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): September 10, 2022

SPRINGWORKS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39044**	**83-4066827**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

100 Washington Blvd
Stamford, CT 06902
(Address of principal executive offices, including zip code)

(203) 883-9490
(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, par value $0.0001 per share	SWTX	The 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 8.01 Other Events.

On September 10, 2022, SpringWorks Therapeutics, Inc. ("SpringWorks" or the "Company") presented data from the Phase 3 DeFi trial of nirogacestat, an investigational oral gamma secretase inhibitor, in adult patients with progressing desmoid tumors, at the European Society for Medical Oncology (ESMO) Congress 2022.

The DeFi trial is a global, randomized, double-blind, placebo-controlled Phase 3 trial evaluating the efficacy, safety and tolerability of nirogacestat in adult patients with progressing desmoid tumors. The double-blind phase of the study randomized 142 patients to receive 150 mg of nirogacestat or placebo twice daily. The study enrolled patients with progressing desmoid tumors at baseline and included a high proportion of patients with multifocal disease and uncontrolled pain.

The DeFi trial met its primary endpoint of improving progression-free survival ("PFS"), as assessed by blinded independent central review, demonstrating a statistically significant improvement for nirogacestat over placebo, with a 71% reduction in the risk of disease progression (hazard ratio (HR) = 0.29 (95% CI: 0.15, 0.55); p< 0.001). The median Kaplan-Meier estimate of PFS was not reached in the nirogacestat arm and was 15.1 months in the placebo arm. A PFS benefit was observed across all prespecified subgroups, including gender, tumor location, prior treatment or surgery, and mutational status. Confirmed objective response rate (complete response + partial response) based on RECIST v1.1 was 41% with nirogacestat versus 8% with placebo (p<0.001). The complete response rate was 7% in the nirogacestat arm and 0% in the placebo arm. Nirogacestat demonstrated statistically significant and clinically meaningful improvements in patient-reported outcomes ("PRO"), which were key secondary endpoints of the study. Specifically, nirogacestat significantly reduced pain (p<0.001) and other DT-specific symptoms (p<0.001) and also significantly improved physical/role functioning (p<0.001) and overall health-related quality of life (p=0.007). Most PRO benefits were observed as early as Cycle 2, which was the first timepoint for post-treatment evaluation, and were sustained over the duration of the study.

At the time of primary analysis, which was April 7, 2022, the median duration of treatment was 20.6 months for participants on nirogacestat and 11.4 months for those on placebo, with the majority of nirogacestat patients continuing on treatment. Nirogacestat exhibited a manageable safety profile in the DeFi trial, with 95% of all treatment-emergent adverse events ("TEAE"s) reported as Grade 1 or 2. The most frequently reported TEAEs in participants receiving nirogacestat as compared to the placebo arm were diarrhea (84% versus 35%), nausea (54% versus 39%), and fatigue (51% versus 36%). Forty-two percent of patients in the nirogacestat arm versus 0% in the placebo arm required dose reductions due to TEAEs and 20% of patients in the nirogacestat arm versus 1% in the placebo arm discontinued treatment due to TEAEs. Ovarian dysfunction, which was defined by investigator-reported events of amenorrhea, premature menopause, menopause, and ovarian failure, was observed in 75% (27/36) of women of childbearing potential receiving nirogacestat. These events resolved in 74% (20/27) of the affected participants, including 64% (9/14) of such participants who remained on nirogacestat treatment and 100% (11/11) of those participants who discontinued treatment for any reason.

A copy of the Company's presentation materials in connection with the ESMO Congress 2022 are attached as Exhibit 99.1 to this Current Report on Form 8-K and are incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.
(d) Exhibits.

Exhibit No.	Description
99.1	ESMO Congress 2022 Presentation by SpringWorks Therapeutics, Inc. on September 10, 2022.
104	Cover page interactive data file (embedded within the Inline XBRL document)

SIGNATURE

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.

SpringWorks Therapeutics, Inc.

