

**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): February 16, 2021 (February 12, 2021)**

**G1 THERAPEUTICS, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**001-38096**  
(Commission  
File Number)

**26-3648180**  
(IRS Employer  
Identification No.)

**700 Park Offices Drive  
Suite 200  
Research Triangle Park, NC**  
(Address of principal executive offices)

**27709**  
(zip code)

**Registrant's telephone number, including area code: (919) 213-9835**

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	Name of each exchange on which registered
Common stock, \$0.0001 par value	GTHX	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 February 12, 2021, G1 Therapeutics, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration approved the Company’s new drug application for COSELA™ (trilaciclib) for injection to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC). A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Also attached hereto as Exhibit 99.2 is a presentation (the “Presentation”), which is incorporated herein by reference. The Company will use the Presentation in various meetings with securities analysts, investors, and others beginning February 16, 2021.

Pursuant to General Instruction B.2 of Current Report on Form 8-K, the information contained in, or incorporated into, Item 7.01, including the press release and Presentation, attached hereto as Exhibit 99.1 and Exhibit 99.2, are being furnished and shall not be deemed “filed” for the 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 they be deemed incorporated by reference into any registration statement or other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference to such filing.

**Item 9.01 Financial Statements and Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	<a href="#">Press Release dated February 12, 2021</a>
99.2	<a href="#">Presentation dated February 16, 2021</a>
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 thereunto duly authorized.

**G1 THERAPEUTICS, INC.**

By: /s/ James Stillman Hanson  
James Stillman Hanson  
General Counsel

Date: February 16, 2021



**FDA Approves G1 Therapeutics' COSELATM (trilaciclib): The First and Only Myeloprotection Therapy to Decrease the Incidence of Chemotherapy-Induced Myelosuppression**

*- COSELA is the only FDA-approved therapy that helps proactively deliver multilineage myeloprotection to patients with **extensive-stage small cell lung cancer** being treated with chemotherapy -*

*- Myeloprotective efficacy of COSELA resulted in reductions in the incidence and duration of severe neutropenia, and impacted anemia and the need for rescue interventions such as growth factors and red blood cell transfusions -*

*- G1 will host conference call Tuesday, February 16, 2021 at 8:00 a.m. ET -*

**RESEARCH TRIANGLE PARK, N.C., February 12, 2021** – G1 Therapeutics, Inc. (Nasdaq: GTHX), a commercial-stage oncology company, today announced that the U.S. Food and Drug Administration (FDA) has approved COSELATM (trilaciclib) for injection to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC). It is the first and only therapy designed to help protect bone marrow (myeloprotection) when administered prior to treatment with chemotherapy. COSELA is expected to be commercially available through G1's specialty distributor partner network in early March.

"The approval of trilaciclib (COSELA) is an important advance in the treatment of patients with extensive-stage small cell lung cancer receiving chemotherapy," said Dr. Jeffrey Crawford, Geller Professor for Research in Cancer in the Department of Medicine and Duke Cancer Institute. "The most serious and life-threatening side effect of chemotherapy is myelosuppression, or damage to the bone marrow, resulting in reduced white blood cells, red blood cells and platelets. Chemotherapy-induced myelosuppression may lead to increased risks of infection, severe anemia, and/or bleeding. These complications impact patients' quality of life and may also result in chemotherapy dose reductions and delays. To date, approaches have included the use of growth factor agents to accelerate blood cell recovery after the bone marrow injury has occurred, along with antibiotics and transfusions as needed. By contrast, trilaciclib provides the first proactive approach to myelosuppression through a unique mechanism of action that helps protect the bone marrow from damage by chemotherapy. In clinical trials, the addition of trilaciclib to extensive-stage small cell lung cancer chemotherapy treatment regimens reduced myelosuppression and improved clinical outcomes. The good news is that these benefits of trilaciclib will now be available for our patients in clinical practice."

Chemotherapy is an effective and important weapon against cancer. However, chemotherapy does not differentiate between healthy cells and cancer cells. It kills both, including important hematopoietic stem and progenitor cells (HSPCs) in the bone marrow that produce white blood cells (immune cells that help fight infection), red blood cells (cells that carry oxygen from the lungs to the tissues), and platelets (cells that prevent bleeding from cancer, surgeries, chronic diseases, and injuries). This chemotherapy-induced bone marrow damage, known as myelosuppression, can lead to increased risk of infection, anemia, thrombocytopenia, and other complications. Myeloprotection is a novel approach of protecting HSPCs



in the bone marrow from chemotherapy-induced damage. This approach can help reduce some chemotherapy-related toxicity, making chemotherapy safer and more tolerable, while also reducing the need for reactive rescue interventions.

