on a country-by-country basis, for net product sales of DalcA by the Company or its affiliates in each country other than South Korea. Pursuant to the A&R License Agreement, the Company will also make up to an aggregate of \$2.5 million in regulatory and development milestone and up to an aggregate of \$17 million in commercial milestone payments to ISU, if the applicable milestones are met.

The A&R License Agreement contains customary representations, warranties, covenants and indemnification provisions. The A&R License Agreement may be terminated by either party, subject to applicable notice and/or cure periods, upon a material breach by or an event of bankruptcy relating to the other party or by mutual consent of both parties.

The foregoing is a summary description of the material terms of the A&R License Agreement, is not complete and is qualified in its entirety by reference to the text of the A&R License Agreement, a copy of which the Company expects to file as an exhibit to the Company’s Annual Report on Form 10-K for the fiscal year ended December 31, 2018. The Company expects to seek confidential treatment of certain terms of the A&R License Agreement at the time it is filed.

Item 7.01 Regulation FD Disclosure

On December 18, 2018, the Company delivered a presentation at its Research and Development Day (the “R&D Day”) in New York, New York to provide updates on its Factor IX (“FIX”) dalcinacog alfa (“DalcA”) and Factor VIIa (“FVIIa”) marzeptacog alfa (activated) (“MarzAA”) hemophilia programs. A copy of the presentation, dated December 18, 2018, is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 8.01 Other Events

In connection with the R&D Day, on December 18, 2018, the Company issued a press release announcing that it is hosting the R&D Day and providing updates on its FIX DalcA and FVIIa MarzAA hemophilia programs. A copy of the press release, dated December 18, 2018, is attached as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit

No.

Description

99.1 [Presentation at the Research and Development Day in New York, New York by Catalyst Biosciences, Inc. on December 18, 2018.](#)

99.2 [Press Release, dated December 18, 2018.](#)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CATALYST BIOSCIENCES, INC.

Date: December 18, 2018

/s/ Fletcher Payne

Fletcher Payne
Chief Financial Officer

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 to differ materially from the forward-looking statements Catalyst makes, including, but not limited to, initiation or enrollment may be delayed, future trials may not achieve the expected results, the clinical trials will not replicate the results of the studies on small numbers of patients, adverse effects may arise from the testing of these products, including the generation of antibodies, the risk that costs required to develop and commercialize Catalyst's products will be higher than expected, competition from other hemophilia products in development, Catalyst's ability to protect its intellectual property rights, and other factors. See the "Risk Factors" section of Catalyst's Form 10-Q for the quarter ended September 30, 2018, filed with the Securities and Exchange Commission on November 1, 2018. Forward looking statements in this presentation speak only as of the date hereof and Catalyst does not assume any obligation to update or revise these forward-looking statements, except as required by law.

Catalyst Biosciences: CBIO



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



2018

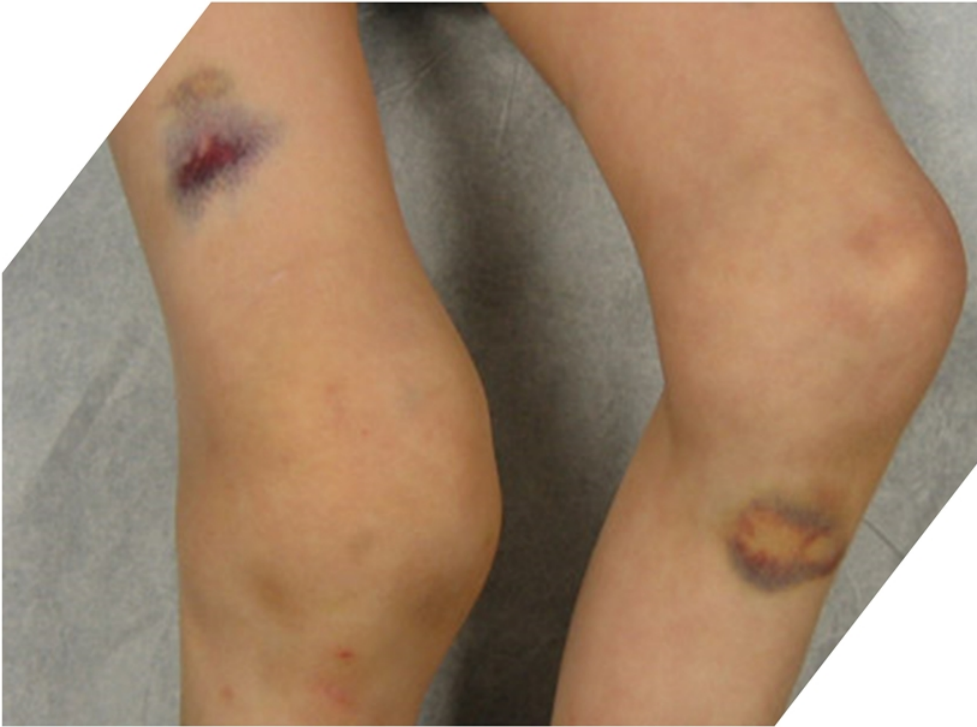
FVIIa & FIX SQ efficacy clinically demonstrated



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



Life with hemophilia



Hemophilia A or B -

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

Acquired Hemophilia

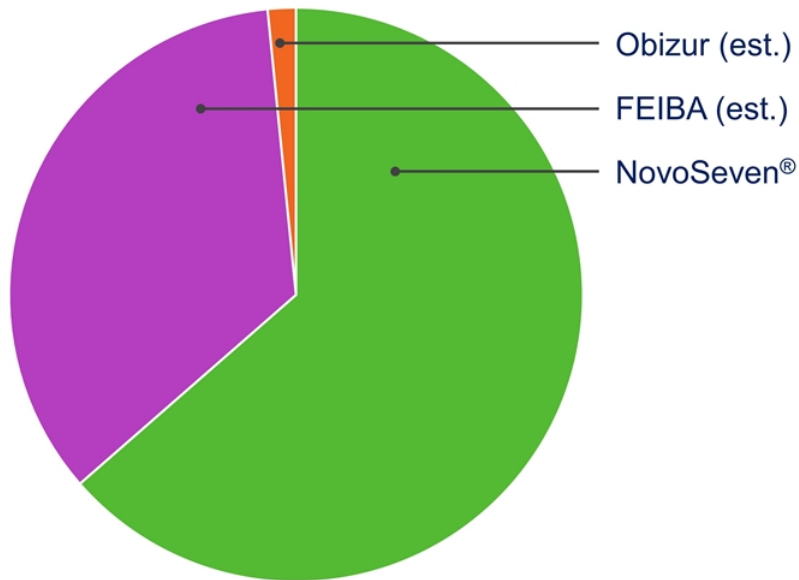
- Rare disorder, occurs spontaneously or is caused by anti-FVIII antibodies
- Currently treated with FVIII bypass agents (FVIIa)
- Unmet need to address

Market

FVIIa & Bypassing Agents: \$2.2B market

Hemop

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

In 2017 o patients

Sources: WFH Annual Global Survey, GlobalData, Roche, Novo Nordisk, Aptevo, SOBI, Bioverativ. *Hemlibra® h

Available treatments



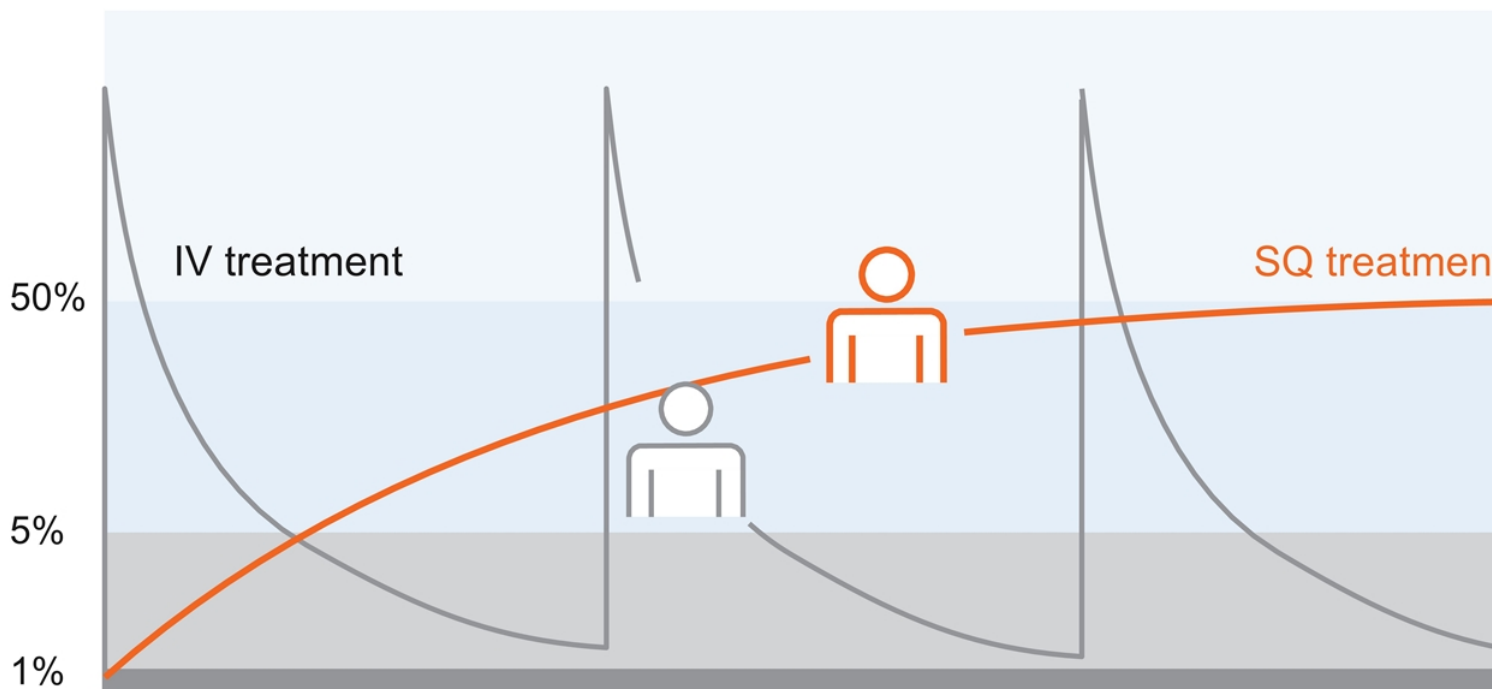
The Catalyst Biosciences solution



catalystbiosciences.com

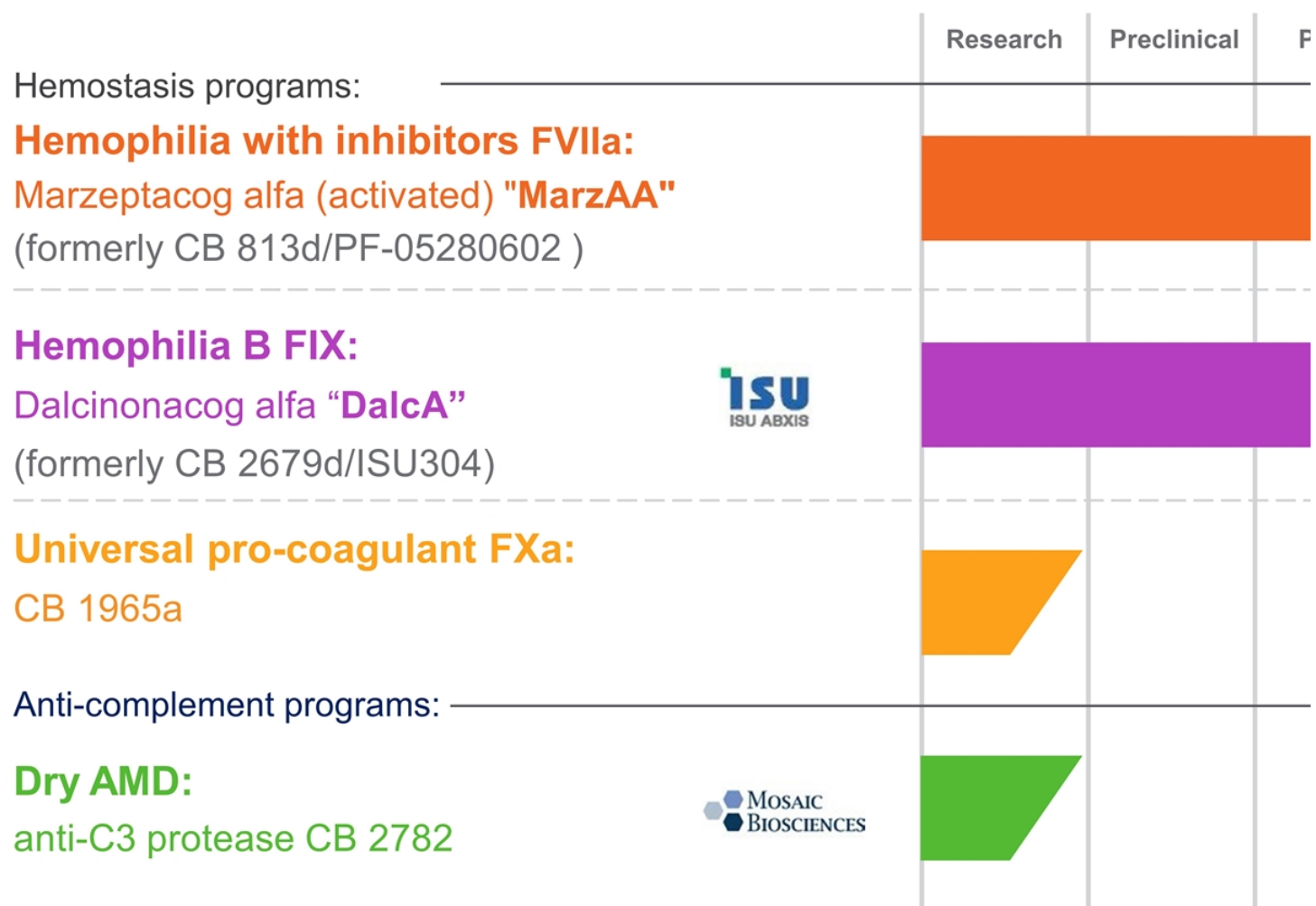
The new standard in hemophilia prophylaxis

Patients in high mild range are protected from spontaneous



- + 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.



26 years
in biotech

SVP, Technical Operat

Andrew Hetherington, M.I.



Chief Medical Officer

Howard Levy, M.B.B.Ch., Ph.D., M.M.M.



18 years
in hematology

VP, Translational Rese

Grant Blouse, Ph.D.