Date: September 12, 2022

By: /s/ Francis I. Perier, Jr.
Francis I. Perier, Jr.
Chief Financial Officer

Exhibit 99.1

PARIS 2022 ESMO congress

DeFi: A Phase 3 Trial of Nirogacestat for Progressing Desmoid Tumors (DT)

Bernd Kasper, Ravin Ratan, Thierry Alcindor, Patrick Schöffski, Winette T. van der Graaf, Breelyn A. Wilky, Richard F. Riedel, Allison Lim, L. Mary Smith, Stephanie Moody, Steven Attia, Sant Chawla, Gina D'Amato, Noah Federman, Priscilla Merriam, Brian A. Van Tine, Bruno Vincenzi, Shivaani Kummar, Mrinal Gounder, on behalf of the DeFi Study Investigators

September 10, 2022

Declaration of Interests

- Bernd Kasper's declaration of interests:
  - Financial interests
    - Ayala (advisory board, personal), Bayer (advisory board, personal), Blueprint, (advisory board, personal), Boehringer Ingelheim (advisory board, personal), GSK (advisory board, personal), PharmaMar (advisory board, personal), SpringWorks Therapeutics (advisory board, personal)
  - Nonfinancial interests
    - Ayala (coordinating PI, institutional, no financial interest), PharmaMar (coordinating PI, institutional, no financial interest), SpringWorks Therapeutics (coordinating PI, institutional, no financial interest), European Organisation for Research and Treatment of Cancer (EORTC; leadership role, Chair of the EORTC Soft Tissue and Bone Sarcoma Group [STBSG])

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Gamma Secretase Inhibition in Desmoid Tumors

- Desmoid tumors (DT) are rare, locally aggressive, and invasive soft-tissue tumors that are challenging to manage due to variable presentation, unpredictable disease course, and a lack of approved therapies[1,2]
- Treatment should be individualized to optimize tumor control and improve symptom burden, including pain, physical function, and overall quality of life[3]
  - A global consensus initiative has been launched by The Desmoid Tumor Working Group aiming to harmonize management strategies[4]
- There is mechanistic rationale for the use of gamma secretase inhibitors (GSI) in DT as these tumors highly express Notch, which can be blocked by GSIs[5,6]
- Nirogacestat is an investigational, oral, selective, small-molecule GSI that has shown evidence of antitumor activity in DT in Phase 1 and 2 trials with a manageable adverse event profile[1,7,8]

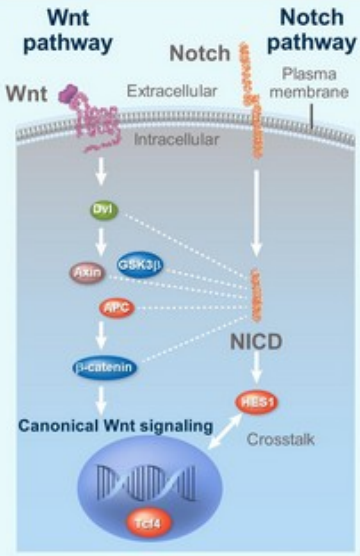

Image adapted from Andersson et al. *Development* (2011) and Bui and Kummar. *Oncotarget* (2017).

DT, desmoid tumor; GSI, gamma secretase inhibitor; NICD, Notch intracellular domain.

1. Villalobos et al. *Ann Surg Oncol.* 2018;25:768-775. **2.** Kasper et al. *Oncologist.* 2011;16:682-693. **3.** Gounder et al. *Cancer.* 2020;126:531-539. **4.** Desmoid Tumor Working Group. *Eur J Cancer.* 2020;127:96-107. **5.** Andersson et al. *Development.* 2011;138:3593-3612. **6.** Gounder et al. *Cancer.* 2015;121:3933-3937. **7.** Messersmith et al. *Clin Cancer Res.* 2015;21:60-67. **8.** Kummar et al. *J Clin Oncol.* 2017;35:1561-1569.

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DeFi: Phase 3 Study of Nirogacestat vs Placebo in Adult Patients With DT

Trial Summary

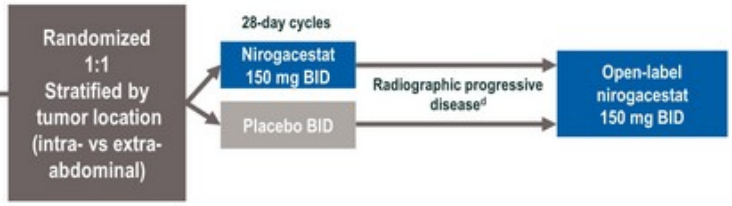
- Global, randomized, double-blind, placebo-controlled, Phase 3 trial comparing the efficacy, safety, and tolerability of nirogacestat vs placebo in adult patients with progressing DT
- 142 patients randomized across 37 sites in North America and Europe