“Chemotherapy is the most effective and widely used approach to treating people diagnosed with extensive-stage small cell lung cancer; however, standard of care chemotherapy regimens are highly myelosuppressive and can lead to costly hospitalizations and rescue interventions,” said Jack Bailey, Chief Executive Officer at G1 Therapeutics. “COSELA will help change the chemotherapy experience for people who are battling ES-SCLC. G1 is proud to deliver COSELA to patients and their families as the first and only therapy to help protect against chemotherapy-induced myelosuppression.”

COSELA is administered intravenously as a 30-minute infusion within four hours prior to the start of chemotherapy and is the first FDA-approved therapy that helps provide proactive, multilineage protection from chemotherapy-induced myelosuppression. The approval of COSELA is based on data from three randomized, placebo-controlled trials that showed patients receiving COSELA prior to the start of chemotherapy had clinically meaningful and statistically significant reduction in the duration and severity of neutropenia. Data also showed a positive impact on red blood cell transfusions and other myeloprotective measures. The trials evaluated COSELA in combination with carboplatin/etoposide (+/- the immunotherapy atezolizumab) and topotecan chemotherapy regimens. Approximately 90% of all patients with ES-SCLC will receive at least one of these regimens during the course of their treatment.

The majority of adverse reactions reported with COSELA were mild to moderate in severity. The most common adverse reactions (≥10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia. Serious adverse reactions occurred in 30% of patients receiving COSELA. Serious adverse reactions reported in >3% of patients who received COSELA included respiratory failure, hemorrhage, and thrombosis. Grade 3/4 hematological adverse reactions occurring in patients treated with COSELA and placebo included neutropenia (32% and 69%), febrile neutropenia (3% and 9%), anemia (16% and 34%), thrombocytopenia (18% and 33%), and leukopenia (4% and 17%), respectively.

“Quite often, people diagnosed with extensive-stage small cell lung cancer rely on chemotherapy to not only extend their lives, but also to acutely alleviate their symptoms,” said Bonnie J. Addario, lung cancer survivor, co-founder and board chair of the Go2 Foundation for Lung Cancer.

“Unfortunately, the vast majority will experience chemotherapy-induced side effects, resulting in dose delays and reductions, and increased utilization of healthcare services. G1 shares our organization’s goal to improve the quality of life of those diagnosed with lung cancer and to transform survivorship among people living with this insidious disease. We are thrilled to see new advancements that can help improve the lives of those living with small cell lung cancer.”

Approximately 30,000 small cell lung cancer patients are treated in the United States annually. G1 is committed to helping patients with extensive-stage small cell lung cancer in the U.S. gain access to treatment with COSELA. For more information on access and affordability programs, patients and providers should call the G1toOne support center at 833-G1toONE (833-418-6663) from 8:00 a.m. to 8:00 p.m. Eastern time.



G1 received Breakthrough Therapy Designation from the FDA in 2019 based on positive data in small cell lung cancer patients from three randomized Phase 2 clinical trials. As is common with breakthrough-designated products that receive priority review, G1 will conduct certain post-marketing activities, including in vitro drug-drug interaction and metabolism studies, and a clinical trial to assess impact of trilaciclib on disease progression or survival in patients with ES-SCLC with chemotherapy-induced myelosuppression treated with a platinum/etoposide-containing or topotecan-containing regimen with at least a two year follow up. G1 intends to initiate the post-approval clinical trial in 2022.

#### **Webcast and Conference Call**

The management team will host a webcast and conference call at 8:00 a.m. ET on Tuesday, February 16, 2021 to discuss the FDA approval of COSELA (trilaciclib). The live call may be accessed by dialing 866-763-6020 (domestic) or (210) 874-7713 (international) and entering the conference code: 6195528. A live and archived webcast will be available on the Events & Presentations page of the company's website: [www.g1therapeutics.com](http://www.g1therapeutics.com). The webcast will be archived on the same page for 90 days following the event.