Chief Financial Officer

Fletcher Payne



26 years
in biotech

VP, Business Develop

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

R310
Resistant
antithrombin



Best-in-class high-potency recombinant FIX product

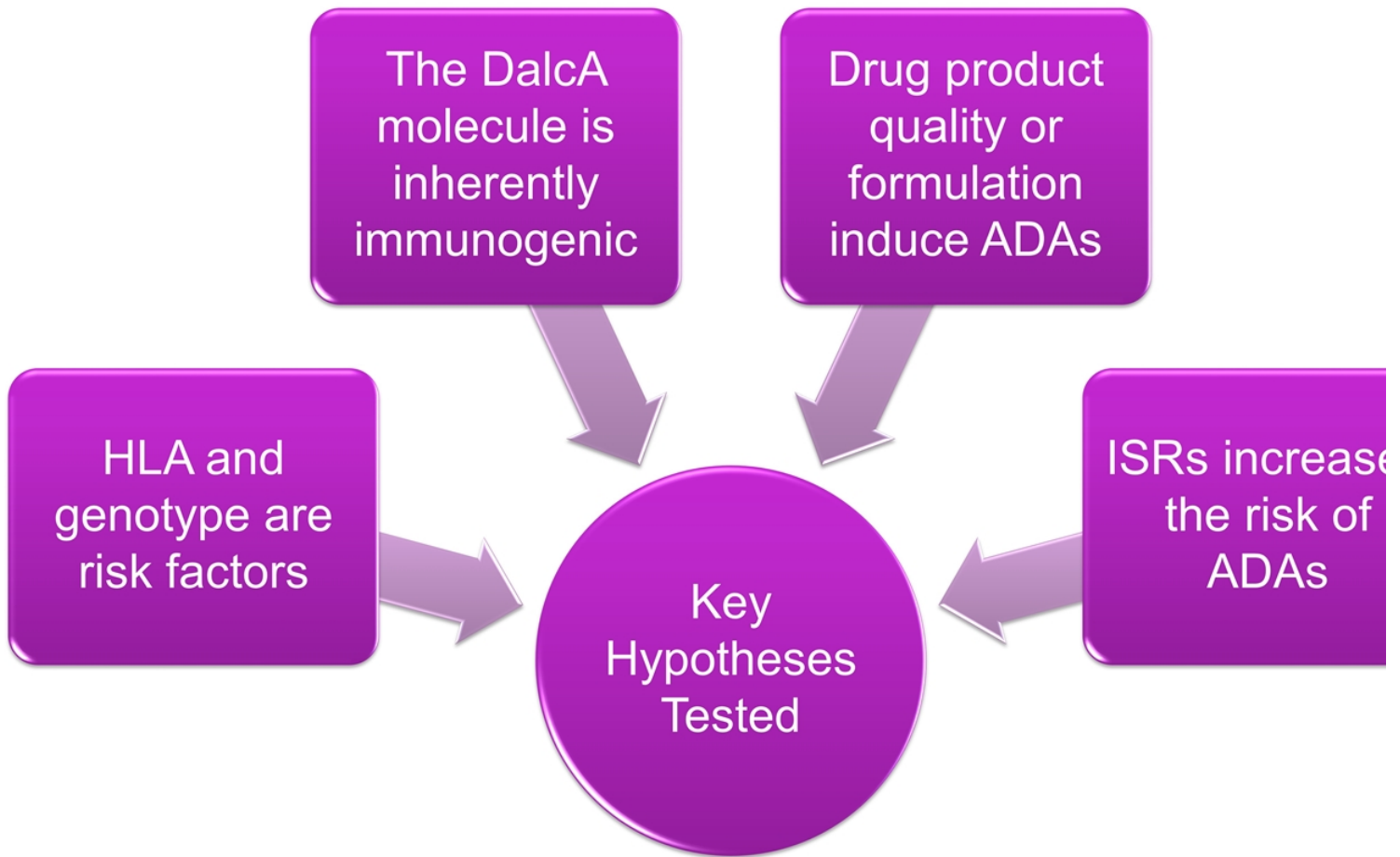
- + 22-fold more potent than BeneFIX in man

Orphan Drug Designation in US & EU

In
&

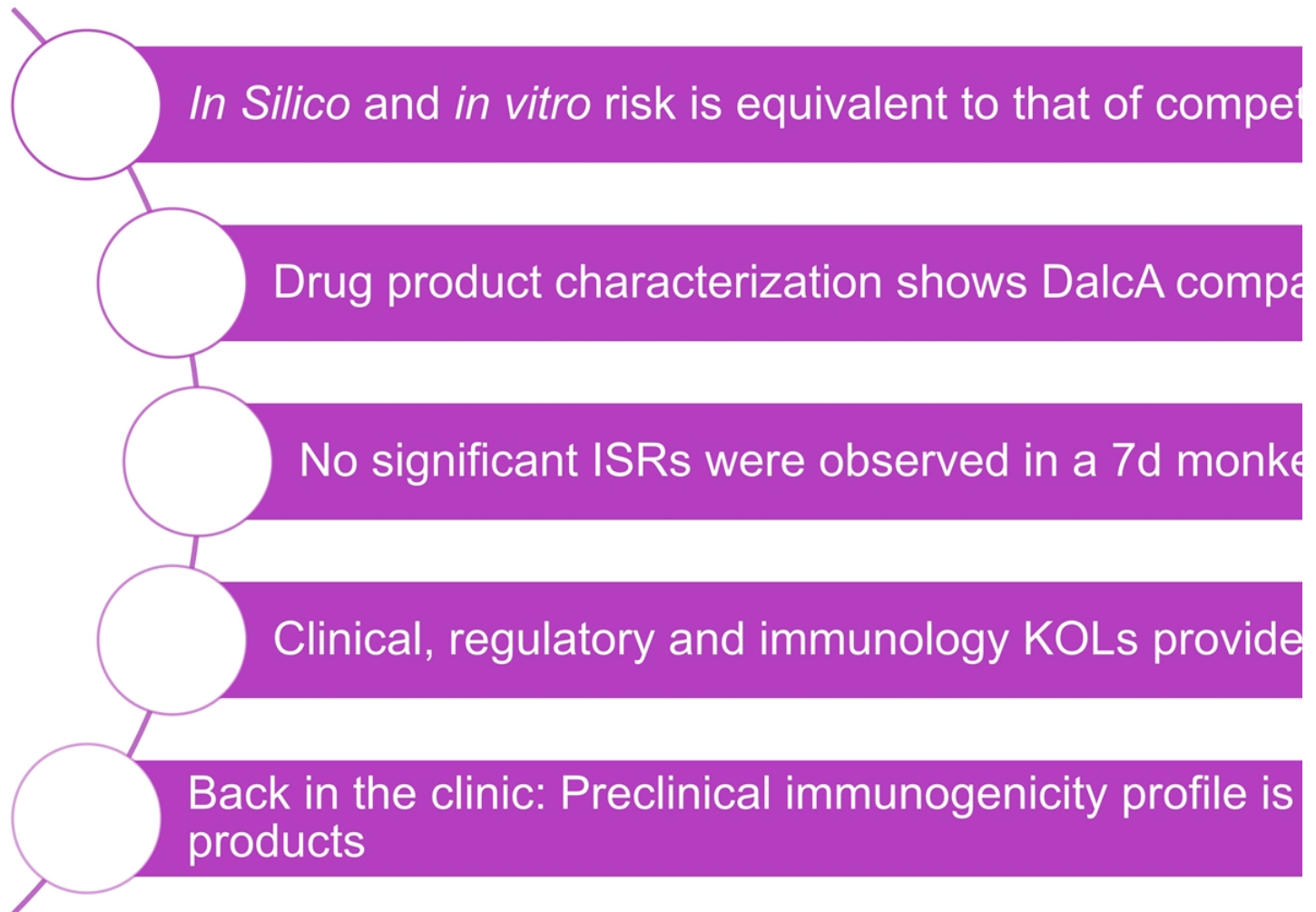
Retrospective immunogenicity assessment

A comprehensive assessment of immunogenicity addresses



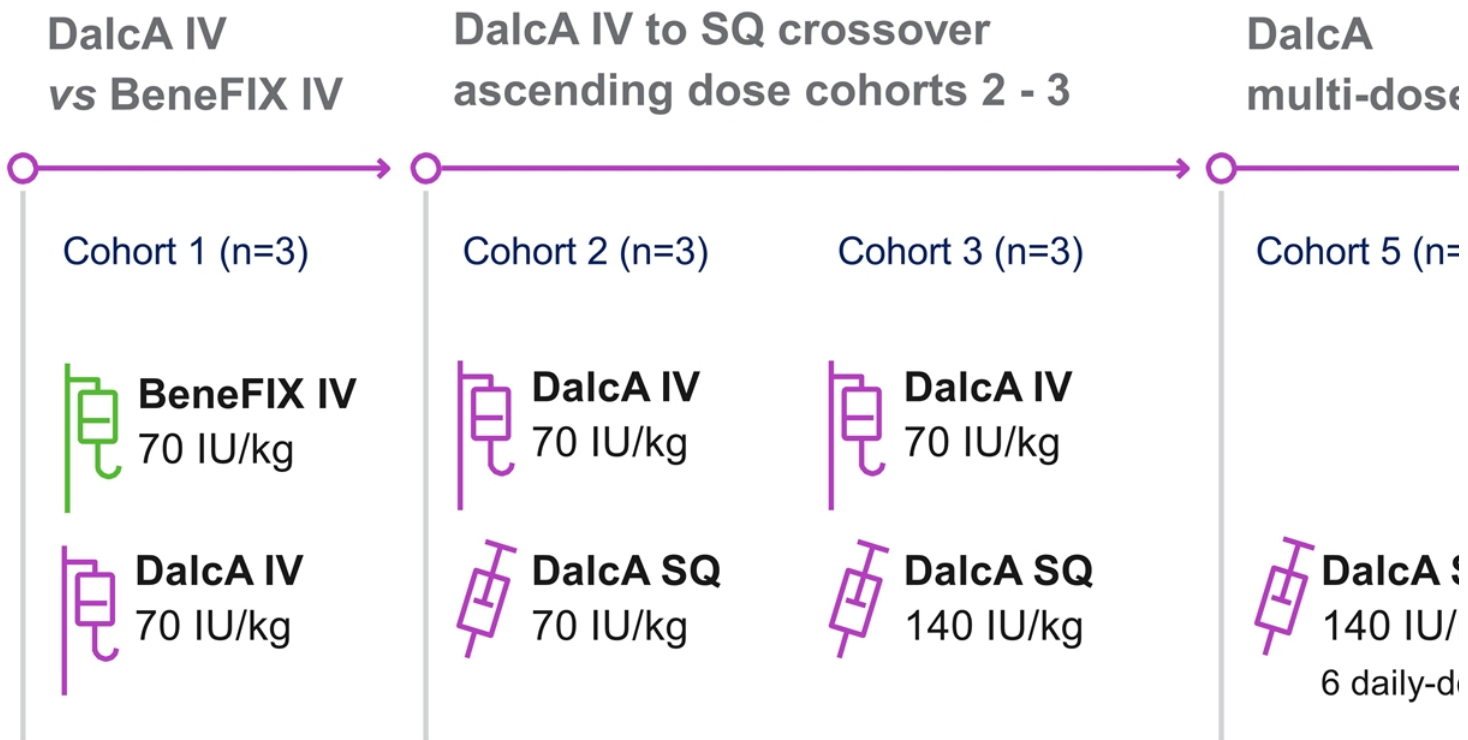
DalcA has low immunogenicity & should pr

Moving forward with dalcinonacog alfa after preclinical imr



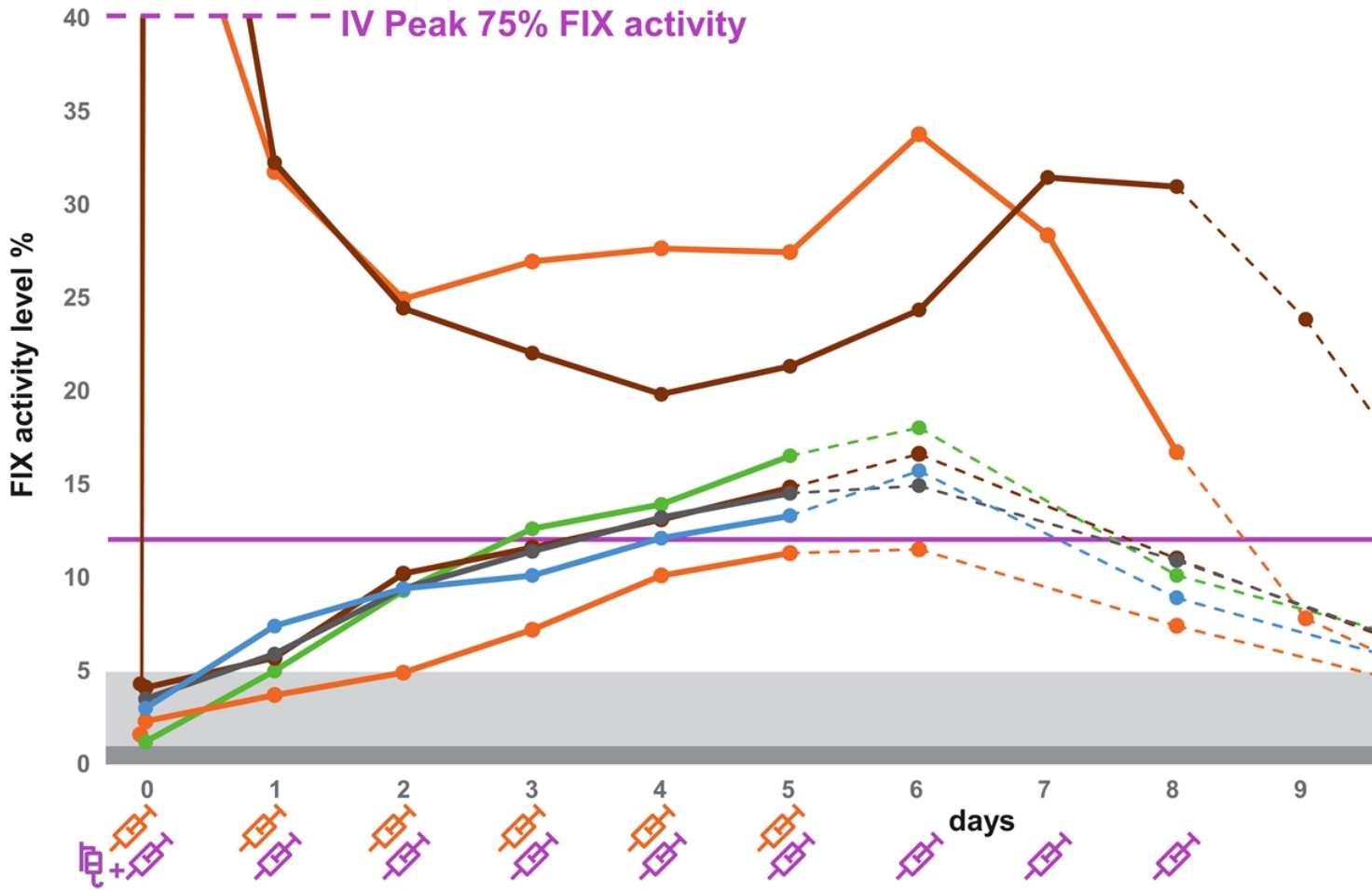
Dalcinonacog Phase 1/2 open label design

Subcutaneous treatment of hemophilia B



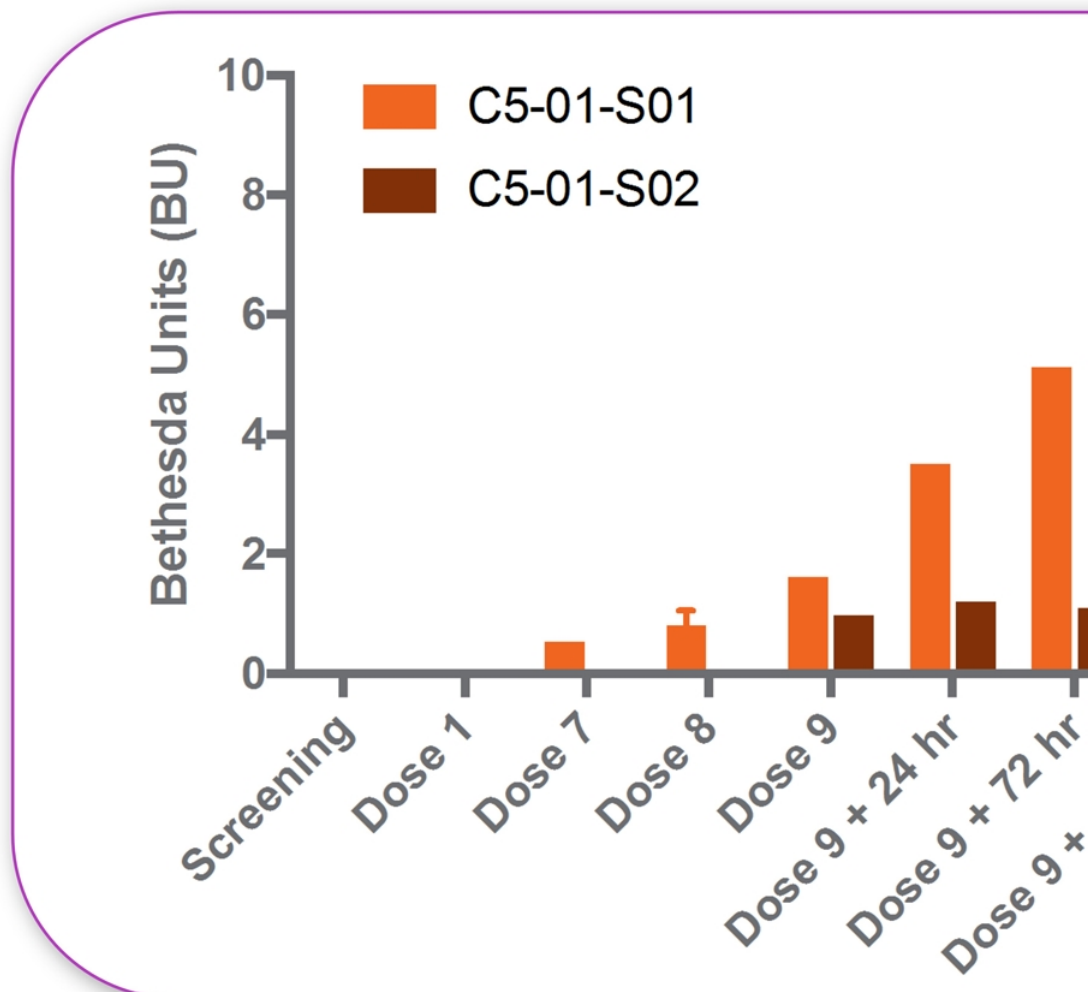
Phase 1/2: Cohort 5 & 6 FIX activity results