Key Endpoints

- **Primary:** Progression-free survival[b]
- **Secondary:** Objective response rate and patient-reported outcomes, such as pain, symptom burden, physical/role function, and overall quality of life[c]

Adult Eligible Patients

- Histologically confirmed DT with progressive disease per RECIST v1.1[a]
  - Treatment-naïve with DT not amenable to surgery, or
  - Refractory or recurrent disease (after ≥1 line of therapy)



Primary Analysis Data Cutoff: April 7, 2022

[a]Progressive disease defined by histologically confirmed DT that has progressed ≥20% within the past 12 months by RECIST v1.1. Target tumors identified at screening by the Investigator.
[b]Progression was determined radiographically using RECIST v1.1 or clinically by independent, blinded, central radiologic or clinical review.
[c]As assessed by change from baseline for BPI-SF, GODDESS DTSS, GODDESS DTIS, and EORTC QLQ-C30 at Cycle 10.
[d]Radiographic disease progression or once the required number of events have been observed and the primary progression-free survival analysis has been completed.
BID, twice-daily dosing; BPI-SF, Brief Pain Inventory–Short Form; DT, desmoid tumor; DTIS, GODDESS DT Impact Scale; DTSS, GODDESS DT Symptom Scale; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; GODDESS, GOunder/Desmoid Tumor Research Foundation DEsmoid Symptom/Impact Scale; RECIST, Response Evaluation Criteria in Solid Tumors.
ClinicalTrials.gov. https://clinicaltrials.gov/ct2/show/NCT03785964. Accessed August 24, 2022.

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Baseline Demographics and Characteristics

Demographics/Characteristics, ITT Population	Nirogacestat (n=70)	Placebo (n=72)
Age, median (range), y	33.5 (18, 73)	34.5 (18, 76)
Sex, n (%)		
Male	25 (36)	25 (35)
Female	45 (64)	47 (65)
Somatic mutations in analyzed patients, n (%)[a]		
APC	11 (22)	11 (21)
CTNNB1	43 (84)	42 (79)
Tumor location, n (%)		
Intra-abdominal	17 (24)	18 (25)
Extra-abdominal	53 (76)	54 (75)
Focal category, n (%)		
Single	43 (61)	41 (57)
Multifocal	27 (39)	31 (43)
Desmoid tumor treatment status, n (%)		
Treatment naïve	18 (26)	14 (19)
Refractory/Recurrent	52 (74)	58 (81)
Number of lines of any prior therapy, median (range)	2 (0, 14)	2 (0, 19)
Prior therapies, n (%)		
Prior systemic therapy	43 (61)	44 (61)
Prior radiation therapy	16 (23)	16 (22)
Prior surgery	31 (44)	44 (61)
Patients with uncontrolled pain per BPI-SF API >4, n (%)[b]	16 (23)	14 (19)

[a]Evaluable samples not available for all patients. Samples were analyzed for 51 and 53 patients in the nirogacestat and placebo arms, respectively.
[b]Defined as a score of >4 calculated as the average of the daily BPI–SF Item 3 "Worst Pain in Past 24 hours" over the 7-day period before the baseline visit.
API, average pain index; BPI-SF, Brief Pain Inventory–Short Form ITT; intention to treat.

