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 9, 2024

SANGAMO THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**000-30171**	**68-0359556**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer ID Number)**

501 Canal Blvd., Richmond, California 94804
(Address of principal executive offices) (Zip Code)

(510) 970-6000
(Registrant's telephone number, including area code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.01 par value per share	**SGMO**	**Nasdaq Global Select Market**

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 7.01 Regulation FD Disclosure.

As previously reported in the October 4, 2024 Form 8-K of Sangamo Therapeutics, Inc., or Sangamo, Sangamo filed a Certificate of Amendment of the Restated Certificate of Incorporation with the Delaware Secretary of State on June 4, 2024, which increased the number of authorized shares of the Common Stock from 640,000,000 to 960,000,000 shares (the "Common Stock Increase Amendment"). At Sangamo's 2024 annual meeting of stockholders held on June 4, 2024 (the "2024 Annual Meeting"), the holders of a majority of the outstanding shares of Common Stock of Sangamo approved the Common Stock Increase Amendment.

In connection with the 2024 Annual Meeting, Sangamo filed a proxy statement on Schedule 14A (the "Proxy Statement") on April 19, 2024. The Proxy Statement described the voting threshold needed to approve the Common Stock Increase Amendment as requiring an affirmative vote of a majority of all votes cast at the 2024 Annual Meeting. Sangamo believes that the Proxy Statement accurately described the vote required to adopt the Common Stock Increase Amendment under a recently enacted provision of the Delaware General Corporation Law (the "DGCL") (Section 242(d)(2)), which became effective on August 1, 2023.

On June 3, 2024, the law firms of Pomerantz LLP and Fields Kupka & Shukurov LLP filed a stockholder class action complaint against Sangamo and Sangamo's board of directors in the Delaware Court of Chancery ("Court of Chancery") on behalf of one purported stockholder of Sangamo. Among other matters, the complaint alleged that because the Proxy Statement had specified that a majority-of-votes-cast voting standard was required for the approval of the Common Stock Increase Amendment, rather than a majority-of-outstanding-shares voting standard, the Common Stock Increase Amendment and any issuances of Common Stock pursuant thereto were and are not validly authorized, despite the fact that both a majority of the votes cast at the 2024 Annual Meeting and a majority of the outstanding shares of Common Stock as of the record date for the 2024 Annual Meeting voted in favor of the Common Stock Increase Amendment. On July 8, 2024, Sangamo and Sangamo's board of directors filed a motion to dismiss the stockholder class action complaint.

To resolve any uncertainty with respect to the validity of the Common Stock Increase Amendment, on August 29, 2024, Sangamo filed an application in the Court of Chancery under Section 205 of the DGCL, seeking to validate the effectiveness of the Common Stock Increase Amendment (the "Section 205 Application"). Section 205 of the DGCL permits the Court of Chancery, in its discretion, to ratify and validate potentially defective corporate acts. As previously reported, the Court of Chancery scheduled a hearing on Sangamo's Section 205 Application for December 12, 2024.

On November 27, 2024, the Court of Chancery issued an opinion in Salama v. Simon, C.A. No. 2024-1124-JTL (Del. Ch.), which confirmed that Sangamo's Proxy Statement accurately described the vote required to adopt the Common Stock Increase Amendment under Section 242(d)(2). As a result of the Court of Chancery's opinion, Sangamo believes that there is no longer any uncertainty concerning the validity of the Common Stock Increase Amendment. On December 6, 2024, Sangamo dismissed the Section 205 Application.

Item 8.01 Other Events.

On December 9, 2024, Pfizer, Inc., or Pfizer, presented detailed data from the Phase 3 AFFINE trial of giroctocogene fitelparvovec, an investigational gene therapy that Sangamo has co-developed with and licensed to Pfizer for the treatment of adults with moderately severe to severe hemophilia A, in an oral presentation at the 66th American Society of Hematology Annual Meeting and Exposition. A copy of slides from the presentation setting forth the data is filed herewith as Exhibit 99.1 and incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) *Exhibits*.