6/7 patients had trough levels >12%, sufficient to protect against bleeding



Phase 1/2: Cohort 6 FIX nAb development t

Time course of neutralizing antibody development after pri



The DalcA drug product is not inherently immunogenic

Investigation Hypothesis

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

Same product

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

Restrict genetic

DP Quality Characterization
(Drug quality induces ADAs)

Same

DP Formulation Characterization
(Formulation induces ADAs)

No consistency

SQ Dosing
(Route of Administration induces ADAs)

No issues with
dosing & Id

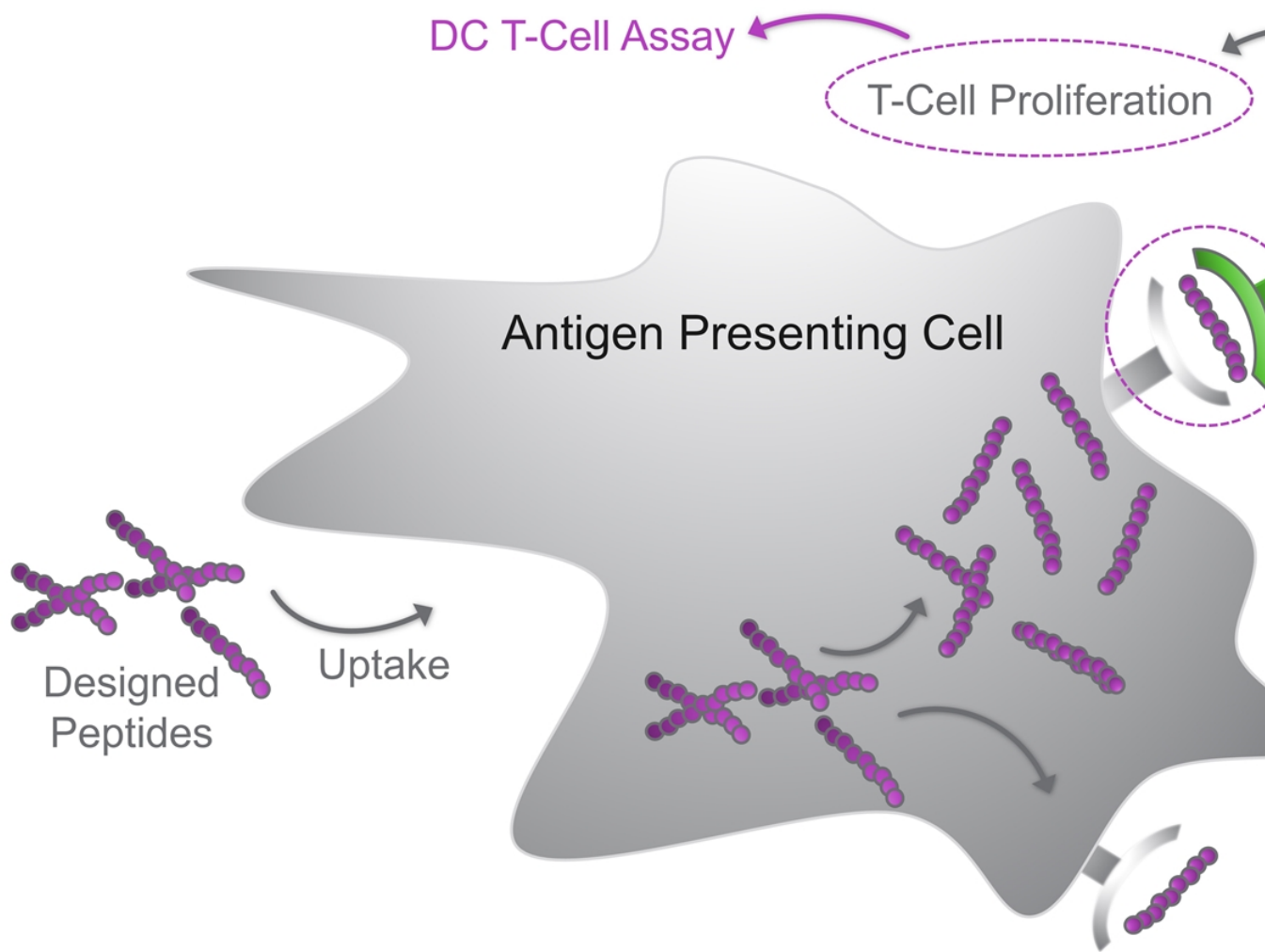
HLA and genotyping

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

Subject ID	DRB1		DPB1		DQA1		DQB1
C5-01-S01	03:01	04:01	02:01	02:01	03:01	05:01	02:01
C5-01-S02	01:01	13:01	02:01	04:01	01:01	01:01	05:01
C4-01-S02	01:01	08:01	02:01	05:01	01:01	01:01	05:01
C4-01-S07	08:01	12:01	02:01	05:01	03:01	05:01	03:01
C2-03-S01	04:01	13:01	04:01	05:01	01:01	03:01	03:01
C3-02-S03	11:01	15:01	05:01	05:01	01:01	05:01	03:01
C3-02-S04	09:01	09:01	02:01	05:01	03:01	03:01	03:01

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

Preclinical toolkit for evaluation of immuno



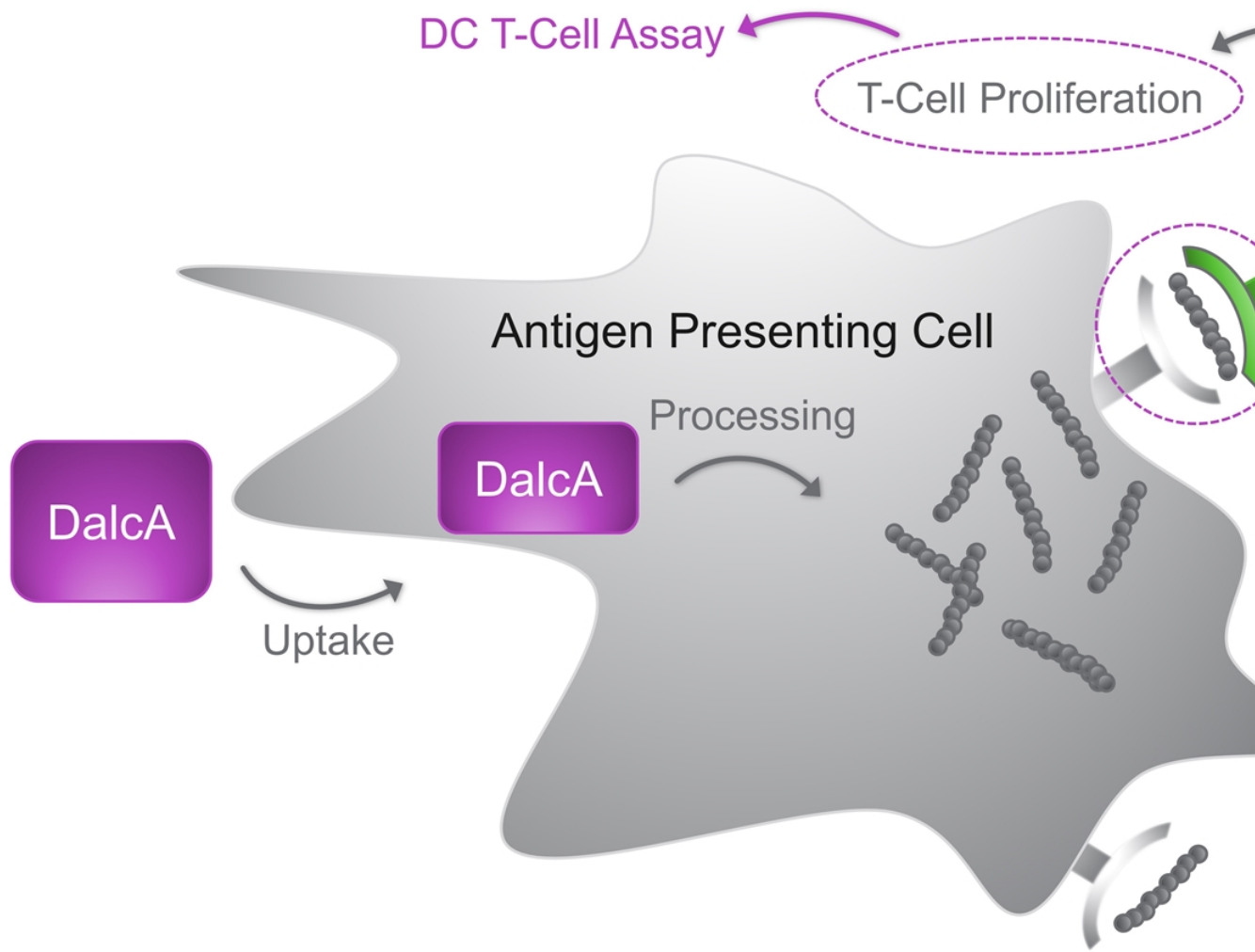
EpiVax




PROIMMUNE
www.proimmune.com

catalystbiosciences.com

Preclinical toolkit for evaluation of immuno



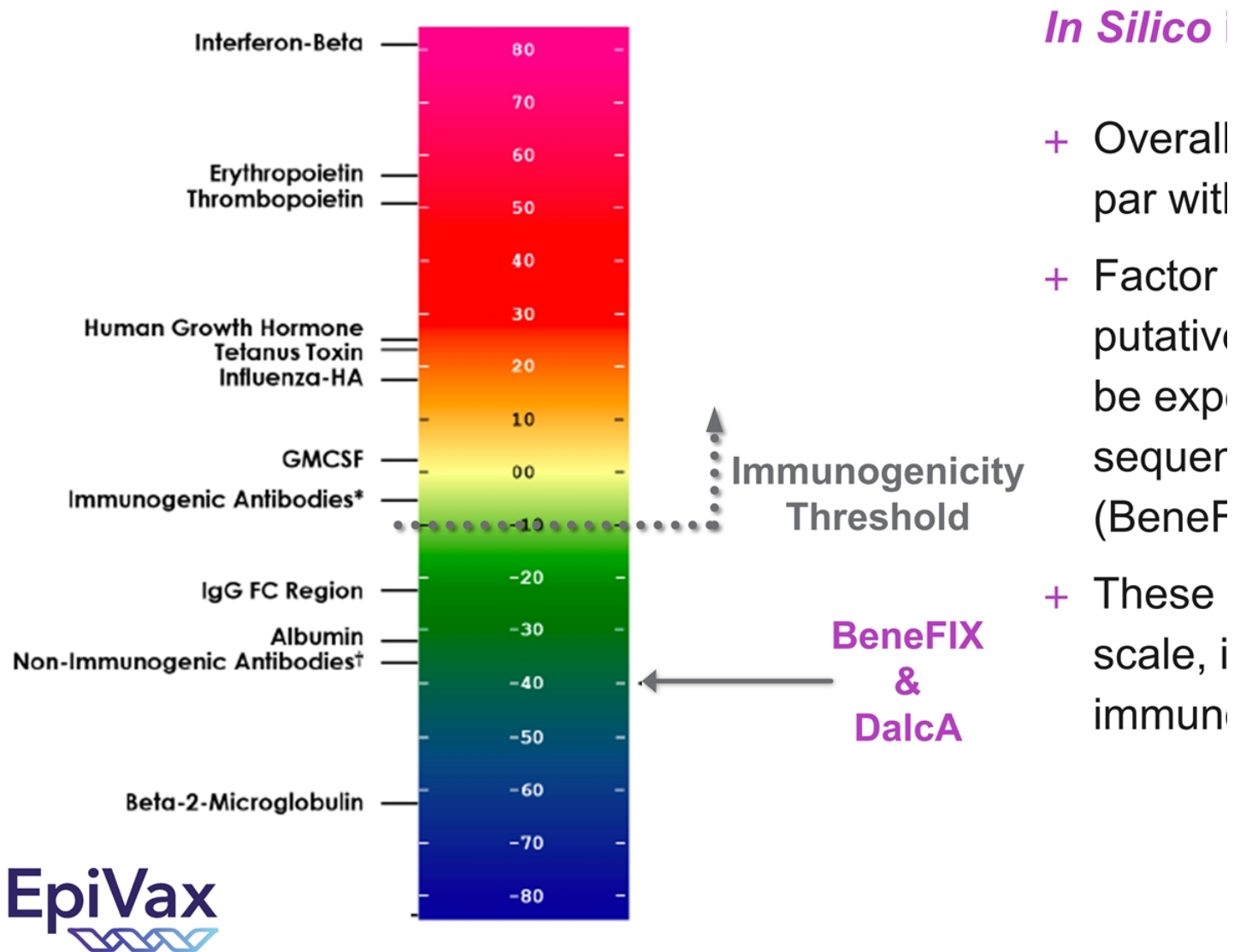
EpiVax



PROIMMUNE
www.proimmune.com

catalystbiosciences.com

The *in silico* immunogenicity assessment s



DalcaA shows a similar *in silico* risk as Bene

In Silico immunogenicity assessment at the R318Y site

Frame Start	AA Sequence	Frame Stop	Hydrophobicity	DRB1*0101 Z-Score	DRB1*0301 Z-Score	DRB1*0401 Z-Score	DRB1*0701 Z-Score	DRB1*0901 Z-Score
310	WGRVFHKGR	318	-1.2	0.99	0.51	0.61	1.26	0.85
311	GRVFHKGRS	319	-1.19	-0.35	0.22	-0.25	-1.09	0.85
312	RVFHKGRSA	320	-0.94	0.55	0.03	0.50	0.85	0.85
313	VFHKGRSAL	321	-0.02	0.74	1.71	-0.63	1.41	0.85
314	FHKGRSALV	322	-0.02	2.73	2.29	2.67	2.59	0.85
315	HKGRSALVL	323	0.09	1.24	-0.06	0.30	1.33	0.85
316	KGRSALVLQ	324	0.06	-0.20	0.84	0.26	0.21	0.85
317	GRSALVLQY	325	0.34	0.37	1.27	0.87	0.23	0.85
318	RSALVLQYL	326	0.81	0.04	0.72	-0.64	0.17	0.85
<hr/>								
310	WGRVFHKGY	318	-0.84	0.93	0.59	0.53	1.02	0.85
311	GRVFHKGYS	319	-0.83	-0.54	0.03	-0.43	-1.28	0.85
312	RVFHKGYSA	320	-0.59	0.37	-0.11	0.71	0.88	0.85
313	VFHKGYSA	321	0.33	0.76	0.59	-0.63	1.42	0.85
314	FHKGYSA	322	0.33	2.58	2.13	2.52	2.44	0.85
315	HKGYSALVL	323	0.44	0.61	-0.06	0.47	1.36	0.85
316	KGYSALVLQ	324	0.41	-0.49	0.55	-0.02	-0.07	0.85
317	GYSALVLQY	325	0.7	0.01	0.90	0.52	-0.13	0.85
318	YSALVLQYL	326	1.17	1.45	1.30	0.73	1.56	0.85