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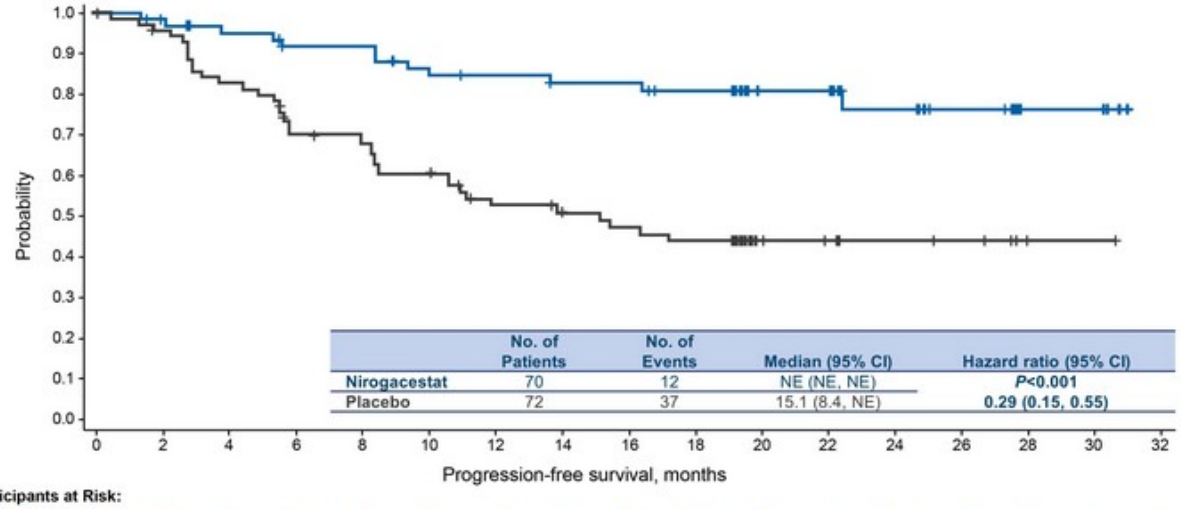
Nirogacestat Significantly Reduced Risk of Disease Progression



	No. of Patients	No. of Events	Median (95% CI)	Hazard ratio (95% CI)
Nirogacestat	70	12	NE (NE, NE)	*P*<0.001
Placebo	72	37	15.1 (8.4, NE)	0.29 (0.15, 0.55)

No. of Participants at Risk:

Nirogacestat	70	63	56	52	52	47	46	44	44	41	26	26	17	12	4	4	0
Placebo	72	67	58	47	45	40	32	29	27	25	10	8	6	5	1	1	0

Median follow-up time was 19.2 months for nirogacestat and 10.9 months for placebo.
NE, not estimable.

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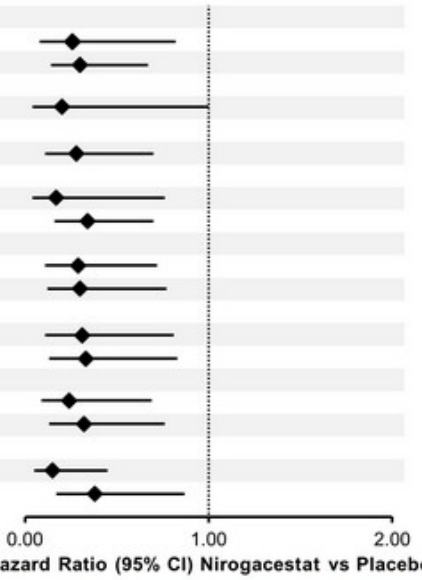
PFS Benefit With Nirogacestat Was Observed Across Prespecified Subgroups

	Hazard Ratio	Nirogacestat Censored/Events	Placebo Censored/Events
Sex			
Male	0.26	21 / 4	14 / 11
Female	0.30	37 / 8	21 / 26
***APC* mutation**			
Yes	0.20	9 / 2	3 / 8
***CTNNB1* mutation**			
Yes	0.28	37 / 6	21 / 21
Target tumor location			
Intra-abdominal	0.17	15 / 2	7 / 11
Extra-abdominal	0.34	43 / 10	28 / 26
Focality			
Single	0.29	37 / 6	22 / 19
Multifocal	0.30	21 / 6	13 / 18
Prior surgery			
Yes	0.31	26 / 5	21 / 23
No	0.33	32 / 7	14 / 14
Prior chemotherapy			
Yes	0.24	19 / 5	10 / 17
No	0.32	39 / 7	25 / 20
Prior TKI treatment			
Yes	0.15	19 / 4	8 / 16
No	0.38	39 / 8	27 / 21



PFS, progression-free survival; TKI, tyrosine kinase inhibitor.

