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): November 27, 2023

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)	(Zip Code)

Registrant's telephone number, including area code: **(203) 883-9490**

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 7.01 Regulation FD Disclosure.

On November 27, 2023, SpringWorks Therapeutics, Inc. ("SpringWorks" or the "Company") issued a press release announcing that the U.S. Food and Drug Administration ("FDA") has approved has approved OGSIVEO™ (nirogacestat), an oral gamma secretase inhibitor, for the treatment of adult patients with progressing desmoid tumors who require systemic treatment. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. A copy of the Company's presentation materials in connection with the announcement is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in Item 7.01 of this Form 8-K, including Exhibits 99.1 and 99.2, 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, nor shall it 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.

On November 27, 2023, SpringWorks announced that the FDA has approved OGSIVEO™ (nirogacestat), an oral gamma secretase inhibitor, for the treatment of adult patients with progressing desmoid tumors who require systemic treatment. The FDA previously granted breakthrough therapy, fast track and orphan drug designations to nirogacestat for the treatment of desmoid tumors.

Desmoid tumors are locally aggressive and invasive soft-tissue tumors that can lead to substantial morbidity. In addition, when vital structures are impacted, desmoid tumors can be life-threatening. Although they do not metastasize, desmoid tumors are often refractory to existing off-label systemic therapies and associated with recurrence rates of up to 77% following surgical resection. Desmoid tumor experts and treatment guidelines now recommend systemic therapies as first-line intervention instead of surgery for most tumor locations requiring treatment.

The FDA approval of OGSIVEO is based on the results from the Phase 3 DeFi trial, which were published in the March 9, 2023 edition of the *New England Journal of Medicine*. OGSIVEO met the primary endpoint of improving progression-free survival ("PFS"), demonstrating a statistically significant improvement 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). Median PFS was not reached in the OGSIVEO arm and was 15.1 months in the placebo arm. Confirmed objective response rate (ORR) based on RECIST v1.1 was 41% with OGSIVEO versus 8% with placebo (p<0.001); the complete response rate was 7% in the OGSIVEO arm and 0% in the placebo arm. The median time to first response was 5.6 months with OGSIVEO and 11.1 months with placebo. PFS and ORR improvements were in favor of OGSIVEO regardless of baseline characteristics including sex, tumor location, tumor focality, treatment status, previous treatments, mutational status, and history of familial adenomatous polyposis. OGSIVEO also demonstrated early and sustained improvements in patient-reported outcomes, including pain (p<0.001), desmoid tumor-specific symptoms (p<0.001), physical/role functioning (p<0.001), and overall health-related quality of life (p≤0.01).

OGSIVEO exhibited a manageable safety and tolerability profile. The most common adverse events (≥15%) reported in patients receiving OGSIVEO were diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respiratory tract infection, and dyspnea.

To support commercialization of OGSIVEO, SpringWorks has assembled a U.S. commercial field organization of 35 territory business managers plus regional business directors. The Company has identified a group of 1,500 physicians that treat a substantial portion of desmoid tumor patients and will focus initial efforts to drive adoption of OGSIVEO among these physicians. The Company has set a wholesale acquisition cost for a 30-day supply of OGSIVEO at $29,000.

Forward-Looking Statements

This Current Report on Form 8-K contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, relating to our business, operations, and financial conditions, including, but not limited to, current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our development and commercialization plans, our preclinical and clinical results, the potential for OGSIVEO to become an important new treatment for patients with desmoid tumors, the potential for a Marketing Authorisation Application for nirogacestat, as well as statements relating to other future conditions. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "should" and "could," and similar expressions or words, identify forward-looking statements. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertainties. Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release, including, without limitation, risks relating to: (i) the success of our commercialization efforts with respect to OGSIVEO, (ii) our limited experience as a commercial company, (iii) our pricing of OGSIVEO and our ability to obtain or maintain adequate coverage and reimbursement for OGSIVEO, (iv) the success and timing of our product development activities, including the initiation and completion of SpringWorks' clinical trials, (v) our expectations regarding the potential clinical benefit of OGSIVEO for patients with desmoid tumors, (vi) the potential for OGSIVEO to become the new standard of care for patients with desmoid tumors, (vii) our expectations regarding when OGSIVEO will be available, (viii) estimates regarding the number of patients who are diagnosed with desmoid tumors annually per year in the U.S. and the potential market for OGSIVEO, (ix) our commercialization strategy and ability to successfully identify physicians focused on desmoid tumors, (x) the success and timing of our collaboration partners' ongoing and planned clinical trials, (xi) the timing of our planned regulatory submissions and interactions, including the timing and outcome of decisions made by the FDA, the European Medicines Agency (EMA) and other regulatory authorities, investigational review boards at clinical trial sites and publication review bodies; (xii) whether FDA, EMA or other regulatory authorities will require additional information or further studies, or may fail or refuse to approve or may delay approval of our product candidates, (xiii) our ability to obtain regulatory approval of any of our product candidates or maintain regulatory approvals granted for our products, (xiv) our plans to research, discover and develop additional product candidates, (xv) our ability to enter into collaborations for the development of new product candidates, (xvi) our ability to establish and maintain manufacturing capabilities, and our and our collaboration partners' abilities to manufacture our products and product candidates and scale production, (xvii) our ability to maintain adequate patent protection and successfully enforce patent claims against third parties, and (xviii) our ability to meet any specific milestones set forth herein.

Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations will prove to be correct. Accordingly, readers are cautioned not to place undue reliance on these
forward-looking statements.

For further information regarding the risks, uncertainties and other factors that may cause differences between SpringWorks' expectations and actual results, you should review the "Risk Factors" in Item 1A of Part II of SpringWorks' Quarterly Report on Form 10-Q for the quarter ended September 30, 2023, as well as discussions of potential risks, uncertainties and other important factors in SpringWorks' subsequent filings.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued by SpringWorks Therapeutics, Inc. on November 27, 2023.
99.2	Company Presentation dated November 28, 2023.
104	Cover Page Interactive Data File (embedded with 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.

Date: November 28, 2023

SpringWorks Therapeutics, Inc.

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

SpringWorks Therapeutics Announces FDA Approval of OGSIVEO™ (nirogacestat) as the First and Only Treatment for Adults with Desmoid Tumors

– Approval based on positive data from Phase 3 DeFi trial, in which OGSIVEO significantly improved progression-free survival and objective response rate, with rapid and sustained improvements in pain, physical functioning and overall quality of life –

– SpringWorks to host conference call tomorrow at 8:00 a.m. ET –

STAMFORD, Conn., November 27, 2023 – SpringWorks Therapeutics, Inc. (Nasdaq: SWTX), a commercial-stage biopharmaceutical company focused on severe rare diseases and cancer, announced today that the U.S. Food and Drug Administration (FDA) has approved OGSIVEO™ (nirogacestat), an oral gamma secretase inhibitor, for the treatment of adult patients with progressing desmoid tumors who require systemic treatment.[1] The FDA previously granted breakthrough therapy, fast track and orphan drug designations to nirogacestat for the treatment of desmoid tumors.

“Our team is honored to deliver the first FDA-approved therapy for patients with desmoid tumors. This community has been waiting for an effective treatment that not only shrinks their tumors but also significantly improves pain, which is the most debilitating symptom reported by people living with desmoid tumors,” said Saqib Islam, Chief Executive Officer of SpringWorks. "We are pleased with the broad label, which includes all progressing adult patients and specifically references improvement in pain, and believe OGSIVEO has the potential to become the new standard of care for people living with these devastating tumors. This is a watershed moment for the desmoid tumor community and we would like to extend our gratitude to the patients, families, investigators, and advocacy groups involved in the journey to making OGSIVEO available in the U.S.”

Desmoid tumors are locally aggressive and invasive soft-tissue tumors that can lead to substantial morbidity.[2,3] In addition, when vital structures are impacted, desmoid tumors can be life-threatening.[3] Although they do not metastasize, desmoid tumors are often refractory to existing off-label systemic therapies and associated with recurrence rates of up to 77% following surgical resection.[4-6] Desmoid tumor experts and treatment guidelines now recommend systemic therapies as first-line intervention instead of surgery for most tumor locations requiring treatment.[6]

“Desmoid tumors can have a significant impact on people’s lives and are difficult to manage due to their invasive nature and high rates of recurrence. OGSIVEO is a highly innovative therapy with efficacy data demonstrating both meaningful antitumor activity and a significant improvement in desmoid tumor symptoms,” said Mrinal M. Gounder, M.D., sarcoma medical oncologist at Memorial Sloan Kettering Cancer Center (MSK) in New York City and an investigator in the Phase 3 DeFi trial. “As a treating physician, it was encouraging to see in the DeFi trial that OGSIVEO achieved statistically significant and clinically meaningful improvements across the primary and all key secondary endpoints, while also having a manageable safety profile. This approval represents an important therapeutic advance for patients.”