#### **COSELA (trilaciclib) Co-Promotion Agreement with Boehringer Ingelheim**

In June 2020, G1 announced a three-year co-promotion agreement with Boehringer Ingelheim for COSELA in small cell lung cancer in the U.S. and Puerto Rico. G1 will lead marketing, market access and medical engagement initiatives for COSELA. The Boehringer Ingelheim oncology commercial team, well-established in lung cancer, will lead sales force engagement initiatives. G1 will book revenue and retain development and commercialization rights to COSELA and pay Boehringer Ingelheim a promotional fee based on net sales. The three-year agreement does not extend to additional indications that G1 is evaluating for trilaciclib. Press release details of the G1/Boehringer Ingelheim agreement can be found [here](#).

#### **About Small Cell Lung Cancer**

In the United States, approximately 30,000 small cell lung cancer patients are treated annually. SCLC, one of the two main types of lung cancer, accounts for about 10% to 15% of all lung cancers. SCLC is an aggressive disease and tends to grow and spread faster than NSCLC. It is usually asymptomatic; once symptoms do appear, it often indicates that the cancer has spread to other parts of the body. About 70% of people with SCLC will have cancer that has metastasized at the time they are diagnosed. The severity of symptoms usually increases with increased cancer growth and spread. From the time of diagnosis, the general 5-year survival rate for people with SCLC is 6%. The five-year survival rates for limited-stage (the cancer is confined to one side of the chest) SCLC is 12% to 15%, and for extensive stage (cancer has spread to the other lung and beyond), survival rates are less than 2%. Chemotherapy is the most common treatment for ES-SCLC.

#### **COSELA™ (trilaciclib) for Injection**

##### **INDICATION**

COSELA is indicated to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer (ES-SCLC).

**IMPORTANT SAFETY INFORMATION****CONTRAINDICATION**

- COSELA is contraindicated in patients with a history of serious hypersensitivity reactions to trilaciclib.

**WARNINGS AND PRECAUTIONS*****Injection-Site Reactions, Including Phlebitis and Thrombophlebitis***

- COSELA administration can cause injection-site reactions, including phlebitis and thrombophlebitis, which occurred in 56 (21%) of 272 patients receiving COSELA in clinical trials, including Grade 2 (10%) and Grade 3 (0.4%) adverse reactions. Monitor patients for signs and symptoms of injection-site reactions, including infusion-site pain and erythema during infusion. For mild (Grade 1) to moderate (Grade 2) injection-site reactions, flush line/cannula with at least 20 mL of sterile 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP after end of infusion. For severe (Grade 3) or life-threatening (Grade 4) injection-site reactions, stop infusion and permanently discontinue COSELA. Injection-site reactions led to discontinuation of treatment in 3 (1%) of the 272 patients.

***Acute Drug Hypersensitivity Reactions***

- COSELA administration can cause acute drug hypersensitivity reactions, which occurred in 16 (6%) of 272 patients receiving COSELA in clinical trials, including Grade 2 reactions (2%). Monitor patients for signs and symptoms of acute drug hypersensitivity reactions. For moderate (Grade 2) acute drug hypersensitivity reactions, stop infusion and hold COSELA until the adverse reaction recovers to Grade 1. For severe (Grade 3) or life-threatening (Grade 4) acute drug hypersensitivity reactions, stop infusion and permanently discontinue COSELA.

***Interstitial Lung Disease/Pneumonitis***

- Severe, life-threatening, or fatal interstitial lung disease (ILD) and/or pneumonitis can occur in patients treated with cyclin-dependent kinases (CDK)4/6 inhibitors, including COSELA, with which it occurred in 1 (0.4%) of 272 patients receiving COSELA in clinical trials. Monitor patients for pulmonary symptoms of ILD/pneumonitis. For recurrent moderate (Grade 2) ILD/pneumonitis, and severe (Grade 3) or life-threatening (Grade 4) ILD/pneumonitis, permanently discontinue COSELA.

***Embryo-Fetal Toxicity***

- Based on its mechanism of action, COSELA can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should use an effective method of contraception during treatment with COSELA and for at least 3 weeks after the final dose.