Exhibit No.	Description
99.1	66th American Society of Hematology Annual Meeting & Exposition Data Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

SANGAMO THERAPEUTICS, INC.

Dated: December 9, 2024

By: /s/ SCOTT B. WILLOUGHBY
Name: Scott B. Willoughby
Title: Senior Vice President, General Counsel and Corporate Secretary

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Efficacy and Safety of Giroctocogene Fitelparvovec in Adults With Moderately Severe to Severe Hemophilia A: Primary Analysis Results From the Phase 3 AFFINE Gene Therapy Trial

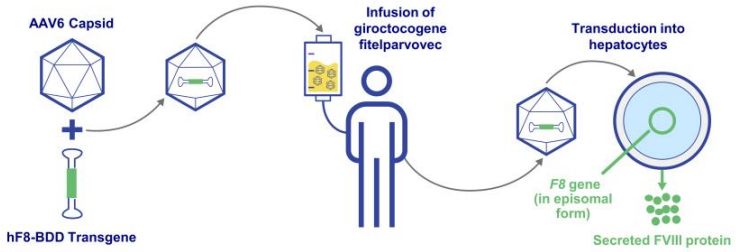
Andrew D Leavitt[1], Kaan Kavakli[2], Laurent Frenzel[3], Ali Bülent Antmen[4], Margareth Ozelo[5], Davide Matino[6,7], Hazza Alzahrani[8], Barbara A Konkle[9], Steven W Pipe[10], Jerome M Teitel[11], Li-Jung Tseng[12], Annie F Fang[12], Florence Ganne[13], Gregory DiRusso[14], Jeremy Rupon[14], Pascal Klaus[15], Jasmine Healy[16], Delphine Agathon[13], Francesca Biondo[17], Frank Plonski[14], on behalf of the AFFINE Investigators

[1]University of California San Francisco, San Francisco, CA, USA; [2]Ege University Faculty of Medicine, Izmir, Turkey; [3]Hemophilia Care and Research, Necker Hospital, Institut Imagine, Paris, France; [4]Acibadem Adana Hospital, Adana, Turkey; [5]Hemocentro UNICAMP, School of Medical Sciences, University of Campinas, Campinas, Brazil; [6]Thrombosis and Atherosclerosis Research Institute (TaARI), McMaster University, Hamilton, ON, Canada; [7]McMaster University, Hamilton, ON, Canada; [8]King Faisal Specialist Hospital and Research Centre, Riyadh, Saudi Arabia; [9]Washington Center for Bleeding Disorders and the University of Washington, Seattle, WA, USA; [10]University of Michigan, Ann Arbor, MI, USA; [11]St. Michael's Hospital, University of Toronto, Toronto, ON, Canada; [12]Pfizer Inc, New York, NY, USA; [13]Pfizer Inc, Paris, France; [14]Pfizer Inc, Collegeville, PA, USA; [15]Pfizer Pharma GmbH, Berlin, Germany; [16]Pfizer Canada ULC, Kirkland, QC, Canada; [17]Pfizer Srl, Rome, Italy

66th Annual Meeting and Exposition of the American Society of Hematology (ASH), December 7–10, 2024, San Diego, CA, USA

Giroctocogene fitelparvovec for hemophilia A

- Liver-tropic recombinant AAV serotype 6 (rAAV6) vector carrying B-domain–deleted human *F8* transgene enabling endogenous FVIII expression in individuals with severe to moderately severe hemophilia A