The FDA approval of OGSIVEO is based on the results from the Phase 3 DeFi trial, which were published in the March 9, 2023 edition of the *New England Journal of Medicine*.[7] OGSIVEO met the primary endpoint of improving progression-free survival (PFS), demonstrating a statistically significant improvement 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). Median PFS was not reached in the OGSIVEO arm and was 15.1 months in the placebo arm. Confirmed objective response rate (ORR) based on RECIST v1.1 was 41% with OGSIVEO versus 8% with placebo (p<0.001); the complete response rate was 7% in the OGSIVEO arm and 0% in the placebo arm. The median time to first response was 5.6 months with OGSIVEO and 11.1 months with placebo.[7] PFS and ORR improvements were in favor of OGSIVEO regardless of baseline characteristics including sex, tumor location, tumor focality, treatment status, previous treatments, mutational status, and history of familial adenomatous polyposis.[7,8] OGSIVEO also demonstrated early and sustained improvements in patient-reported outcomes (PROs), including pain (p<0.001), desmoid tumor-specific symptoms (p<0.001), physical/role functioning (p<0.001), and overall health-related quality of life (p≤0.01).[7]

OGSIVEO exhibited a manageable safety and tolerability profile. The most common adverse events (≥15%) reported in patients receiving OGSIVEO were diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respiratory tract infection, and dyspnea. Please see Important Safety Information below, including Warnings & Precautions relating to diarrhea, ovarian toxicity, hepatotoxicity, non-melanoma skin cancers, electrolyte abnormalities, and embryo-fetal toxicity.[1]

“Today is an extraordinary day for the desmoid tumor community. This approval is the culmination of a collaborative effort between the patient community, academia and the biopharmaceutical industry, who worked together with tenacity and persistence to advance promising science,” said Jeanne Whiting, Executive Director Emeritus and Co-Founder of the Desmoid Tumor Research Foundation. “Our hope is that patients and their families will benefit from greater awareness of desmoid tumors, faster diagnoses, and better outcomes now that there is an approved and effective treatment.”

SpringWorks is dedicated to helping patients with desmoid tumors access OGSIVEO and to providing support throughout their treatment journey. As part of this commitment, the Company is introducing SpringWorks CareConnections™, a comprehensive patient support program that offers personalized services to eligible OGSIVEO patients, including insurance coverage information and access support, financial assistance and personalized educational and emotional support. Physicians and patients can contact 1-844-CARES-55 (1-844-227-3755) or visit www.springworkstxcares.com for more information.

OGSIVEO will be available to order through a specialty pharmacy and specialty distributor network in the United States within five to ten business days. SpringWorks expects to file a Marketing Authorisation Application for OGSIVEO in desmoid tumors with the European Medicines Agency in the first half of 2024.

Conference Call and Webcast Information

SpringWorks will host a conference call and webcast to discuss the FDA approval of OGSIVEO on Tuesday, November 28, at 8:00 a.m. ET. To join the live webcast and view the corresponding slides, please click here. To access the live call by phone, please pre-register for the call here. Once registration is complete, participants will be provided with a dial-in number and conference code to access the call. A replay of the webcast will be available for a limited time following the event on the Investors and Media section of the Company's website at https://ir.springworkstx.com.

About OGSIVEO™ (nirogacestat)

OGSIVEO™ (nirogacestat) is an oral, selective, small molecule gamma secretase inhibitor approved in the United States for the treatment of adult patients with progressing desmoid tumors who require systemic treatment.

OGSIVEO is not approved for the treatment of any other indication in the United States, or for any indication in any other jurisdiction by any other health authority.

SpringWorks is also evaluating nirogacestat as a potential treatment for patients with ovarian granulosa cell tumors and for patients with multiple myeloma as part of several B-cell maturation agent (BCMA) combination therapy regimens in collaboration with leaders in industry and academia.

IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

- **Diarrhea:** Diarrhea occurred in 84% of patients treated with OGSIVEO. Grade 3 events occurred in 16% of patients. Monitor patients and manage using antidiarrheal medications. Modify dose as recommended.
- **Ovarian Toxicity:** Female reproductive function and fertility may be impaired in patients treated with OGSIVEO. Impact on fertility may depend on factors like duration of therapy and state of gonadal function at time of treatment. Long-term effects on fertility have not been established. Advise patients on the potential risks for ovarian toxicity before initiating treatment. Monitor patients for changes in menstrual cycle regularity or the development of symptoms of estrogen deficiency, including hot flashes, night sweats, and vaginal dryness.
- **Hepatotoxicity:** ALT or AST elevations occurred in 30% and 33% of patients, respectively. Grade 3 ALT or AST elevations (>5 × ULN) occurred in 6% and 2.9% of patients. Monitor liver function tests regularly and modify dose as recommended.
- **Non-Melanoma Skin Cancers:** New cutaneous squamous cell carcinoma and basal cell carcinoma occurred in 2.9% and 1.4% of patients, respectively. Perform dermatologic evaluations prior to initiation of OGSIVEO and routinely during treatment.

- **Electrolyte Abnormalities:** Decreased phosphate (65%) and potassium (22%) occurred in OGSIVEO-treated patients. Phosphate <2 mg/dL occurred in 20% of patients. Grade 3 decreased potassium occurred in 1.4% of patients. Monitor phosphate and potassium levels regularly and supplement as necessary. Modify dose as recommended.
- **Embryo-Fetal Toxicity:** Oral administration of nirogacestat to pregnant rats during the period of organogenesis resulted in embryo-fetal toxicity at maternal exposures below human exposure at the recommended dose of 150 mg twice daily. Advise pregnant women of the potential risk to a fetus. Advise females and males of reproductive potential to use effective contraception during treatment with OGSIVEO and for 1 week after the last dose.

ADVERSE REACTIONS

- The most common (≥15%) adverse reactions were diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respiratory tract infection, and dyspnea.
- Serious adverse reactions occurring in ≥2% of patients were ovarian toxicity (4%).
- The most common laboratory abnormalities (≥15%) were decreased phosphate, increased urine glucose, increased urine protein, increased AST, increased ALT, and decreased potassium.

DRUG INTERACTIONS

- **CYP3A Inhibitors and Inducers:** Avoid concomitant use with strong or moderate CYP3A inhibitors (including grapefruit products, Seville oranges, and starfruit) and strong or moderate CYP3A inducers.
- **Gastric Acid Reducing Agents:** Avoid concomitant use with proton pump inhibitors and H2 blockers. If concomitant use cannot be avoided, OGSIVEO can be staggered with antacids (e.g., administer OGSIVEO 2 hours before or 2 hours after antacid use).
- Consult the full Prescribing Information prior to and during treatment for important drug interactions.

To report suspected adverse reactions, contact SpringWorks Therapeutics at 1-888-400-SWTX (1-888-400-7989) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information for OGSIVEO for more information.

About Desmoid Tumors

Desmoid tumors (sometimes referred to as aggressive fibromatosis, or desmoid fibromatosis) are rare, aggressive, locally invasive tumors of the soft tissues that can be serious, debilitating, and, in rare cases when vital structures are impacted, life-threatening.[2,3]

Desmoid tumors are most commonly diagnosed in patients between the ages of 20 and 44 years, with a two-to-three times higher prevalence in females.[4,9] It is estimated that there are 1,000-1,650 new cases diagnosed per year in the United States. [9-11]

Although they do not metastasize, desmoid tumors are associated with recurrence rates of up to 77% after surgical resection.[4-6] Desmoid tumor experts and treatment guidelines now recommend systemic therapies as first-line intervention instead of surgery for most tumor locations requiring treatment.[6]

About SpringWorks Therapeutics

SpringWorks is a commercial-stage biopharmaceutical company applying a precision medicine approach to developing and delivering life-changing medicines for people with severe rare diseases and cancer.

Founded in 2017, SpringWorks has a diversified targeted oncology pipeline spanning solid tumors and hematological cancers, including clinical trials in rare tumor types and highly prevalent, genetically defined cancers. OGSIVEO™, approved in the United States for the treatment of adult patients with progressing desmoid tumors who require systemic treatment, is SpringWorks' first FDA-approved therapy. SpringWorks' strategic approach and operational excellence in clinical development have enabled it to rapidly advance its lead product candidates into late-stage trials and enter into multiple collaborations with innovators in industry and academia to unlock the full potential for its portfolio and create more solutions for patients with cancer.

For more information, visit www.springworkstx.com and follow @SpringWorksTx on X (formerly Twitter), LinkedIn, and YouTube.