DalcaA shows a similar risk as BeneFIX at R

In Silico immunogenicity assessment at the R338E site

	Frame Start	AA Sequence	Frame Stop	Hydrophobicity	DRB1*0101 Z-Score	DRB1*0301 Z-Score	DRB1*0401 Z-Score	DRB1*0701 Z-Score	DRB1*0701 Z-Score
BeneFIX	330	LVDRATCLR	338	0.32	0.41	-0.46	-0.64	0.26	
	331	VDRATCLRS	339	-0.19	0.47	1.26	1.99	0.42	
	332	DRATCLRST	340	-0.73	-0.11	-0.93	-0.47	0.32	
	333	RATCLRSTK	341	-0.78	-1.52	-0.63	-1.28	-1.76	
	334	ATCLRSTKF	342	0.03	0.71	0.43	0.91	1.02	
	335	TCLRSTKFT	343	-0.24	0.46	-2.06	-0.18	0.54	
	336	CLRSTKFTI	344	0.33	0.67	1.45	-1.15	0.53	
	337	LRSTKFTIY	345	-0.09	0.58	1.21	0.37	0.78	
	338	RSTKFTIYN	346	-0.9	-0.90	-0.66	-0.70	-0.56	
DalcaA	330	LVDRATCLE	338	0.43	-0.21	-0.86	-0.99	0.03	
	331	VDRATCLES	339	-0.08	0.23	1.02	1.76	0.18	
	332	DRATCLEST	340	-0.62	-0.43	-1.01	-0.51	0.17	
	333	RATCLESTK	341	-0.67	-2.31	-1.39	-1.28	-1.89	
	334	ATCLESTKF	342	0.14	0.43	0.15	0.64	0.74	
	335	TCLESTKFT	343	-0.13	0.78	-1.21	0.84	0.65	
	336	CLESTKFTI	344	0.44	0.21	0.99	-1.59	0.08	
	337	LESTKFTIY	345	0.02	0.07	0.69	-0.13	0.27	
	338	ESTKFTIYN	346	-0.79	-0.82	-1.30	-0.62	-0.48	



DalcaA shows a similar risk as BeneFIX at T343R site

In Silico immunogenicity assessment at the T343R site

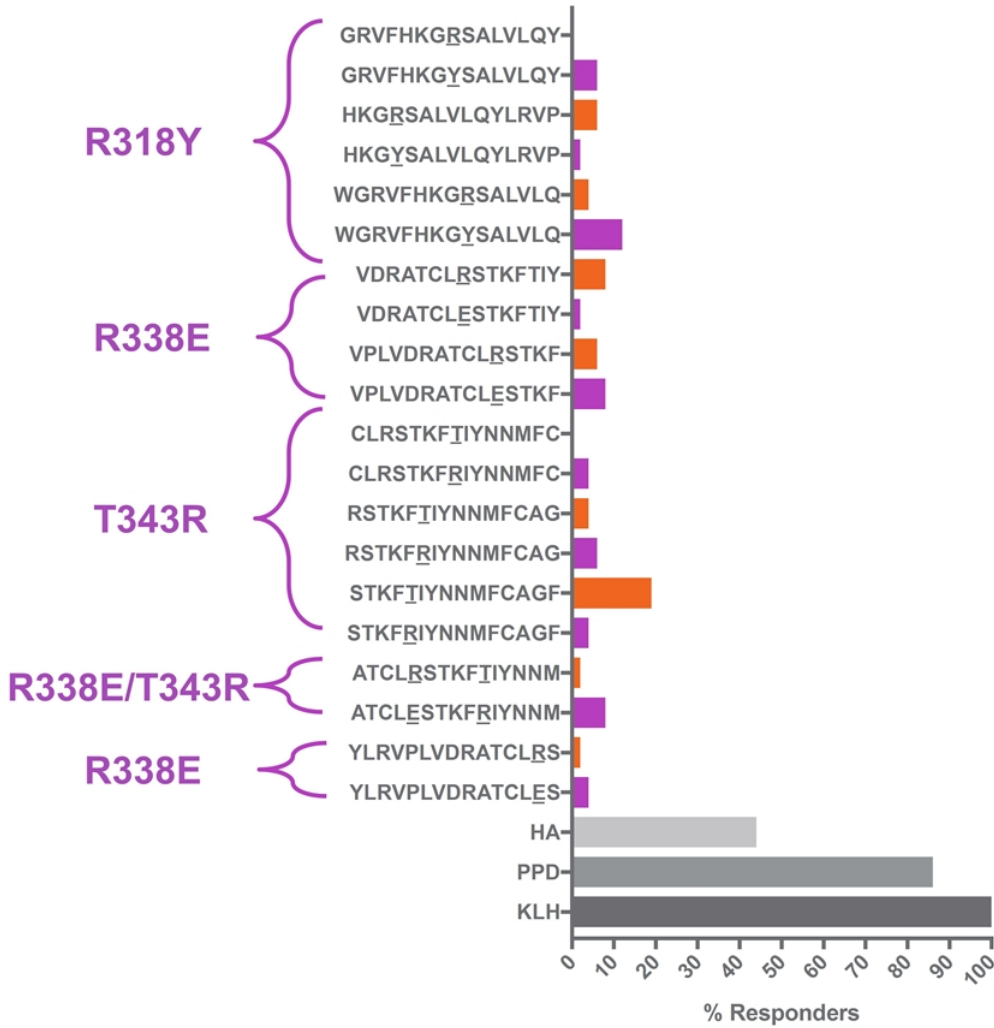
	Frame Start	AA Sequence	Frame Stop	Hydrophobicity	DRB1*0101 Z-Score	DRB1*0301 Z-Score	DRB1*0401 Z-Score	DRB1*0701 Z-Score	DRB1*0901 Z-Score
BeneFIX	335	TCLRSTKFT	343	-0.24	0.46	-2.06	-0.18	0.54	
	336	CLRSTKFTI	344	0.33	0.67	1.45	-1.15	0.53	
	337	LRSTKFTIY	345	-0.09	0.58	1.21	0.37	0.78	
	338	RSTKFTIYN	346	-0.9	-0.90	-0.66	-0.70	-0.56	
	339	STKFTIYNN	347	-0.79	-0.98	-1.59	-0.09	-0.20	
	340	TKFTIYNNM	348	-0.49	0.53	-0.35	-0.47	1.00	
	341	KFTIYNNMF	349	-0.1	0.50	0.57	1.19	1.15	
	342	FTIYNNMFC	350	0.61	1.21	0.24	1.37	1.14	
	343	TIYNNMFCA	351	0.5	-0.19	-0.66	-0.87	-0.72	
DalcaA	335	TCLRSTKFR	343	-0.67	0.10	-0.91	-0.47	-0.12	
	336	CLRSTKFRI	344	-0.09	0.80	1.58	-1.02	0.66	
	337	LRSTKFRIY	345	-0.51	0.72	1.28	0.34	0.98	
	338	RSTKFRIYN	346	-1.32	-1.16	-0.40	-2.08	-0.83	
	339	STKFRIYNN	347	-1.21	-0.76	-1.38	0.12	0.01	
	340	TKFRIYNNM	348	-0.91	0.52	-0.48	-1.03	0.52	
	341	KFRIYNNMF	349	-0.52	0.98	1.05	1.66	1.62	
	342	FRIYNNMFC	350	0.19	1.46	0.51	1.62	1.39	
	343	RIYNNMFCA	351	0.08	-0.30	-0.02	-0.97	-0.82	



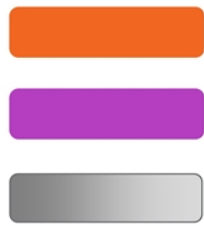
Peptides from DalcA show low immunogen

% Responding Donors

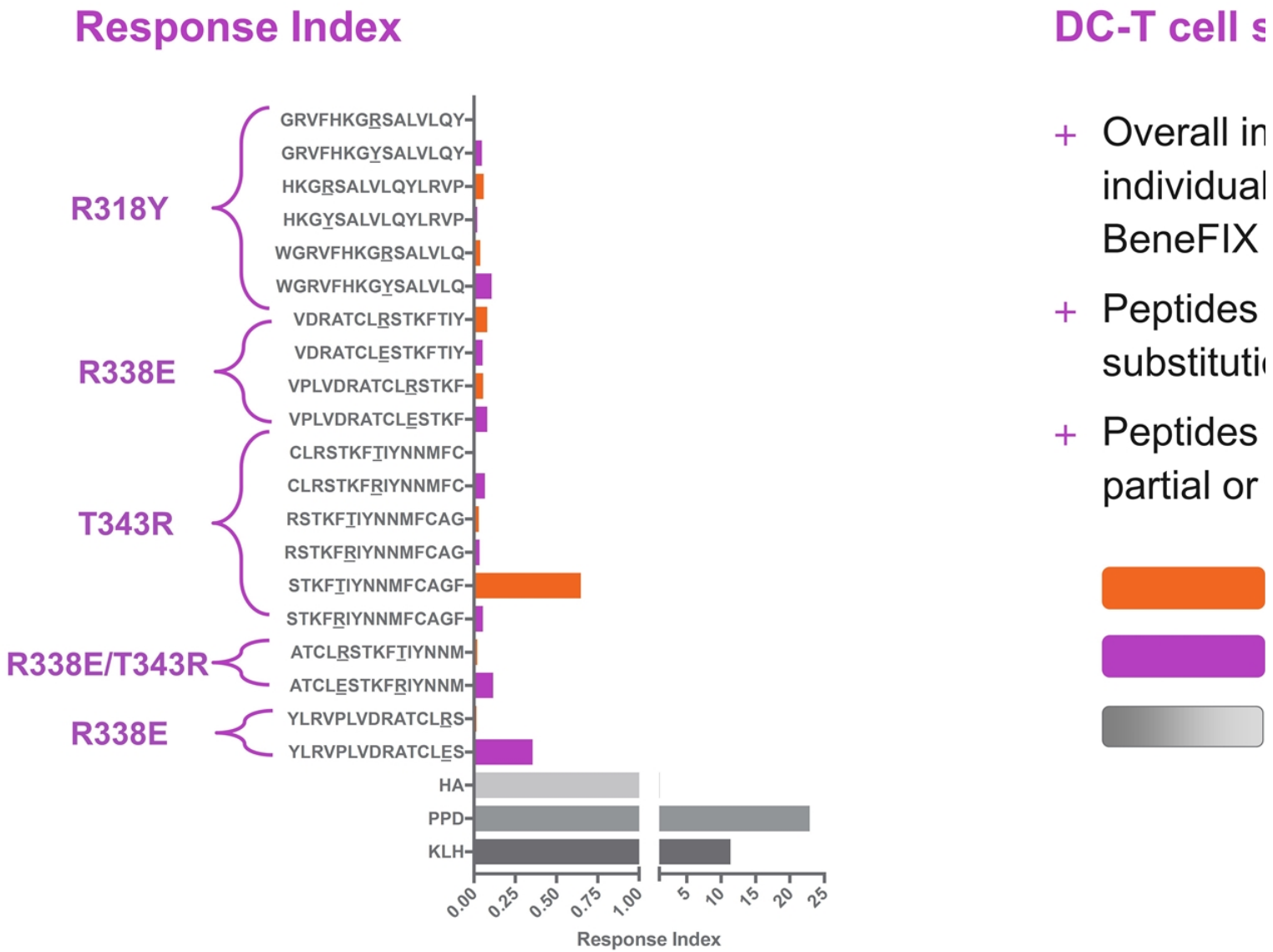
DC-T cell s



- + Overall in individual BeneFIX
- + Peptides substituti
- + Peptides partial or



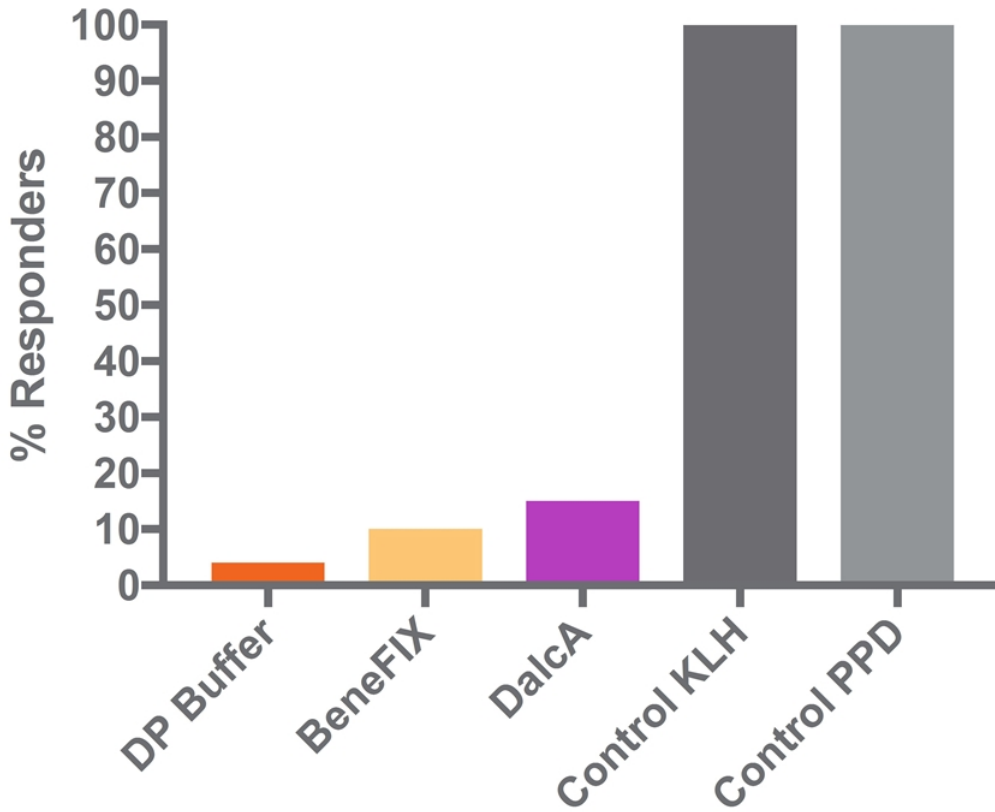
Peptides from DalcA show low immunogen



The DalcA drug product shows low immunogenicity

Responding Donors

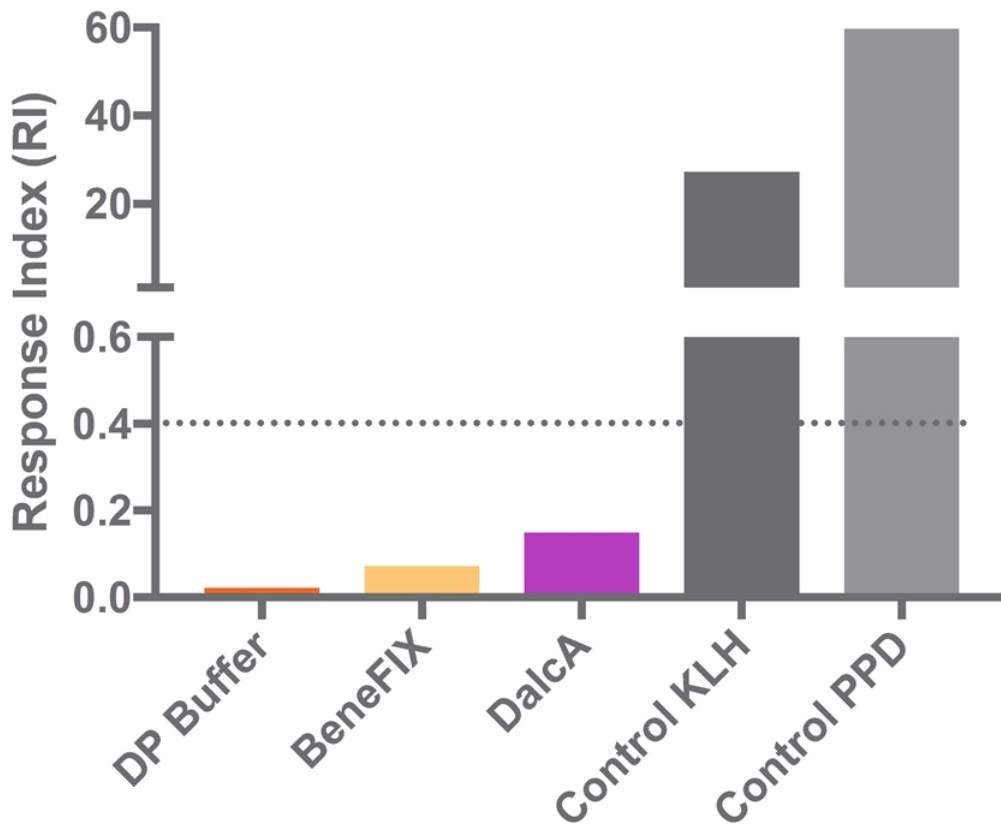
DC-T cell s



- + Overall immunogenicity is low and comparable to control
- Formulation does not impact immunogenicity
- + 8/52 responders were also responders for both controls
- + No significant difference between DalcA and BeneFIX