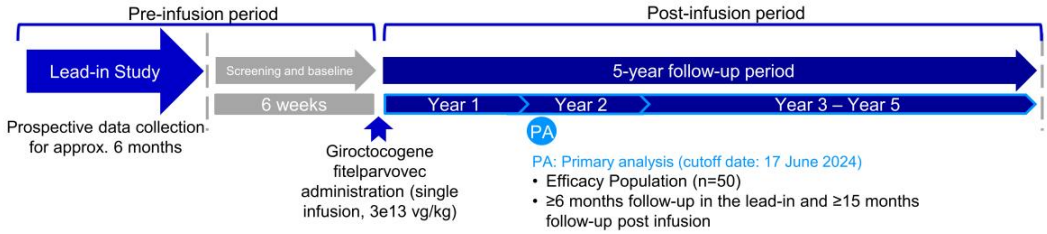


- The completed Alta phase 1/2 dose-ranging study[1,2] (up to 5 years) demonstrated a single infusion of giroctocogene fitelparvovec in the 3e13 vg/kg cohort (n=5) was well tolerated and resulted in:
  - Sustained FVIII activity levels in the moderate-to-normal range in most participants, no bleeds in the first year post infusion in all participants, and low bleeding rates through follow-up in 4 of 5 participants

AAV=adeno-associated virus; BDD=B-domain–deleted; FVIII=factor VIII; hF8=human factor 8; vg=vector genome

1. Harrington TJ, et al. Blood 2023;142(suppl 1):1054. **2.** Leavitt AD, et al. Blood 2024;143(9):796–806.

AFFINE study design



PA: Primary analysis (cutoff date: 17 June 2024)
- Efficacy Population (n=50)
- ≥6 months follow-up in the lead-in and ≥15 months follow-up post infusion

Key eligibility criteria
- Adult males with moderately severe to severe hemophilia A (FVIII activity level ≤1%)
- No anti-AAV6 NAbs or prior history FVIII inhibitors
- No significant liver dysfunction or fibrosis
- No active Hepatitis B or C, well controlled HIV
- No history of thrombotic events or major thromboembolic risk

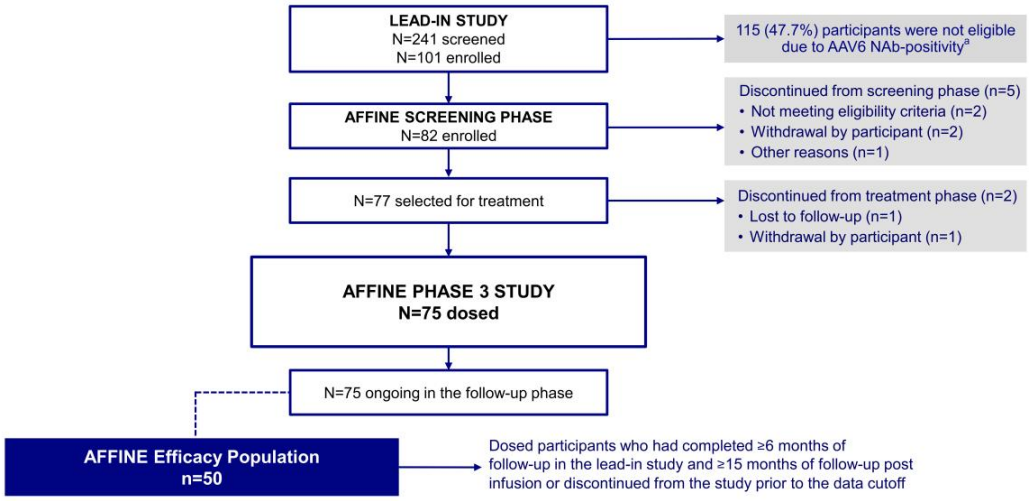
Primary endpoint
- ABR for total bleeds (treated and untreated) from Week 12 through ≥15 months

Key secondary endpoints
- Percentage of participants with FVIII activity level >5% at Month 15
- ABR for treated bleeds from Week 12 through ≥15 months

Secondary endpoint
- AIR of exogenous FVIII from Week 12 through ≥15 months

AAV-6=adeno-associated virus serotype 6; ABR=annualized bleeding rate; AIR=annualized infusion rate; FVIII=factor VIII; NAb=neutralizing antibody; vg=vector genome

Participant disposition



[a] anti-AAV-6 NAb titer ≥1:4.