SpringWorks Forward-Looking Statements

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Contacts

Kim Diamond
Vice President, Communications and Investor Relations
Phone: 203-561-1646
Email: kdiamond@springworkstx.com

Samantha Hilson Sandler
Senior Director, Investor Relations
Phone: 203-461-5501
Email: samantha.sandler@springworkstx.com

References

[1] OGSIVEO. Prescribing Information. SpringWorks Therapeutics, Inc.

[2] Sbaraglia M, Bellan E, Dei Tos AP. The 2020 WHO Classification of Soft Tissue Tumours: news and perspectives. *Pathologica*. 2021;113(2):70-84. doi:10.32074/1591-951X-213.

[3] Penel N, Chibon F, Salas S. Adult desmoid tumors: biology, management and ongoing trials. *Curr Opin Oncol*. 2017;29(4):268-274. doi:10.1097/CCO.0000000000000374.

[4] Skubitz KM. Biology and treatment of aggressive fibromatosis or desmoid tumor. *Mayo Clin Proc*. 2017;92(6):947-964. doi:10.1016/j.mayocp.2017.02.012.

[5] Easter DW, Halasz NA. Recent trends in the management of desmoid tumors. Summary of 19 cases and review of the literature. *Ann Surg*. 1989;210(6):765-769. doi:10.1097/00000658-198912000-00012.

[6] Gronchi A, Kasper B, et al. Desmoid Tumor Working Group. The management of desmoid tumours: a joint global consensus-based guideline approach for adult and paediatric patients. *Eur J Cancer*. 2020;127:96-107. doi:10.1016/j.ejca.2019.11.013.

[7] Gounder M, Ratan R, Alcindor T, et al. Nirogacestat, a Gamma-Secretase Inhibitor for Desmoid Tumors. *N Engl J Med*. 2023;388:898-912. doi:10.1056/NEJMoa2210140.

[8] Data on file. SpringWorks Therapeutics, Inc.

[9] van Broekhoven DLM, Grünhagen DJ, den Bakker MA, van Dalen T, Verhoef C. Time trends in the incidence and treatment of extra-abdominal and abdominal aggressive fibromatosis: a population-based study. *Ann Surg Oncol*. 2015;22(9):2817-2823. doi:10.1245/s10434-015-4632-y.

[10] Orphanet Report Series: Rare Diseases collection. Prevalence and incidence of rare diseases: bibliographic data. Number 1, January 2022. Accessed November 24, 2023. https://www.orpha.net/orphacom/cahiers/docs/GB/Prevalence_of_rare_diseases_by_alphabetical_list.pdf.

[11] U.S. Department of Commerce. News Blog. U.S. population estimated at 332,403,650 on Jan. 1, 2022. Accessed November 24, 2023. https://www.commerce.gov/news/blog/2022/01/us-population-estimated-332403650-jan-1-2022#:~:


Ogsiveo
(nirogacestat)
50 mg tablets
FDA Approval Call
November 28, 2023
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Forward-Looking Statements

Note: Unless otherwise indicated, the information presented herein is as of November 28, 2023.