The DalcA drug product shows low immunogenicity

Response Index



DC-T cell s

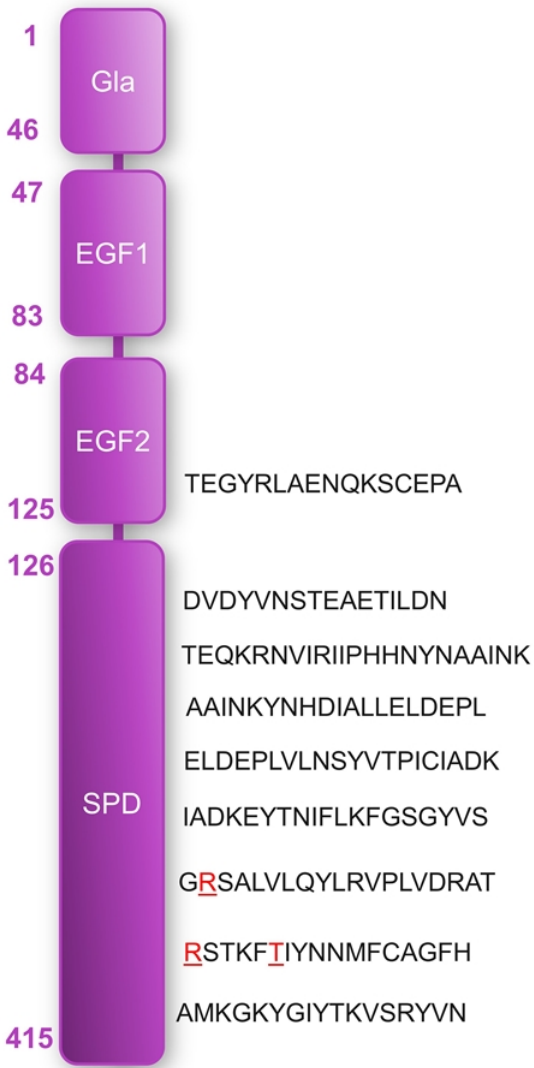
- + Overall immunogenicity is low and comparable to control
- Formulation does not impact immunogenicity
- + Clinical trial results show Response Index (RI) of 0.4 and 0.4
- Consistent observations across therapeutic areas
- + No significant difference in RI of C

Presented peptides are comparable for Dalci

BeneFIX HLA-DR

Donors

D1581	D1714	D1837	D1842	D1858	D1863	D1867
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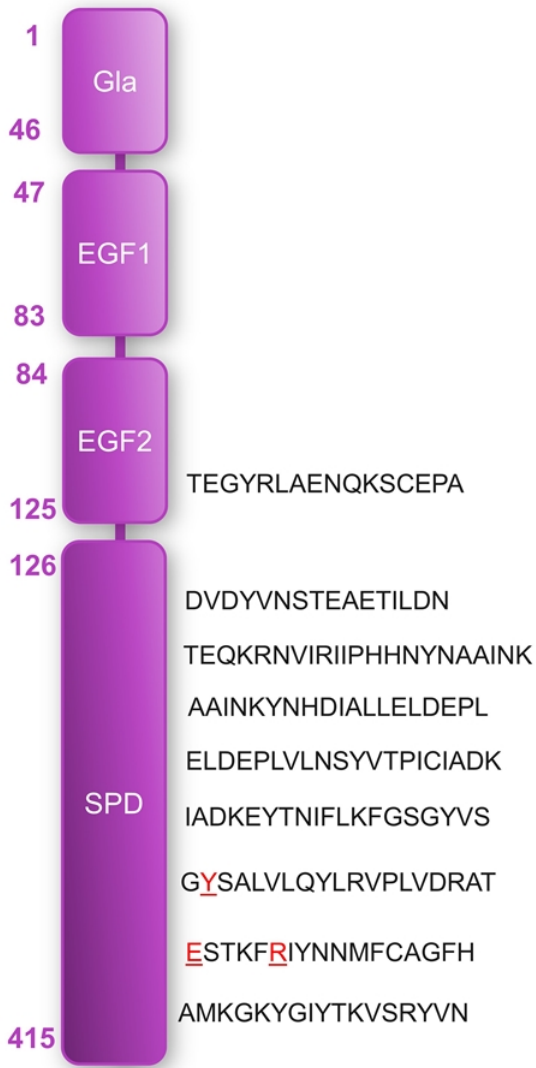
No peptides identified from (



Presented peptides are comparable for Dalca

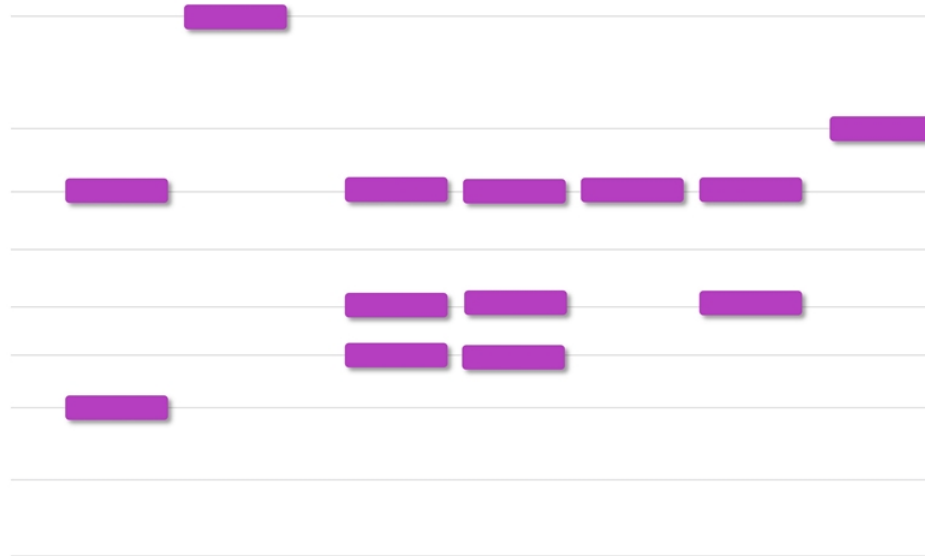
Dalca HLA-DR

Donors



D1581	D1714	D1837	D1842	D1858	D1863	D1867
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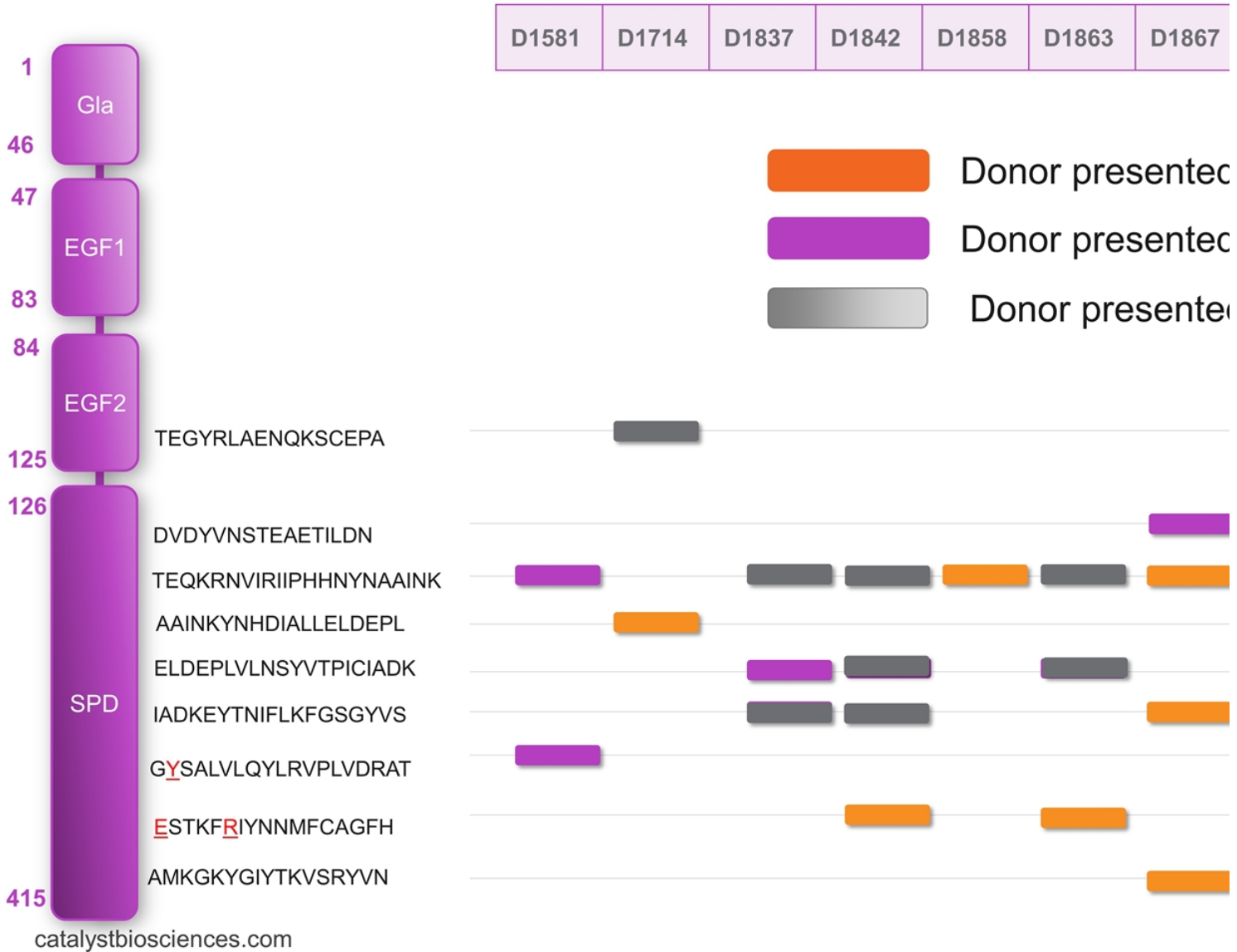
No peptides identified from (



Presented peptides are comparable for Dal

Overlap HLA-DR

Donors



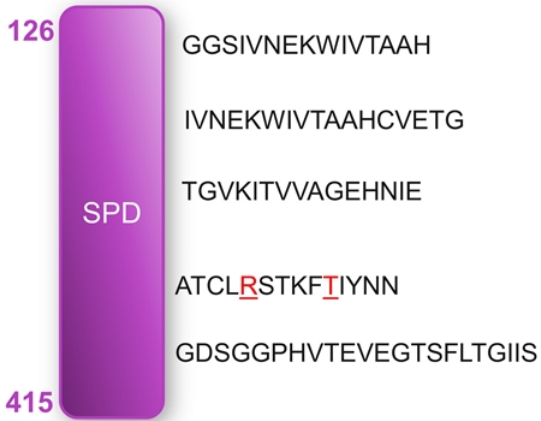
Presented peptides are comparable for DalcA

HLA-DP profile

Donors

D1581	D1714	D1837	D1842	D1858	D1863	D1867
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BeneFIX