AAV-6=adeno-associated virus serotype 6; NAb=neutralizing antibody

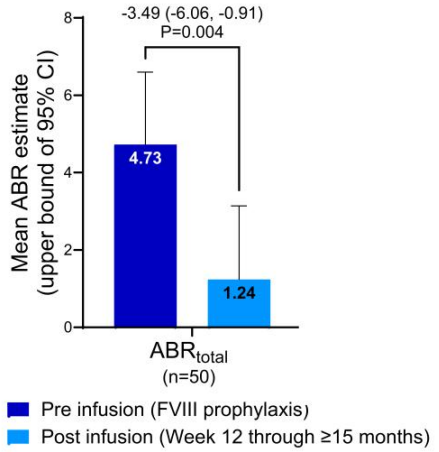
Baseline demographics and characteristics

n (%)[a]	N=75
Age (range), y	32.3 (19–59)
BMI ± SD, kg/m^2	26.1 ± 5.1
Male	75 (100)
Race	
White	56 (74.7)
Asian	14 (18.7)
Black	5 (6.7)
Ethnicity	
Non-Hispanic	59 (78.7)
Hispanic	3 (4.0)
Not reported	13 (17.3)

n (%)[a]	N=75
Region	
North America	12 (16.0)
Europe	19 (25.3)
Middle East	30 (40.0)
Asia Pacific	10 (13.3)
South America	3 (4.0)
Australia	1 (1.3)
Ongoing controlled HIV	6 (8.0)
History of hepatitis B	11 (14.7)
History of hepatitis C	19 (25.3)
Target joints at baseline	25 (33.3)

[a] n (%) unless otherwise noted.
BMI=body mass index

Annualized bleeding rate: Total (treated and untreated) bleeds

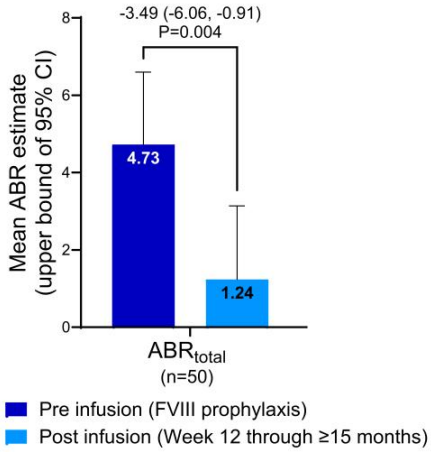


Superiority demonstrated vs FVIII prophylaxis
(Efficacy Population, n=50)

64.0% (32/50) of participants had no bleeding events
(median duration of follow-up, 33.6 months [range 14.5–44.4])

Numbers above graph represent treatment difference and 95% CI. Estimates and 1-sided P-value were obtained from a repeated measures generalized linear model with negative binomial distribution and identity link function with participant as a random effect and treatment and duration of follow-up (in years) as fixed effects.
ABR_{total}=annualized bleeding rate for total (treated and untreated) bleeds; CI=confidence interval; FVIII=factor VIII

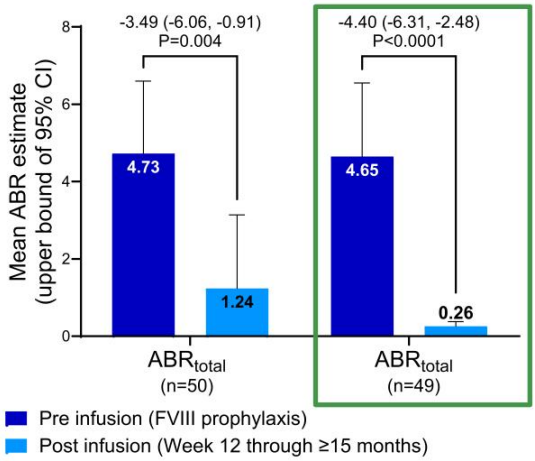
Annualized bleeding rate: Total (treated and untreated) bleeds



- 1 participant had inconsistencies in bleed reporting
  - High number of bleeds (126, total ABR = 47.4) starting at Month 18 post infusion
  - Maintained FVIII activity levels >150% (via CA) through data cutoff
- Median (min, max) bleeds excluding participant: 0.0 (0, 5)