This presentation may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, relating to our business, opera conditions, including but not limited to current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, our development and comme preclinical and clinical results, the market potential of OGSIVEO for adult patients with desmoid tumors, the potential for a Marketing Authorisation Application for nirogacestat with Agency, the potential for the results of the Phase 2b ReNeu clinical trial to support an NDA submission for mirdametinib, the potential for mirdametinib to become an important new NF1-PN, our plans for seeking regulatory approval for and making mirdametinib available for NF1-PN patients, if approved, expectations regarding the timing and initial data from tl nirogacestat in patients with recurrent ovarian granulosa cell tumors, expectations regarding the timing and results of topline data from the Phase 2b ReNeu clinical trial, our plans Drug Application for SW-682 in 2023, our plans to report additional clinical data of nirogacestat in combination with BCMA-directed therapies and initiate additional planned Phase expectations regarding the potential for the Phase 1b dose expansion phase of brimarafenib, expectations about whether our patents for our lead assets will adequately protect Spr competition, as well as relating to other future conditions. Words such as, but not limited to, "look forward to," "believe," "expect," "anticipate," "estimate," "intend," "plan," "would," "s similar expressions or words, identify forward-looking statements. New risks and uncertainties may emerge from time to time, and it is not possible to predict all risks and uncertain statements in this presentation are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cau differ materially from those expressed or implied by any forward-looking statements contained in this presentation, including, without limitation, risks relating to: (i) the success of ou with respect to OGSIVEO, (ii) our limited experience as a commercial company, (iii) our ability to obtain or maintain adequate coverage and reimbursement for OGSIVEO, (iv) the s product development activities, including the initiation and completion of SpringWorks' clinical trials, (v) our expectations regarding the potential clinical benefit of OGSIVEO for pati (vi) the potential for OGSIVEO to become the new standard of care for patients with desmoid tumors, (vii) our expectations regarding when OGSIVEO will be available, (viii) estima adult patients who are diagnosed with desmoid tumors annually per year in the U.S. and the potential market for OGSIVEO, (ix) the fact that topline or interim data from clinical stu the final or more detailed results of such study or the results of other ongoing or future studies, (x) the success and timing of our collaboration partners' ongoing and planned clinica planned regulatory submissions and interactions, including the timing and outcome of decisions made by the U.S. Food and Drug Administration (FDA), European Medicines Agen regulatory authorities, investigational review boards at clinical trial sites and publication review bodies, (xii) whether FDA, EMA, or other regulatory authorities will require additional studies, or may fail or refuse to approve or may delay approval of our product candidates, including nirogacestat and mirdametinib, (xiii) our ability to obtain regulatory approval of a or maintain regulatory approvals granted for our products, (xiv) our plans to research, discover and develop additional product candidates, (xv) our ability to enter into collaboration product candidates and our ability to realize the benefits expected from such collaborations, (xvi) our ability to maintain adequate patent protection and successfully enforce patent (xvii) the adequacy of our cash position to fund our operations through any time period indicated herein, (xviii) our ability to establish manufacturing capabilities, and our and our co to manufacture our product candidates and scale production, and (xix) our ability to meet any specific milestones set forth herein.

Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, futu circumstances or otherwise. Although we believe the expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such expectations w Accordingly, readers are cautioned not to place undue reliance on these forward-looking statements.

For further information regarding the risks, uncertainties and other factors that may cause differences between SpringWorks' expectations and actual results, you should review the our filings with the Securities and Exchange Commission.

Certain information contained in this presentation relates to or is based on studies, publications, surveys and other data obtained from third-party sources and our own internal esti SpringWorks believes these third-party sources to be reliable as of the date of this presentation, we have not independently verified, and make no representation as to the adequac completeness of, any information obtained from third-party sources. In addition, all of the market data included in this presentation involves a number of assumptions and limitations guarantee as to the accuracy or reliability of such assumptions. Finally, while we believe our own internal research is reliable, such research has not been verified by any independ

Today's Speakers and Agenda

Sections	Presenter
Opening Remarks	**Saqib Islam** *Chief Executive Officer*
U.S. Prescribing Information	**Jim Cassidy, MD, PhD** *Chief Medical Officer*
U.S. Launch Plans for OGSIVEO	**Bhavesh Ashar** *Chief Commercial Officer*
Closing Remarks	**Saqib Islam** *Chief Executive Officer*
Q&A	**All**

Opening Remarks

Saqib Islam

Chief Executive Officer

First and Only FDA Approv
Therapy for Adult Patients
Desmoid Tumors

Desmoid Tumor Patients Have Been Waiting for a Safe and Effective Therapy

Aggressive, invasive and highly debilitating soft-tissue tumors

Can cause severe and chronic pain, loss of physical functioning and disfigurement

No prior FDA-approved therapies

Off-label systemic treatments are often poorly tolerated with limited efficacy

High rates of post-surgical recurrence

> My desmoid tumor wrapped around my nerves, veins and artery b
> I've had **ten surgeries total**, six to remove the tumor and four rela
> complications, and **it keeps growing back**.
>
> – DeAnn, desmoid tumor patient

OGSIVEO Can Address the Needs of Desmoid Tumor Patients at All Stages of Trea

U.S. Patient Population

~1,000-1,650
new patients diagnosed annually

Incidence of 3 – 5 per million per year[1-3] with over 90% of patients receiving active intervention over the course of their disease

~5,500-7,000
patients actively managed annually

Includes patients under continuous management since first diagnosis and those with tumor recurrence

30,000
total diagn
prevalent pa

Meaningful proportion o
prevalent population cou
with a new treatm

We believe OGSIVEO has the potential to become a practice-changing therapy for the broad spectrum of adult desmoid tumor patients

Sources: SWTX Primary Research; (1) Van Broekhoven et al., Annals of Surgical Oncology, 2015; (2) Reitamo et al., American Journal of Clinical Pathology, 1982; (3) Anneberg et al., Cancer Epidemiology, 2022.