PARIS 2022 ESMO congress

Kasper et al. DeFi Phase 3 in Adult Desmoid Tumors

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Objective Response Rate by Blinded Independent Central Review

	Nirogacestat (n=70)	Placebo (n=72)
Objective response rate (CR+PR), n (%) 95% CI Two-sided *P* value	**29 (41)** **(30.2, 54.5)** **<0.001**	**6 (8)** **(3.1, 17.3)**
Best overall response, n (%)		
Complete response	5 (7)	0
Partial response	24 (34)	6 (8)
Stable disease	35 (50)	55 (76)
Progressive disease	1 (1)	10 (14)
Not evaluable	4 (6)	1 (1)
Time to objective response, median (range), mo	5.6 (2.6, 19.4)	11.1 (2.8, 16.4)
Kaplan-Meier estimate of median duration of objective response (95% CI), mo[a]	NE (NE, NE)	NE (8.3, NE)

[a]Duration of objective response was defined as duration in months from the time CR or PR (which ever came first) was met until the date of progression, death, or censoring.
CR, complete response; NE, not estimable; PR, partial response.

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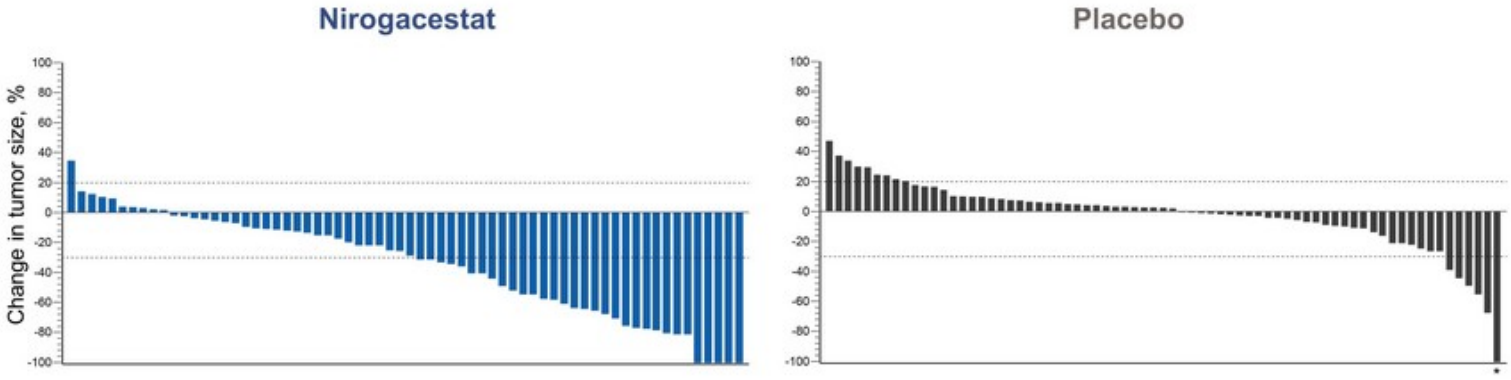
Nirogacestat Treatment Resulted in Substantial Reductions in Tumor Size



*Patient had a complete resolution of the target lesion but still had documented non-target lesion; therefore, not a complete response.
Best percent change values are averaged between 2 blinded independent reviewers unless a reader was selected for adjudication, in which case only the adjudicated value is presented.

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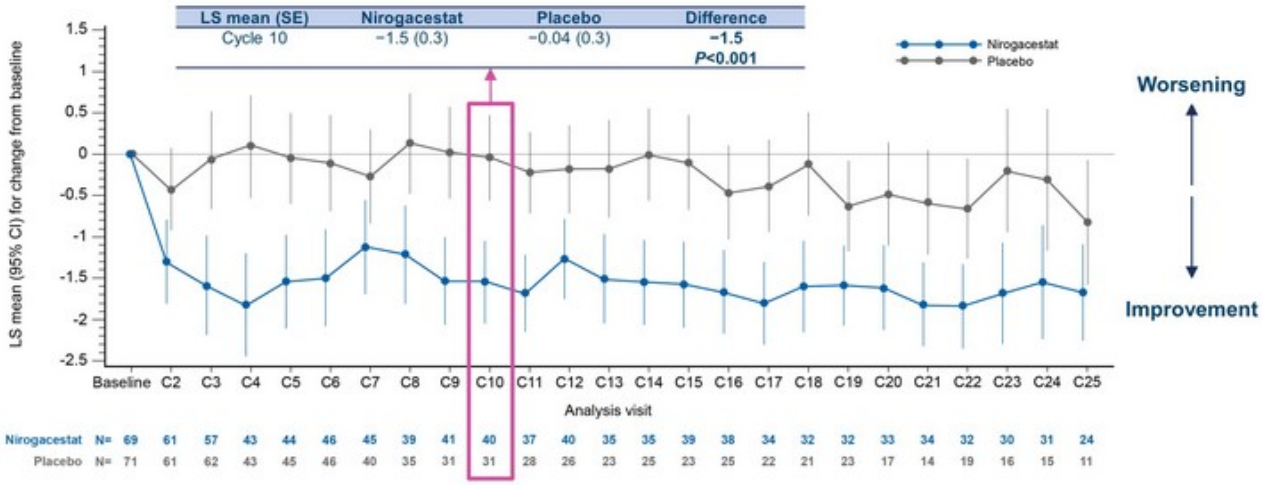
Nirogacestat Significantly Reduced Pain Severity Compared With Placebo