Numbers above graph represent treatment difference and 95% CI. Estimates and 1-sided P-value were obtained from a repeated measures generalized linear model with negative binomial distribution and identity link function with participant as a random effect and treatment and duration of follow-up (in years) as fixed effects.
ABR_{total}=annualized bleeding rate for total (treated and untreated) bleeds; CA=chromogenic assay; CI=confidence interval; FVIII=factor VIII; max=maximum; min=minimum

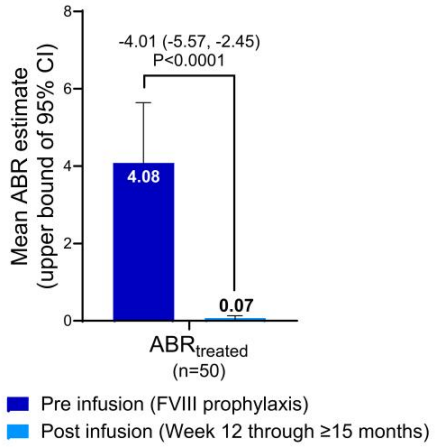
Annualized bleeding rate: Total (treated and untreated) bleeds



Post hoc sensitivity analysis excluding 1 participant (n=49) demonstrated superiority vs FVIII prophylaxis

Numbers above graph represent treatment difference and 95% CI. Estimates and 1-sided P-value were obtained from a repeated measures generalized linear model with negative binomial distribution and identity link function with participant as a random effect and treatment and duration of follow-up (in years) as fixed effects.
ABR_{total}=annualized bleeding rate for total (treated and untreated) bleeds; CI=confidence interval; FVIII=factor VIII

Annualized bleeding rate: Treated bleeds



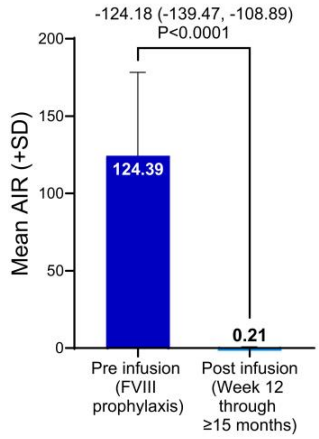
Pre infusion (FVIII prophylaxis)
Post infusion (Week 12 through ≥15 months)

Superiority demonstrated vs FVIII prophylaxis
(Efficacy Population, n=50)

88.0% (44/50) of participants had no treated bleeds
(median duration of follow-up, 33.6 months [range 14.5–44.4])

Numbers above graph represent treatment difference and 95% CI. Estimates and 1-sided P-value were obtained from a repeated measures generalized linear model with negative binomial distribution and identity link function with participant as a random effect and treatment and duration of follow-up (in years) as fixed effects.
$ABR_{treated}$=annualized bleeding rate for treated bleeds; CI=confidence interval; FVIII=factor VIII

Annualized infusion rate of exogenous FVIII

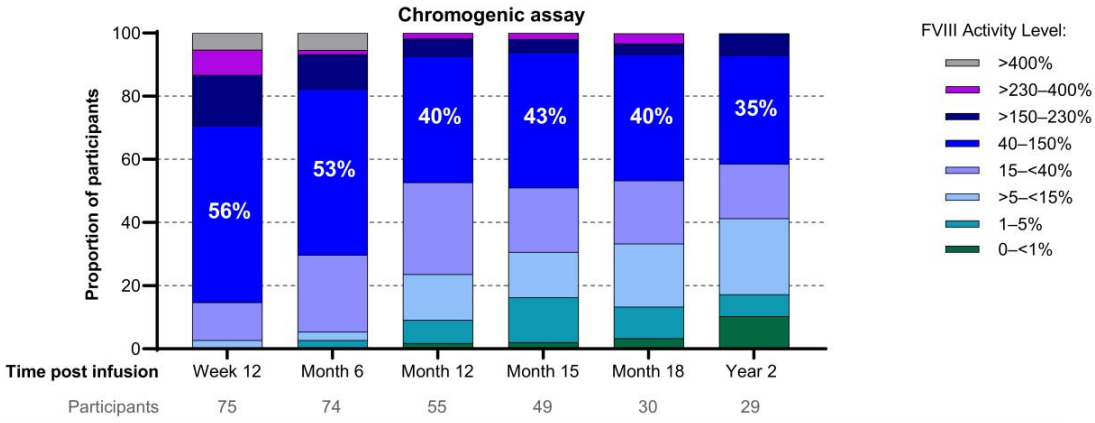


Superiority demonstrated vs FVIII prophylaxis
(Efficacy Population, n=50)