Delivering the First FDA-Approved Therapy for Patients With Desmoid Tumors

Ogsiveo™
(nirogacestat)
50 mg tablets

- *Broad label that enables patients at their treatment journey to be eligibl*
- *Significantly reduces disease progr tumor size while addressing pain a debilitating symptoms of desmoid t*
- *Generally manageable tolerability w support extended treatment duratio*
- *Potential to change the treatment p become the new standard of care*

U.S. Prescribing Information

Jim Cassidy, MD, PhD

Chief Medical Officer

OGSIVEO U.S. Prescribing Information Overview

INDICATION

OGSIVEO is a gamma secretase inhibitor indicated fo
with progressing desmoid tumors who require system

RECOMMENDED DOSE

150 mg administered orally twice daily until disease p
unacceptable toxicity; OGSIVEO may be taken with o

FIRST AND ONLY FDA-APPROVED THERAP
DESMOID TUMOR PATIENTS

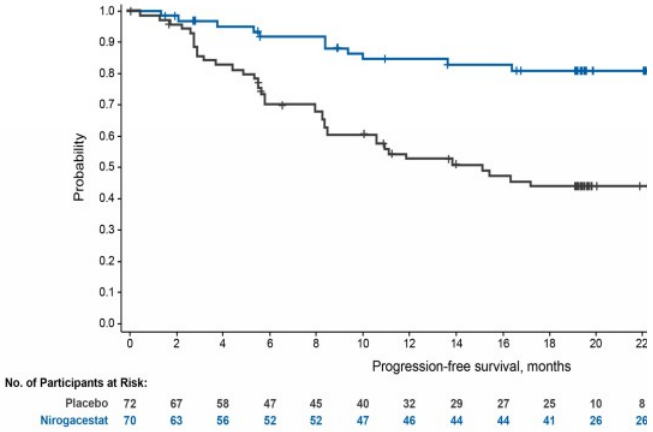
Full prescribing information is available at www.OGSIVEO.com.

Efficacy Summary From OGSIVEO Prescribing Information

Efficacy Results of DeFi

	OGSIVEO (n=70)	Placebo (n=72)
Progression-Free Survival		
Number (%) of patients with event	12 (17)	37 (51)
Radiographic progression[a]	11 (16)	30 (42)
Clinical progression[a]	1 (1)	6 (8)
Death	0	1 (1)
Median (months) (95% CI)[b]	NR (NR, NR)	15.1 (8.4, NR)
Hazard ratio (95% CI)	0.29 (0.15, 0.55)	
p-value[c]	<0.001	
Objective Response Rate[a]		
ORR, n (%)	29 (41)	6 (8)
95% CI[d]	(29.8, 53.8)	(3.1, 17.3)
CR	5 (7)	0
PR	24 (34)	6 (8)
p-value[e]	<0.001	

Kaplan-Meier Curve of Progression-Free Surv



"Progression-free survival results were supported by change from baseline ir patient-reported worst pain favoring the OGSIVEO arm"

- OGSIVEO U.S. Prescribing Informat

Full prescribing information is available at www.OGSIVEO.com.
Note: CI: confidence interval; ORR: objective response rate; CR: complete response; PR: partial response; NR: not reached.

a) Assessed by blinded independent central review.
b) Obtained using Kaplan-Meier Methodology.
c) p-value was from a one-sided stratified log-rank test with placebo as reference.
d) Obtained using exact method based on binomial distribution.
e) p-value was from a two-sided Cochran-Mantel-Haenszel test.

Safety Summary From OGSIVEO Prescribing Information

Warnings and Precautions

- Diarrhea, ovarian toxicity, hepatotoxicity, non-melanoma skin cancers, electrolyte abnormalities, embryo-fetal toxicity

Most Common Adverse Reactions(1)

- Diarrhea, ovarian toxicity, rash, nausea, fatigue, stomatitis, headache, abdominal pain, cough, alopecia, upper respir infection, and dyspnea

No Boxed Warnings

No REMS Program

No Contraindications

Full prescribing information is available at www.OGSIVEO.com.

(1) Reported in over 15% of patients.