Brief Pain Inventory-Short Form – Average Pain Intensity



Mean (SD) baseline scores: nirogacestat, 3.2 (3.26); placebo, 3.3 (3.31). Differences at Cycle 10 were statistically significant and clinically meaningful. LS mean change from baseline represents the 7-day average.
LS, least squares.

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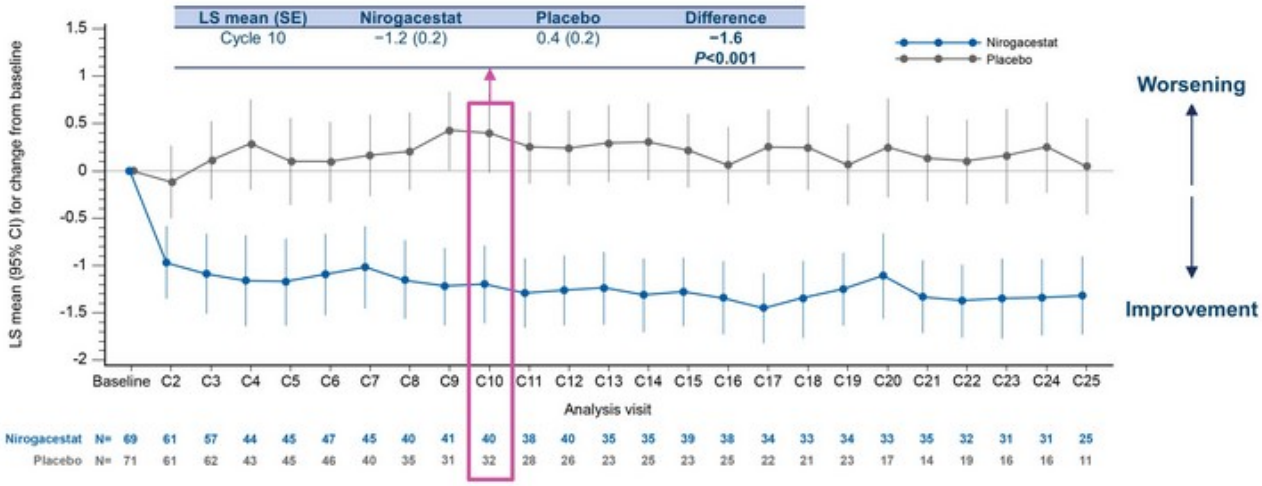
Nirogacestat Significantly Reduced DT-Specific Symptom Severity

GODDESS DTSS – Total Symptom Score



Mean (SD) baseline scores: nirogacestat, 3.4 (2.34); placebo, 3.5 (2.57). Differences at Cycle 10 were statistically significant and clinically meaningful.
DTSS total symptom score includes pain, fatigue, swelling, muscle weakness, and difficulty moving.
DT, desmoid tumor; DTSS, GODDESS DT Symptom Scale; GODDESS, GOunder/Desmoid Tumor Research Foundation DEsmoid Symptom/Impact Scale; LS, least squares.