1 of 75 dosed participants resumed FVIII prophylaxis (time to resumption, 16.07 months)

The mean difference (95% CI) and 1-sided P-value were obtained from paired *t*-test.
AIR=annualized infusion rate; FVIII=factor VIII; SD=standard deviation

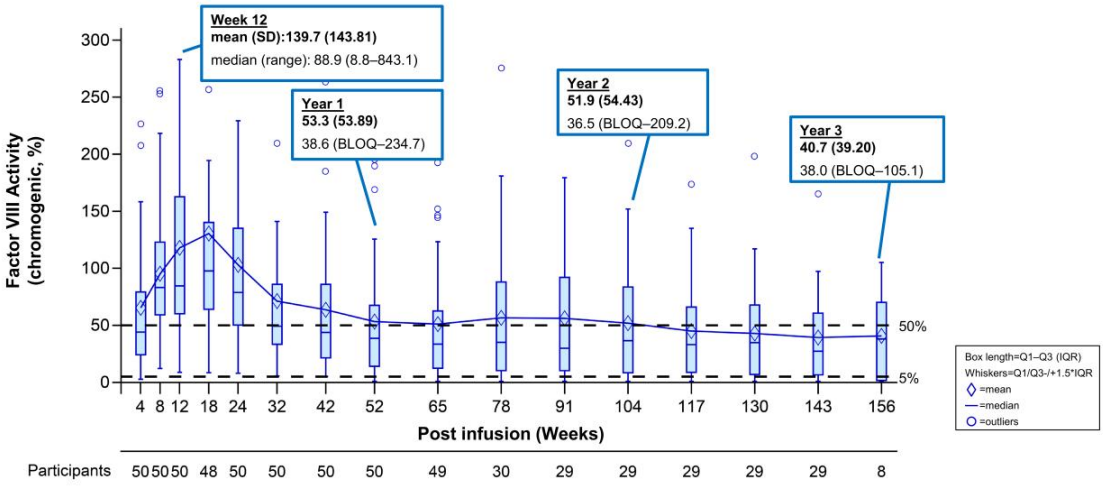
FVIII activity levels post infusion



At Month 15, 84% (95% CI 70.9, 92.8) of participants in the Efficacy Population (n=50) had FVIII activity levels >5% (via CA); 1-sided P=0.0086 vs null hypothesis of ≤68%

CA=chromogenic assay; FVIII=factor VIII; LLOQ=lower limit of quantification

FVIII activity levels through Year 3



Values >300% not shown.
CA=chromogenic assay; BLOQ=below lower limit of quantification; FVIII=factor VIII; IQR=interquartile range; max=maximum; min=minimum; Q=quartile

Safety overview

- No infusion interruptions or rate slowing
- Infusion-related reactions (events occurring within 2 days post infusion) in 58 (77.3%) participants
  - Mostly mild (n=39/58; 67.2%) with resolution within 2 days
- At data cutoff (mean [range] follow-up, 21.88 [7.8-44.4] months):
  - No FVIII inhibitors
  - No malignancies related to study drug
  - One thrombotic event in a participant with major protocol deviation (prior history of DVT and PE) and multiple thrombotic risk factors

Participants with AEs, n (%) and number of events (when specified)	Dosed Population N=75
AEs	74 (98.7)
Number of events	740
Discontinued due to AEs	0 (0)
SAEs	15 (20.0)
Number of events	26
Treatment-related AEs	68 (90.7)
Selected treatment-related AESIs	
Hepatotoxicity (transaminase increased)	47 (62.7)
Infusion-related reactions	55 (73.3)
Pyrexia	38 (50.7)
Headache	23 (30.7)
Chills	14 (18.7)
Deep vein thrombosis	1 (1.3)