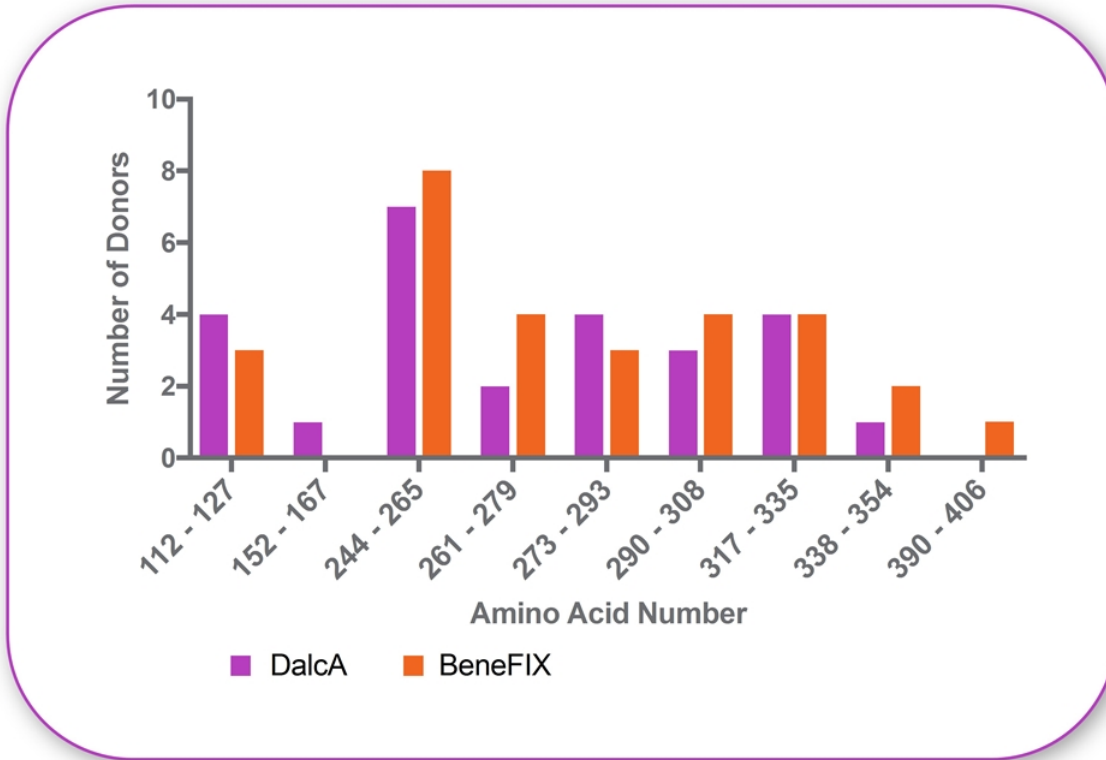


DalcA

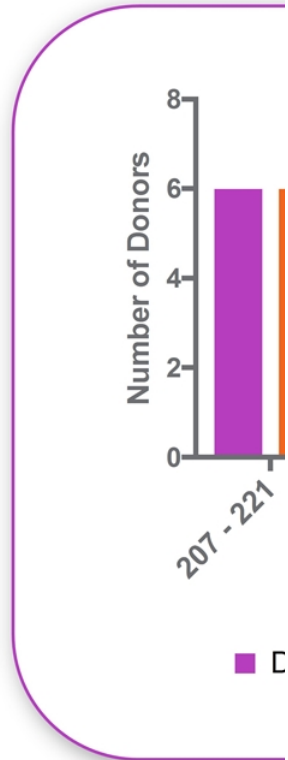


Comparable peptide presentation by HLA-D

Peptide presentation by HLA-DR

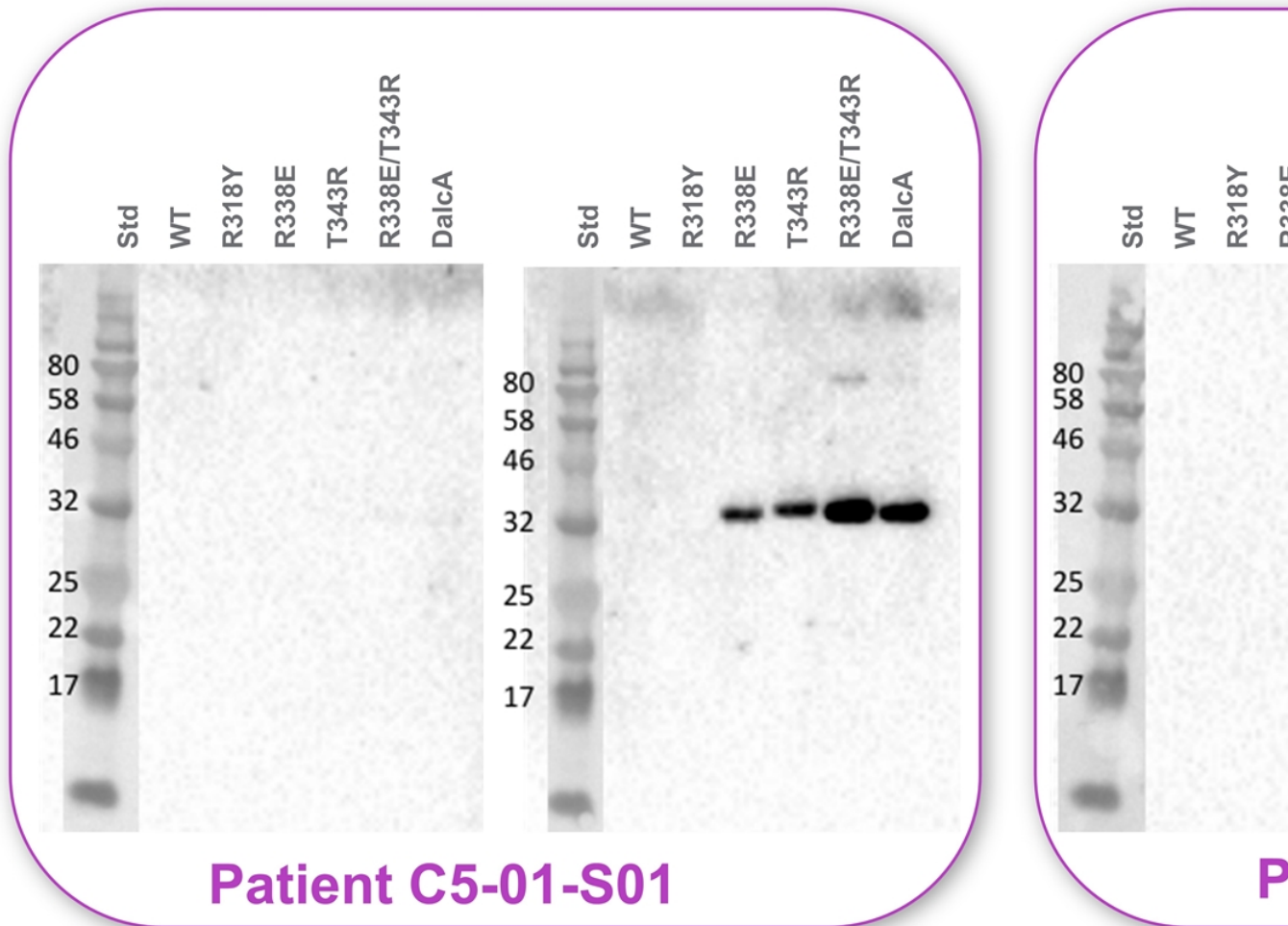


Peptide presentation by HLA-D



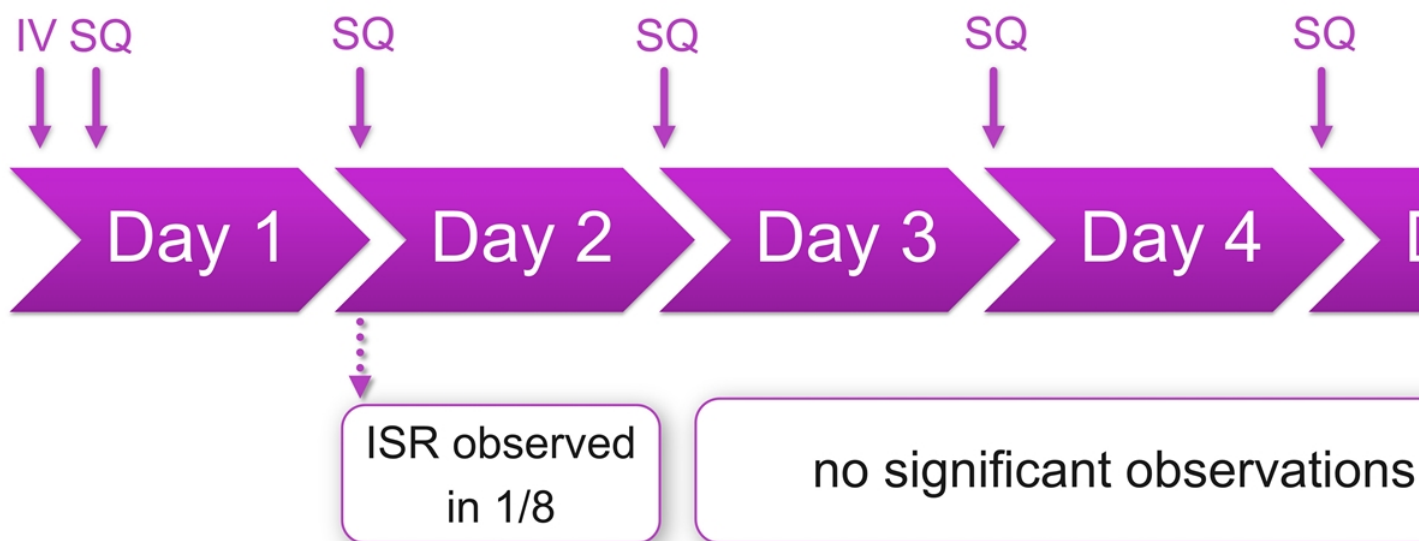
Epitope mapping identified nAb binding to

Overview of native western blot analysis



+ Neutralizing antibody epitopes are centered on R338E and T343R

Consistent ISRs were not observed in the 7



- + Lack of consistent response across sites within an animal and between 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

DalcA is comparable to BeneFIX & RIXUBIS

Multiple industry standard characterizations performed

Potency

Biological Activity

Product Purity

Biophysical and Structural Properties

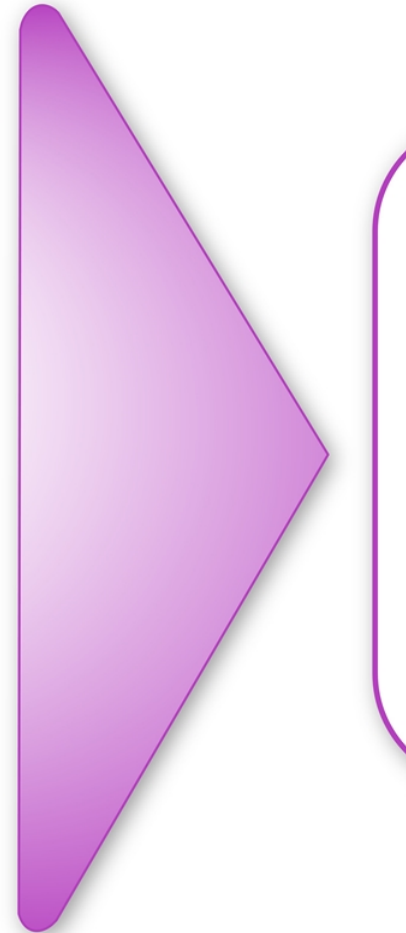
Chemical Modifications

Post Translational Modifications

Host Cell Impurities

Product and Process Related Impurities

Thermal Stability upon Reconstitution



What may have led to the development of nAbs

The DalcA molecule is not inherently immunogenic – What

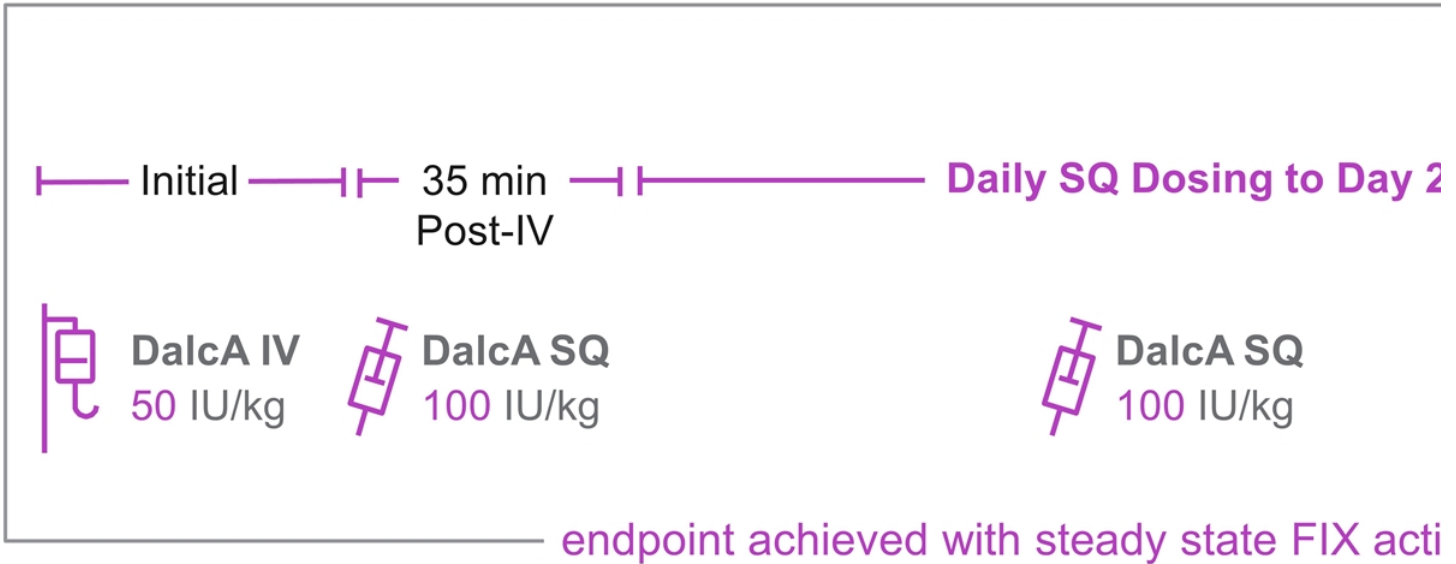
- The nAbs were associated with the rare genotype and/or cell
- The nAbs did not cross-react with BeneFIX or RIXUBIS so
- The nAbs were a rare event observed early in the trial withi

Conclusion – Evaluate further safety & efficacy in a Phase

- + Broaden the subject population to have a diverse ethnic and
 - + Exclude the rare genotype of the two subjects who develop
 - + Consider HLA profile and exclude those with HLA types tha
 - + Execute the P2b trial (28 days of dosing) with careful monito
- 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: FIX activity level above baseline
- + Secondary endpoints: FIX activity, FIX formation, pharmacodynamic

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 concerns
 - Complementary on the completeness of CBIO's investigation

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 input

Conclusions on the dalcinonacog alfa program

Moving forward in clinical development after an extensive immunogenicity assessment

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

A comprehensive evaluation of the drug product's quality to marketed rFIX products

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

CATALYST BIOSCIENCES

December 18th 2018

Marzeptacog alfa (activated)

Marzeptacog alfa (activated)

Marzeptacog alfa (activated), a novel clinical stage SQ FVIIa 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

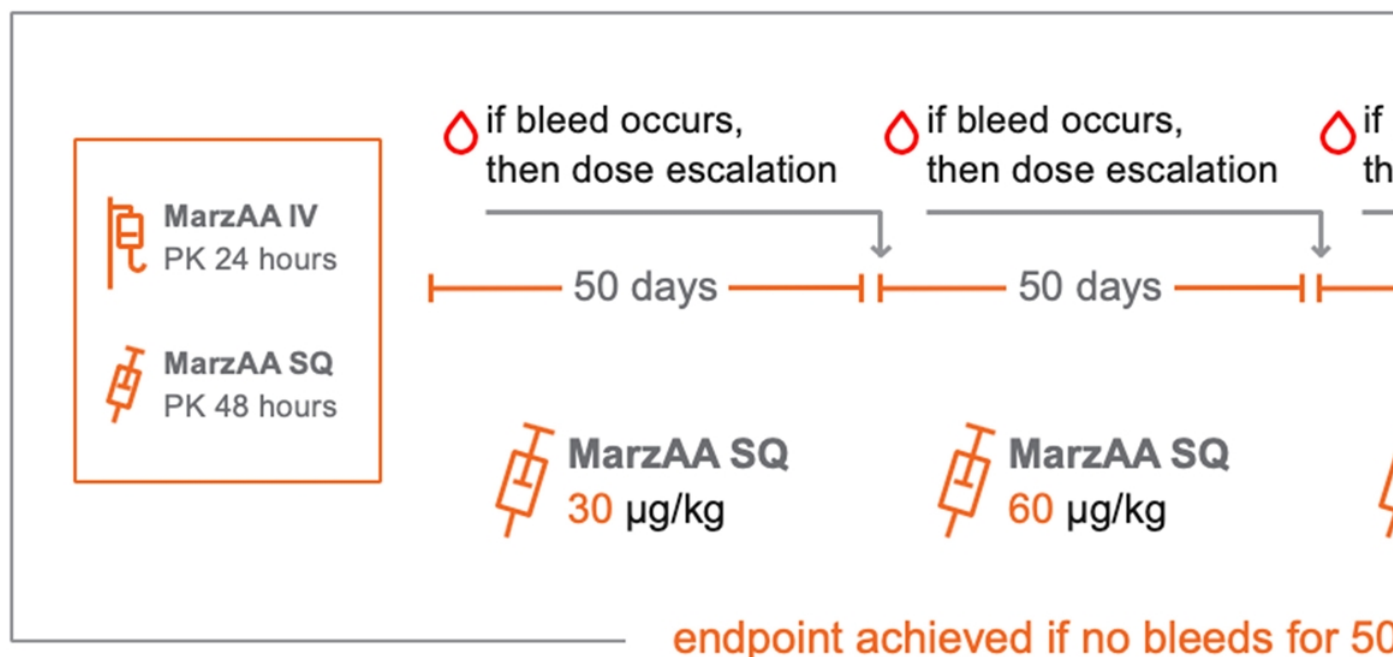
- + 9-fold more potent than NovoSeven RT

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: bleed rate
- + Secondary endpoints: tolerability, no