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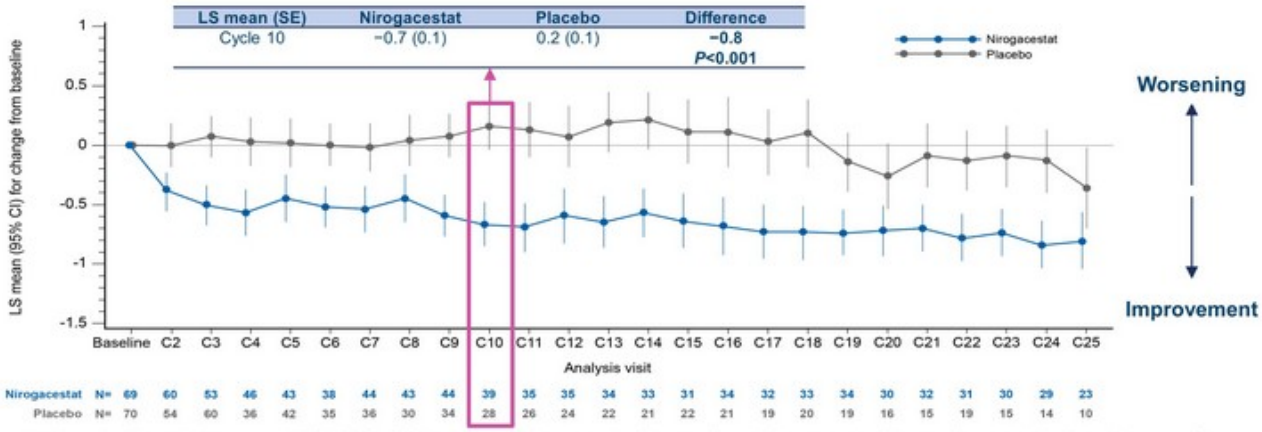
Nirogacestat Significantly Improved Physical/Role Functioning and QoL

GODDESS DTIS – Physical Functioning Impact Score



- **Nirogacestat also significantly improved EORTC QLQ-C30 physical functioning (*P*<0.001), role functioning (*P*<0.001), and global health status/QoL (*P*=0.007) at Cycle 10 compared with placebo**

Mean (SD) baseline scores: nirogacestat, 2.8 (1.14); placebo, 2.7 (1.24). Differences at Cycle 10 were statistically significant and clinically meaningful. DTIS physical functioning includes moving, reaching, vigorous activity, moderate activity, accomplishing less. DT, desmoid tumor; DTIS, GODDESS DT Impact Scale; EORTC QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30; GODDESS, GOunder/Desmoid Tumor Research Foundation DEsmoid Symptom/Impact Scale; LS, least squares; QoL, quality of life.

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Nirogacestat Safety Profile

Safety population, n (%)	Nirogacestat (n=69)		Placebo (n=72)	
Duration of study drug exposure, median (range), months	20.6 (0.3, 33.6)		11.4 (0.2, 32.5)	
Dose intensity, median (range), mg/d	288.3 (169, 300)		300.0 (239, 300)	
	Any Grade	Grade ≥3	Any Grade	Grade ≥3
Any TEAE	69 (100)	39 (57)	69 (96)	12 (16)
TEAEs of any grade reported in ≥25% of patients in either arm				
Diarrhea	58 (84)	11 (16)	25 (35)	1 (1)
Nausea	37 (54)	1 (1)	28 (39)	0
Fatigue	35 (51)	2 (3)	26 (36)	0
Hypophosphatemia	29 (42)	2 (3)	5 (7)	0
Rash, maculopapular	22 (32)	4 (6)	4 (6)	0
Headache	20 (29)	0	11 (15)	0
Stomatitis	20 (29)	3 (4)	3 (4)	0
TEAEs leading to death	0		1 (1)[a]	
Dose reductions due to TEAEs	29 (42)		0	
Discontinuations due to TEAEs	14 (20)[b]		1 (1)[b]	

- **95% of TEAEs were Grade 1 or 2; the first onset of TEAEs in most patients occurred during Cycle 1**

[a]Death due to sepsis.
[b]TEAEs leading to discontinuations in ≥1 patient include gastrointestinal disorders (n=5 [4%]), ovarian dysfunction (n=4 [3%]), alanine aminotransferase increase (n=3 [2%]), aspartate aminotransferase increase (n=2 [1%]), and metabolism/nutritional disorders (n=2 [1%]).
TEAE, treatment-emergent adverse event.