AE=adverse event; AESI=adverse event of special interest; DVT=deep vein thrombosis; FVIII=factor VIII; PE=pulmonary embolism; SAE=serious adverse event

ALT elevations and corticosteroid use

- ALT elevations were mild and manageable
  - ALT elevations resolved within a median of 28.0 days
- Overall, corticosteroids were well tolerated, with corticosteroid-related AEs reported in 19 (25.3%) participants
- At the time of the data cutoff, no participants in the Efficacy Population remained on corticosteroids
- 5 (6.7%) participants received alternative immunosuppressive therapies following corticosteroid treatment, including MMF in 4 participants, and azathioprine in 1 participant

ALT and corticosteroid use	N=75
Treatment-related AEs related to hepatotoxicity (transaminase increased), n (%)	47 (62.7)
SAEs related to transaminase increased, n (%)	2 (2.7)
Participants with ALT increase >ULN, n (%)	46 (61.3)
ALT grades (CTCAE grading)[a] among all dosed participants, n (%)	
Normal	30 (40.0)
Grade 1	40 (53.3)
Grade 2	4 (5.3)
Grade 3	1 (1.3)
Grade 4	0 (0)
Pts with corticosteroid use, n (%)	47 (62.7)
Time to corticosteroid initiation, median (range), days	84 (7–193)
Corticosteroid courses per participant, mean (range), days	2.0 (1–5)
Duration of corticosteroid use, mean (range), days	114.6 (11–296)

[a] The highest CTCAE grade among all post baseline assessments from each participant are reported.
AE=adverse event; ALT=alanine aminotransferase; CTCAE=common terminology criteria for adverse events; MMF=mycophenolate mofetil; pts=participants; SAE=serious adverse event; ULN=upper limit of normal

FVIII activity elevations

- DOACs were well tolerated, with no significant bleeding events while on DOAC
  - In total, 6 participants reported ≥1 bleed while on DOAC, none were treated
- 1 participant (major PD with prior history of DVT and PE and multiple thrombotic risk factors) experienced a thromboembolic event
- No other thromboembolic events were reported

FVIII elevations throughout follow-up	N=75
≥1 FVIII activity level >150% (CA), n (%)	37 (49.3)
Time to first FVIII activity level >150%, mean (range), days	74.7 (15–540)
Days with FVIII >150%, mean (range)	143.8 (4–953)
Received prophylactic DOAC, n (%)	23 (30.7)
Time to DOAC initiation, mean (range), days	86.13 (28–370)
Total duration of DOAC, mean (range), days	166 (7–944)

CA=chromogenic assay; DOAC=direct oral anticoagulant; DVT=deep vein thrombosis; FVIII=factor VIII; OSA=one-stage assay; PD=protocol deviation; PE=pulmonary embolism

Summary: Efficacy and safety of giroctocogene fitelparvovec

- A single IV infusion of 3e13 vg/kg was generally well tolerated and exhibited an acceptable and manageable safety profile
- The study met the primary endpoint with a significantly reduced mean ABR_{total} vs FVIII prophylaxis: 1.24 vs 4.73 (0.26 vs 4.65 in post hoc sensitivity analysis)
- Mean $ABR_{treated}$ was significantly reduced vs FVIII prophylaxis (0.07 vs 4.08)
- Mean AIR was also significantly reduced vs FVIII prophylaxis (0.21 vs 124.39)
- Mean FVIII activity levels >50% of normal (via CA) were achieved and stable up to 2 years post infusion
- At the time of primary analysis, 1 participant returned to prophylaxis at month 16

ABR_{total}=total annualized bleeding rate; $ABR_{treated}$=treated annualized bleeding rate; AIR=annualized infusion rate; CA=chromogenic assay; FVIII=factor VIII; IV=intravenous; vg=vector genome