Subject demographics & disposition

High pre-treatment ABRs reduced to a median of 0

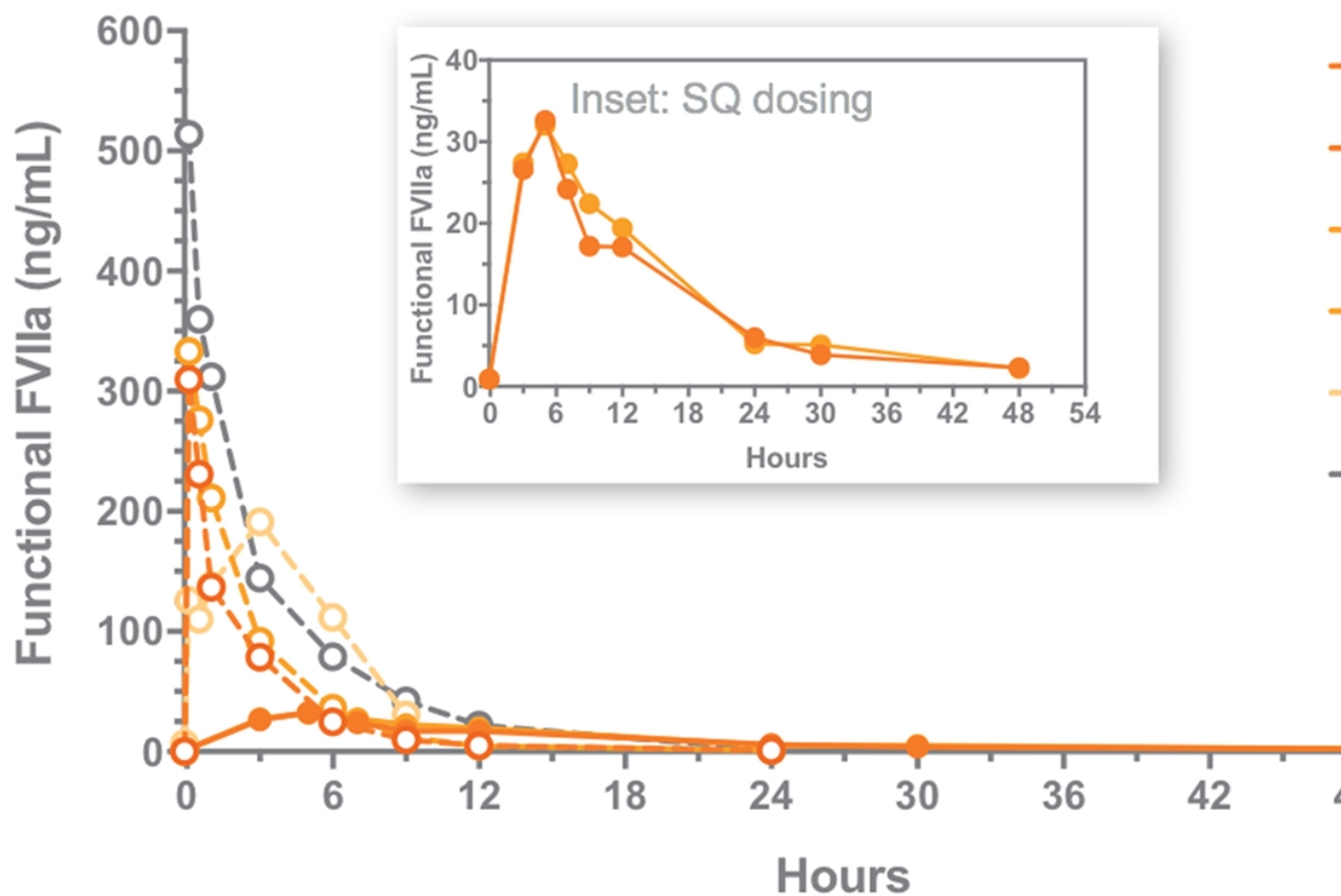
- + 13 subjects have been consented and 9 enrolled (Median AE
- + 5 subjects have completed dosing with clinically significant re
- + 4 subjects had no bleeds at their final dose level
- + IV half-life of 3.9 hours was increased to SQ half-life of 13.1 h
- + No anti-drug antibodies have been detected to date
- + After more than 325 SQ injections, only one injection site rea without sequelae

Subject demographics & disposition

Subject ID	Age	Highest Inhibitor level BU	Age when inhibitor diagnosed	Hemophilia A or B	ABR	ABR on treatment
2680101	36	16	15	A	12.2	Revoked c
2680301	18	5	14	A	26.7	Zero at 60 3.8 ove
2680302	30	2.7	26	A	18.3	Fatal unrela
6430201	29	4.2	27	A	15.9	Zero
6430202	35	4.7	35	A	16.6	Zero
0510101	43	5.5	39	A	22.2	Untreated tr hematoma D 7.3
0510104	31	1.73	31	B	27.7	Dosir
6430204	18	56	6	A	15.9	Dosir
6430203	23	4.5	21	A	15.2	Zero
7100101	23	2.94	19	A		In scree

MarzAA Phase 2 study interim PK results

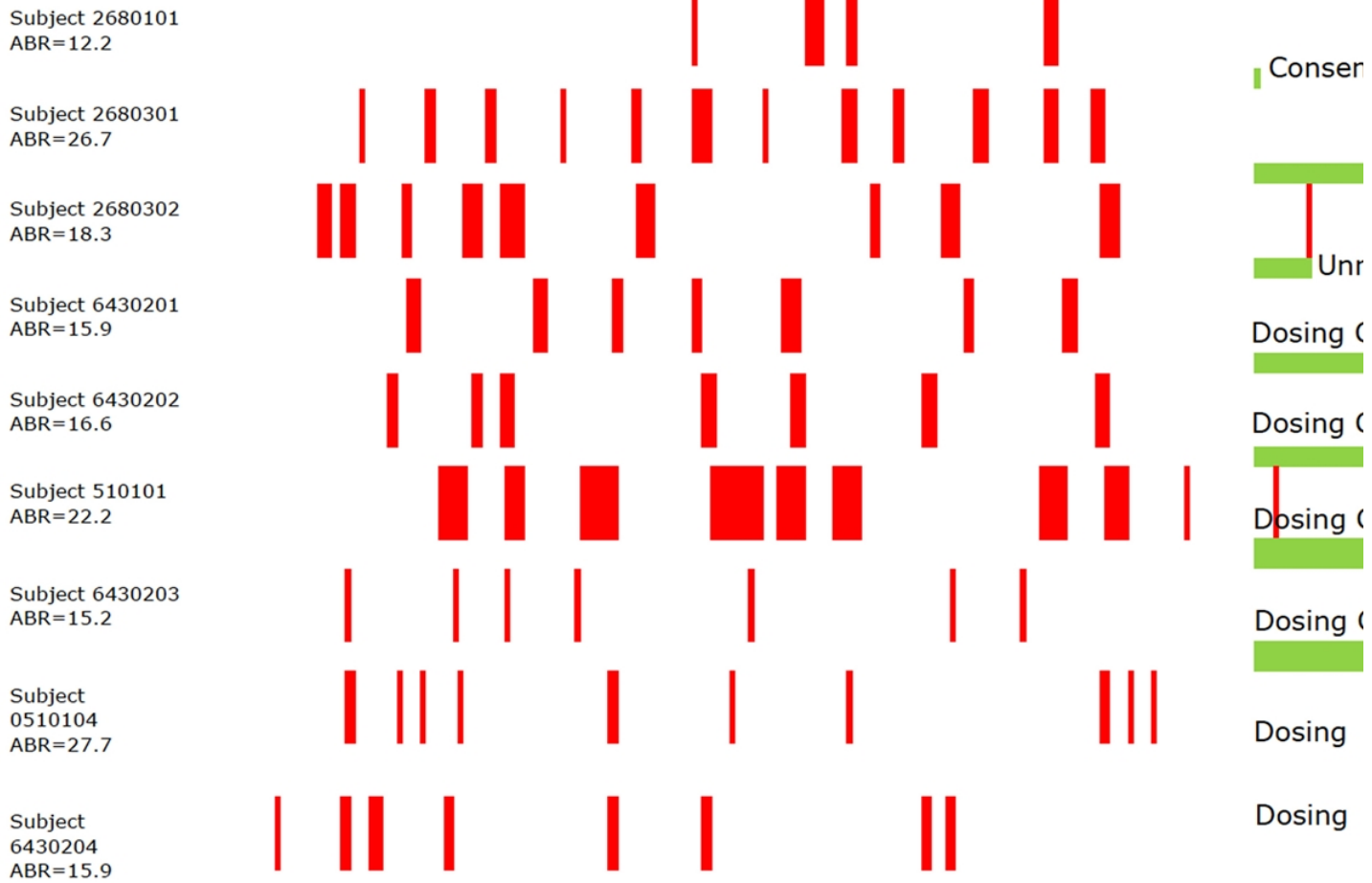
FVIIa functional activity after IV or SQ administration



MarzAA pharmacokinetics

Route	Half-life alpha (hr)	Half-life beta (hr)	Mean Residence Time (hr)	Cmax (ng/mL)	Tmax (hr)	
IV Median ± Interquartile Range	1.1 ± 1.2	3.9 ± 1.4	4.5 ± 2.5	309.5 ± 267.0	0.083 ± 1.5	10
SQ Median ± Interquartile Range		13.1 ± 12.2	20.6 ± 16.5	22.0 ± 20.3	6 ± 3.5	3

MarzAA reduces annualized bleed rate (ABR)



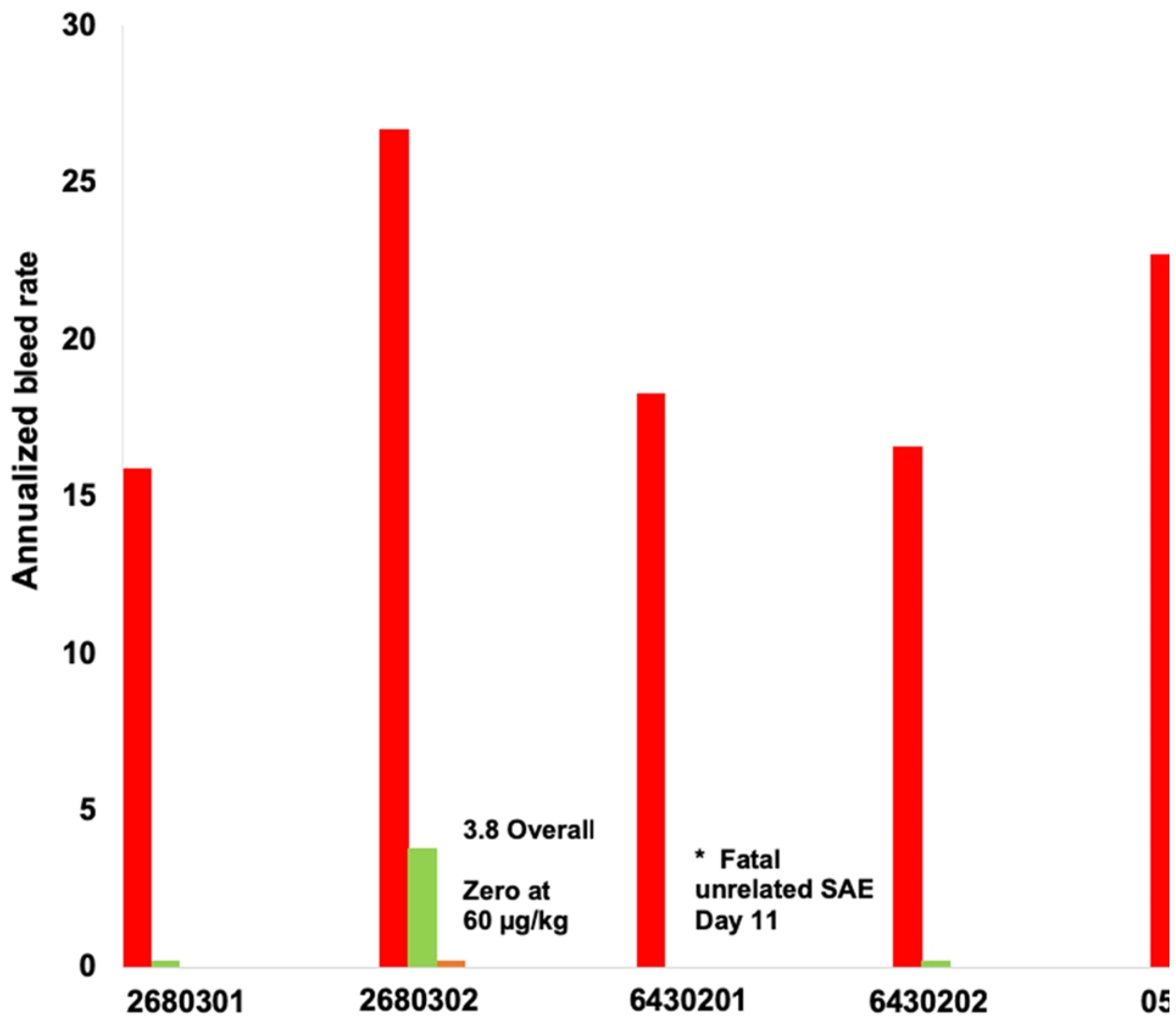
The width of the red bar represents bleed duration: 1 to 9 days



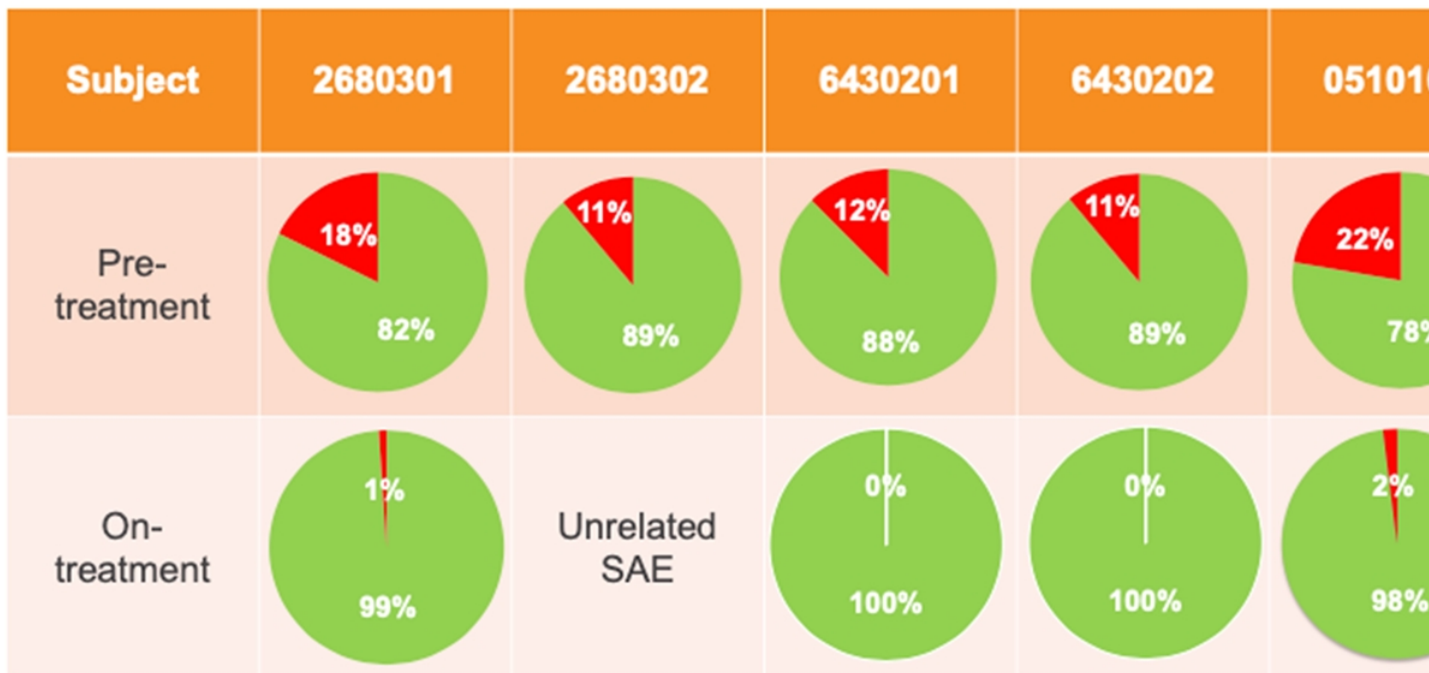
6-month recorded bleeds

Tre:
P:

Pre-treatment ABR & ABR during treatment



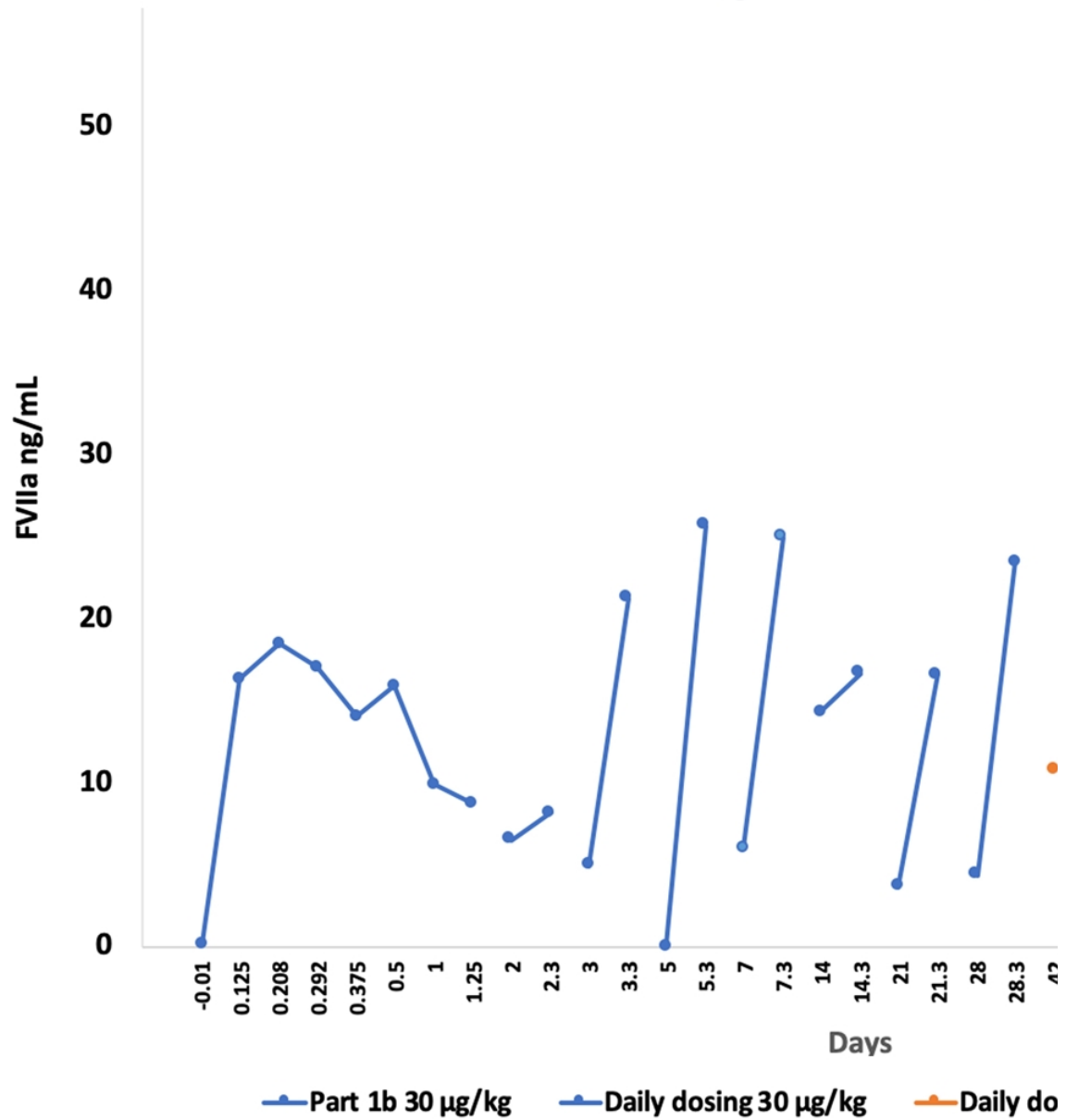
Pre- and on-treatment proportion of bleeding



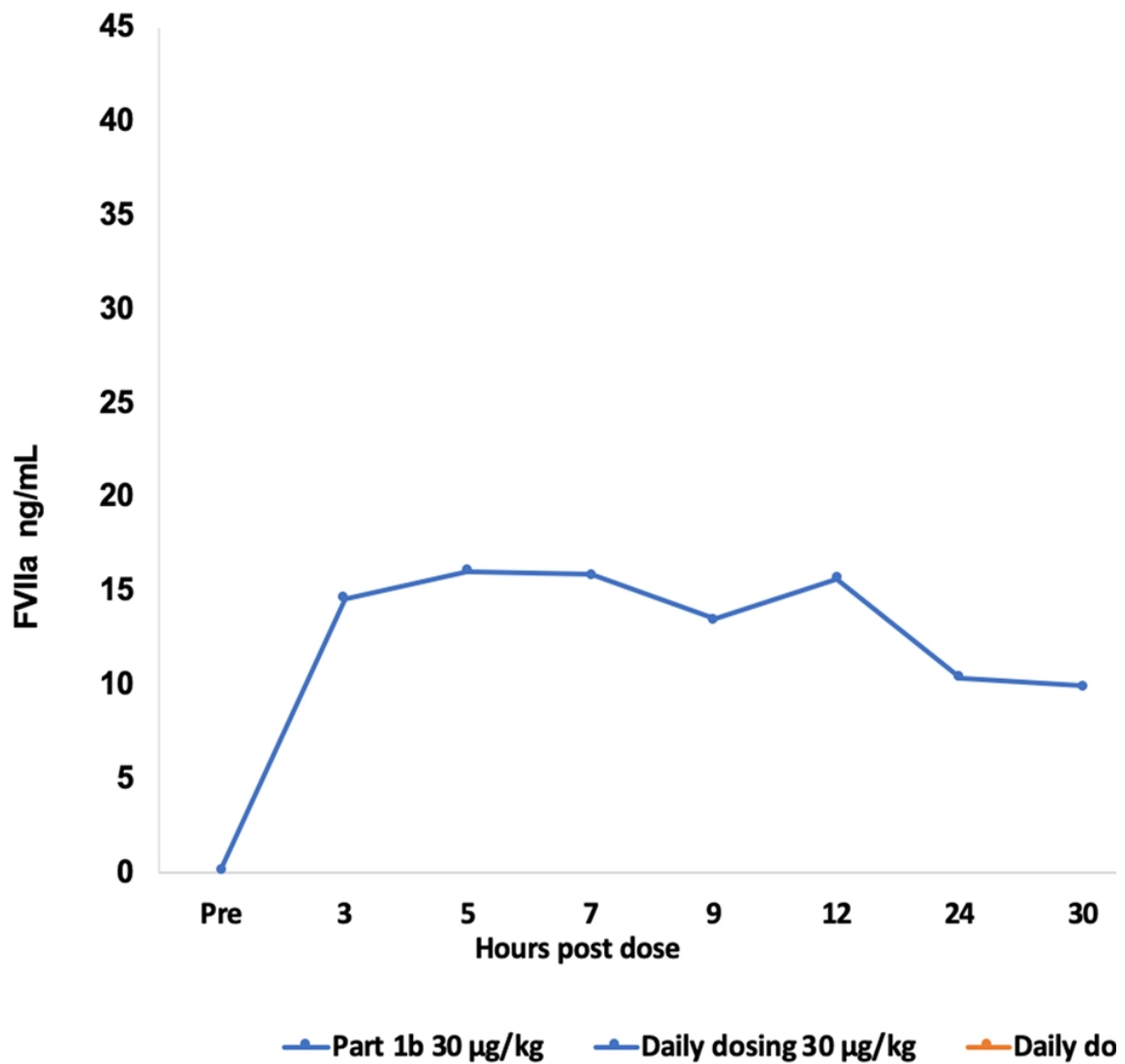
Red denotes the proportion of days with bleeding during observation period

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

Mean First SQ dose PK and trough & 7h po



Mean First SQ dose PK and trough & 7h po level by dose



MarzAA regulatory

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 completion of Phase 2

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

Non-clinical strategy developed with four experts ex CBER review

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

Conclusions on the marzeptacog alfa (activ

Moving forward in clinical development after clinical proof

Clinical efficacy and tolerability demonstrated

Additional clinical data at EAHAD 2019 and ISTH

Trial guidance obtained from EMA & MHRA, will c
phase 2 in late 2019

CATALYST BIOSCIENCES

December 18th 2018

Financial Information

MarzAA US Revenue Forecast \$196M (~\$40

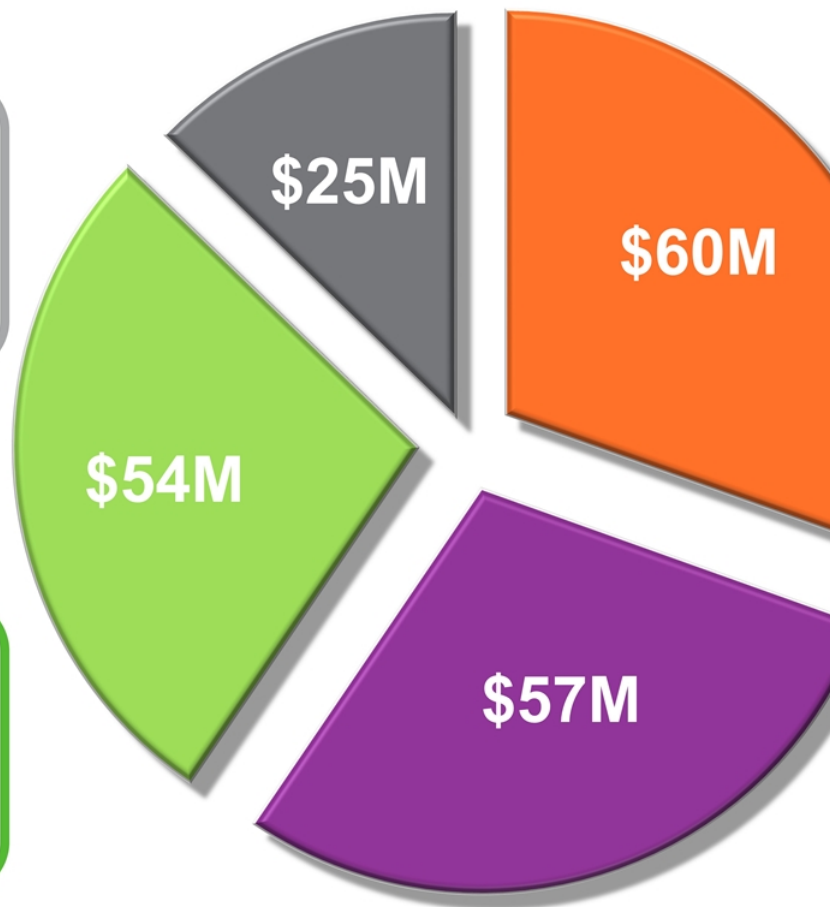
Target Product Profile Strongly Resonates Across Multiple

Factor VII Deficiency

>50% “very willing” to use MarzAA

Acquired Hemophilia A

>75% “very willing” to use MarzAA



Financial information

Selected data

Operating Results	Q3 2018	Q3 YTD
Operating Expense	\$8.3 M	\$22.1 M
Net Loss	(\$7.7 M)	(\$19.2 M)
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 DalcaA Collaboration

ISU gains Korean commercial rights, CBIO to pay ISU a fixed fee

Prior Agreement

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

Restructured Agreement

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

Milestones

2018

	Q1	Q2	Q3	Q4	Q1
MarzAA (FVIIa)	P2 Initiated ✓		ISTH Interim P2 data ✓	ASH P2 data ✓	EAHAD P2 data
DalcA (FIX)	EAHAD Top-line multidose clinical data (oral) ✓	WFH Final Cohort 5 data Initiate Cohort 6 ✓	ISTH Phase 1/2 Cohort 6 data ✓		Initiate P2b EAHAD
Anti-C3 (dAMD)					PK/PD

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% reduction in ABR on subcutaneous dosing

Potential for mild hemophilia

+ Initial data



Anti-C3

multi-kilogram

C3 is a key target to gene therapy

+ Pre-clinical data



Strong

THANK YOU

Nasdaq: CBIO

catalystbiosciences.com

Catalyst Biosciences Hosts Research & Development Day Focused on Factor VIIa and Factor IX Hemophilia Programs

SOUTH SAN FRANCISCO, Calif., Dec. 18, 2018 — Catalyst Biosciences, Inc. (NASDAQ: CBIO), a clinical-stage biopharmaceutical company focused on developing novel medicines to address hematology indications, is hosting a Research & Development (R&D) Day today in New York to provide updates on its Factor IX (FIX) dalcinonacog alfa (DalcA) and Factor VIIa (FVIIa) marzeptacog alfa (activated) (MarzAA) hemophilia programs.

Members of the Catalyst management team, including, Nassim Usman, Ph.D., chief executive officer; Howard Levy, M.B.B.Ch., Ph.D., M.M.M., chief medical officer; Fletcher Payne, chief financial officer; and Grant Blouse, Ph.D., vice president of translational research, will be presenting beginning at 12:00 p.m. EST. A live and archived webcast of the event may be accessed [here](#) and on the [Events and Presentations](#) section of the Catalyst website.

“The results of our extensive DalcA immunogenicity risk assessment revealed a similar low immunogenicity potential compared with BeneFIX and other commercial wildtype FIXs; therefore, we will be moving forward with the clinical development of DalcA,” said Dr. Usman. “We plan to initiate a Phase 2b trial that will include 28 days of daily subcutaneous dosing in the first quarter of 2019. Based on the efficacy data that we have previously shown in which subjects achieved high mild hemophilia FIX activity, we believe that DalcA has the potential to provide a conveniently-dosed subcutaneous prophylactic treatment option for those suffering from hemophilia B.”

Dr. Usman continued, “Given the promising interim results from our Phase 2/3 study of MarzAA, in which all five subjects that have completed dosing experienced clinically significant reductions in their annualized bleed rates, and the results of our commercial assessment, showing a several hundred million dollar revenue forecast globally, we believe that MarzAA has significant clinical and commercial potential.”

Select R&D Day Highlights**DalcA**

- A comprehensive immunogenicity risk assessment to investigate the development of neutralizing antidrug antibodies in Cohort 6 of the Phase 1/2 program concluded:
 - The DalcA drug product does not appear to be inherently immunogenic.
 - *In silico*, *in vitro* and *ex vivo* analyses indicate that the immunogenicity risk for DalcA is similar to commercial wildtype recombinant FIX products.
 - The DalcA drug product quality is similar to marketed FIX products.
 - 7-day subcutaneous non-human primate toxicology studies showed that DalcA subcutaneous injections were well tolerated.

- Catalyst plans to move forward with clinical development of DalcA to further evaluate the safety and efficacy of the product in a Phase 2b study that is expected to begin in Q1 2019.

MarzAA

- In the Phase 2 portion of the Phase 2/3 trial of MarzAA for the treatment of hemophilia A or B with inhibitors:
 - Nine subjects have been enrolled to date (median annualized bleed rate of 16.25; range of 12.2-27.7).
 - Of the five subjects that have completed dosing, all had clinically significant reductions in annualized bleed rate (ABR).
 - Two subjects are currently dosing and others are undergoing screening.
 - After more than 325 subcutaneous injections, no antidrug antibodies have been detected, and only one injection site reaction of swelling that resolved without sequelae has occurred.
- Catalyst plans to conduct a global Phase 3 clinical study assessing reductions in ABR in 20-40 patients with hemophilia with six months of daily subcutaneous dosing of MarzAA.

About Catalyst Biosciences

Catalyst is a clinical-stage biopharmaceutical company developing novel medicines to address hematology indications. Catalyst is focused on the field of hemostasis, including the subcutaneous prophylaxis of hemophilia and facilitating surgery in individuals with hemophilia. For more information, please visit www.catalystbiosciences.com.

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Forward-looking statements include statements about the relative safety of DalcA compared with BeneFIX and other recombinant Factor IX products, Catalyst's plans to commence a Phase 2b clinical trial of DalcA in the first quarter of 2019, the potential for DalcA to provide a conveniently-dosed subcutaneous prophylactic treatment option for patients suffering from hemophilia B, the potential for MarzAA to provide prophylaxis therapy in patients with hemophilia A or B with inhibitors, the potential commercial market for MarzAA, and plans to continue the ongoing Phase 2/3 clinical trial of MarzAA and for a Phase 3 clinical study of MarzAA. Actual results or events could differ materially from the plans, intentions, expectations and projections disclosed in the forward-looking statements. Various important factors could cause actual results or events to differ materially from the forward-looking statements that the Company makes, including, but not limited to, the risk that trials and studies may be delayed and may not have satisfactory outcomes, that additional human trials will not replicate the results from earlier trials, that potential adverse effects may arise from the testing or use of MarzAA or DalcA, including the generation of antibodies, which has been observed in patients treated with DalcA, the risk that costs required to develop or manufacture the Company's products will be higher than anticipated, competition and other factors that affect our ability to establish collaborations on commercially reasonable terms and other risks.

described in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018 filed with the Securities and Exchange Commission on November 1, 2018, and with other filings with the Securities and Exchange Commission. The Company does not assume any obligation to update any forward-looking statements, except as required by law.

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