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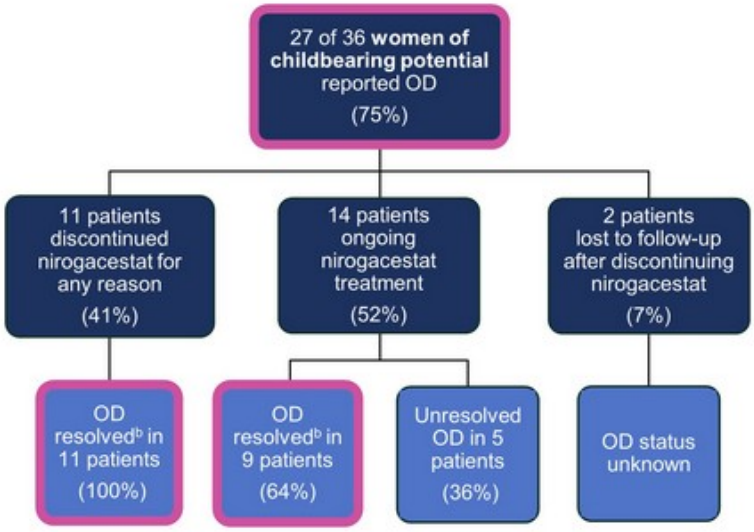
Frequency and Resolution of Ovarian Dysfunction Observed With Nirogacestat

- OD is a composite adverse event associated with changes in female reproductive hormone levels and clinical manifestations[1,2]
- Protocol-mandated serum hormone collection at baseline and cycles 1, 2, 4, and every 3 thereafter
- Among women of childbearing potential, OD[a] was observed in 75% receiving nirogacestat and 0% receiving placebo
  - Median time to first onset of OD: 8.9 weeks
  - Median duration of OD events: 21.3 weeks



[a]OD among women of childbearing potential was defined by investigators who reported the MedDRA Preferred Terms of amenorrhea, premature menopause, menopause, and ovarian failure.
[b]As of July 20, 2022.
[c]Resolution of OD events was defined by the investigator.
OD, ovarian dysfunction.

1. Thurston et al. *Obstet Gynecol Clin North Am.* 2011;38:489-501. **2.** Mauri et al. *Front Endocrinol (Lausanne).* 2020;11:572388.

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Summary

- **DeFi represents the largest and most rigorous randomized controlled trial conducted to date in DT**
  - DeFi is also the first Phase 3, randomized, controlled trial to demonstrate clinical benefit with a GSI in any indication
- **Nirogacestat demonstrated rapid, sustained, and statistically significant improvements in all primary and secondary efficacy endpoints**
  - 71% reduction in the risk of disease progression as compared with placebo
  - Objective response rate of 41%, including a 7% complete response rate
  - Statistically significant and clinically meaningful improvements in pain, disease-specific symptom burden, physical/role functioning, and overall quality of life ($P \leq 0.007$)
- **Nirogacestat exhibited a manageable safety profile, with 95% of all treatment-emergent adverse events being Grade 1 or 2**
- **Nirogacestat has the potential to become the standard of care for patients with DT requiring systemic treatment**

DT, desmoid tumor, GSI, gamma secretase inhibitor.

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Acknowledgments

- We thank the DeFi trial participants, their families, and trial personnel
- We thank these DeFi Principal Investigators for their contributions to participant enrollment and data acquisition: Charlotte Benson, Nam Quoc Bui, Rashmi Chugh, Gabriel Tinoco, John Charlson, Palma Dileo, Lee Hartner, Lore Lapeire, Filomena Mazzeo, Emanuela Palmerini, Peter Reichardt, Silvia Stacchiotti, Howard H. Bailey, Melissa A. Burgess, Gregory M. Cote, Lara E. Davis, Hari Deshpande, Hans Gelderblom, Giovanni Grignani, Elizabeth Loggers, Tony Philip, Joseph G. Pressey
- We thank the former DeFi Principal Investigators for their contributions: Victor Villalobos, Jonathan Trent, Robert Maki, Suzanne George, Michael Nathenson, and Amanda Parkes; and the DeFi Principal Investigators who contributed to the screening of trial participants: Christian Meyer, Mark Agulnik, James Hu, Vicki Keedy, and Jade Homsi
- We thank the data monitoring committee members: Timothy Cripe, Damon Reed, Stephen Skapek, and Barry Turnbull
- We thank The Desmoid Tumor Research Foundation and Sarcoma Patients Advocacy Global Network (SPAGN)
- Medical writing and editorial support was provided by MedThink SciCom
- DeFi was sponsored by SpringWorks Therapeutics, Inc.

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PARIS 2022 ESMO congress

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