U.S. Launch Plans for OGSIVEO

Bhavesh Ashar

Chief Commercial Officer

Foundation in Place for OGSIVEO to Become the Standard of Care

Ogsiveo™ (nirogacestat) 50 mg tablets

Motivated patient population

Preference for medication over surgery

Dissatisfaction with current treatments

High awareness, anticipation, and willingness to self-advocate

Favorable shifts in market dynamics

Guidelines recommend systemic therapy as first-line intervention for most tumor locations

Educated, engaged, and activated KOLs and patients

New desmoid tumor-specific ICD-10 codes in effect

First and only approved therapy

First and only FDA-approved therapy for desmoid tumors

Durable tumor shrinkage and improved quality of life

Tolerable profile with data supporting extended duration of treatment

Physician e and familia

SARC Center p DeFi trial

Stated expecta first year of app

Expressed willi and recontact p

Source: SWTX Primary Research, 2Q22; aided awareness.

Strategic Imperatives For OGSIVEO Launch

ADOPT
Position OGSIVEO as first or next systemic treatment and standard of c

SUPPORT
Provide comprehensive patient support to help maximize patient acces

LEAD
Reinforce commitment to desmoid tumor community and improve patie

EXPAND
Educate physicians and patients to broaden the role of systemic therap

Targeted Launch Strategy With a Highly Experienced Field Team

5,500 – 7,000 desmoid tumor patients actively managed each year

35 Territory Business Managers supported by:

- Regional Business Managers
- Thought Leader Liaisons
- Field Access Managers
- Nurse Advocates
- National Account Directors
- Medical Science Liaisons

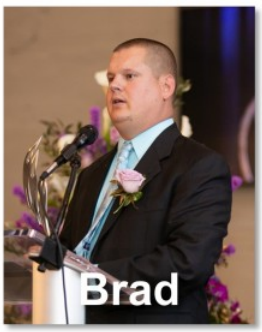
- Drive rapid adoption among **~1,500** pre SARC / NCCN and other higher-volum
- **New desmoid ICD-10 codes** further e rapidly reach treating healthcare provic
- Continue disease and guideline educat **broader belief in systemic treatment**
- Supplement field efforts with **peer-to-p boost awareness** among healthcare p

Position OGSIVEO as first or next systemic treatment and establish the standard o

Sources: SWTX Primary Research; (1) Van Broekhoven et al., Annals of Surgical Oncology, 2015; (2) Reitamo et al., American Journal of Clinical Pathology, 1982; (3) Anneberg et al., Cancer Epidemiology, 2022.

A Compelling Value Proposition for Stakeholders

- Transformative Clinical Benefit to Patients
- First and Only FDA-Approved Therapy
- Aggressive and Debilitating Rare Disease
- Ongoing Commitment to the Desmoid Tumor Community



Our objective is that every ap
patient who can benefit from
will have access to i

Robust and Tailored Patient Support and Access Program

SpringWorks CareConnections™

Coverage and Access Support

Resources to facilitate reimbursement and timely and appropriate access to OGSIVEO

Financial Assistance

Financial support for eligible patients, including co-pay program and Patient Assistance Program

Personalized Sup

Dedicated nurse advoc support patients through treatment journe

My tumor grew while on oral chemo
was switched to IV chemo, which sh
tumor, but I had such bad side-effec
had to take a break. My latest MRI s
my tumor is stable, but it is pushing
tailbone and causing excruciating pa
taking heavy duty pain medication th
providing much relief. At this point m
and I are hoping that my disease wil
under control until a new treatment c
becomes available.

– Stephanie, desmoid tumor patient

Closing Remarks

Saqib Islam

Chief Executive Officer

Rapidly Transitioning Into a Commercial-Stage Company With Multiple Potential Va

Successfully launch OGSIVEO for adults with desmoid tumors in the U.S.

U.S. approval of OGSIVEO represents the first and only approved treatment for desmoid tumors, with data supporting a potentially practice-changing therapeutic profile for patients and meaningful commercial opportunity

Achieve second product approval by 2025

Topline readout of mirdametinib in NF1-PN demonstrated potentially best-in-class product profile across full age spectrum and supports near-term approval path

Advance emerging p of differentiated targ oncology assets

Substantial upside oppo across wholly-owned an programs with the poten value-creating and thesi data

PATIENTS HAV
WAITING FOR ANS
LET'S G

Thank You

Sp

Q&A

Saqib Islam
Chief Executive Officer

Badreddin Edris, PhD
Chief Operating Officer

Jim Cassidy, MD, PhD
Chief Medical Officer

Bhavesh Ashar
Chief Commercial Officer


SpringWorks
THERAPEUTICS