#### **ADVERSE REACTIONS**

- Serious adverse reactions occurred in 30% of patients receiving COSELA. Serious adverse reactions reported in >3% of patients who received COSELA included respiratory failure, hemorrhage, and thrombosis.
- Fatal adverse reactions were observed in 5% of patients receiving COSELA. Fatal adverse reactions for patients receiving COSELA included pneumonia (2%), respiratory failure (2%), acute respiratory failure (<1%), hemoptysis (<1%), and cerebrovascular accident (<1%).
- Permanent discontinuation due to an adverse reaction occurred in 9% of patients who received COSELA. Adverse reactions leading to permanent discontinuation of any study treatment for patients receiving COSELA included pneumonia (2%), asthenia (2%), injection-site reaction, thrombocytopenia, cerebrovascular accident, ischemic stroke, infusion-related reaction, respiratory failure, and myositis (<1% each).
- Infusion interruptions due to an adverse reaction occurred in 4.1% of patients who received COSELA.
- The most common adverse reactions (≥10%) were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache, and pneumonia.

#### **DRUG INTERACTIONS**

- COSELA is an inhibitor of OCT2, MATE1, and MATE-2K. Co-administration of COSELA may increase the concentration or net accumulation of OCT2, MATE1, and MATE-2K substrates in the kidney (e.g., dofetilide, dalfampridine, and cisplatin).

To report suspected adverse reactions, contact G1 Therapeutics at [1-800-790-G1TX](tel:1-800-790-G1TX) or FDA at [1-800-FDA-1088](tel:1-800-FDA-1088) or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

#### **Please see full Prescribing Information here**

For more information about COSELA, please call 1-800-790-G1TX (1-800-790-4189)

#### **About G1 Therapeutics**

G1 Therapeutics, Inc. is a commercial-stage biopharmaceutical company focused on the discovery, development and delivery of next generation therapies that improve the lives of those affected by cancer, including the Company's first commercially available product COSELA™ (trilaciclib), a first-in-class therapy approved by the U.S. Food and Drug Administration to help protect against chemotherapy-induced myelosuppression in patients with extensive-stage small cell lung cancer being treated with chemotherapy. Trilaciclib is also being evaluated in other solid tumors, including colorectal, breast and bladder cancers. G1 Therapeutics is based in Research Triangle Park, N.C. For additional information, please visit [www.g1therapeutics.com](http://www.g1therapeutics.com) and follow us on Twitter [@G1Therapeutics](https://twitter.com/G1Therapeutics).

Tecentriq® (atezolizumab) is a registered trademark of Genentech.



#### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as “may,” “will,” “expect,” “plan,” “anticipate,” “estimate,” “intend” and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this press release include, but are not limited to, those relating to the therapeutic potential of COSELA (trilaciclib), and COSELA’s (trilaciclib) possibility to improve patient outcomes, are based on the company’s expectations and assumptions as of the date of this press release. Each of these forward-looking statements involves risks and uncertainties. Factors that may cause the company’s actual results to differ from those expressed or implied in the forward-looking statements in this press release are discussed in the company’s filings with the U.S. Securities and Exchange Commission, including the “Risk Factors” sections contained therein and include, but are not limited to, the company’s ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates; the company’s initial success in ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials; the inherent uncertainties associated with developing new products or technologies and operating as a development-stage company; and market conditions. Except as required by law, the company assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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## Optimizing Chemotherapy, Advancing Survival

February 16, 2021



## Forward-Looking Statements

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Words such as "may," "will," "expect," "plan," "anticipate," "estimate," "intend" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) are intended to identify forward-looking statements. Forward-looking statements in this presentation include, but are not limited to, those relating to the therapeutic potential of COSELA™ (trilaciclib), rintodestrant and lerociclib, COSELA's possibility to improve patient outcomes across multiple indications, rintodestrant's potential to be best-in-class oral SERD, our reliance on partners to develop and commercial licensed products, and the impact of pandemics such as COVID-19 (coronavirus), and are based on the company's expectations and assumptions as of the date of this presentation. Each of these forward-looking statements involves risks and uncertainties. Factors that may cause the company's actual results to differ from those expressed or implied in the forward-looking statements in this presentation are discussed in the company's filings with the U.S. Securities and Exchange Commission, including the "Risk Factors" sections contained therein and include, but are not limited to, the company's ability to complete clinical trials for, obtain approvals for and commercialize any of its product candidates; the company's initial success in ongoing clinical trials may not be indicative of results obtained when these trials are completed or in later stage trials; the inherent uncertainties associated with developing new products or technologies and operating as a development-stage company; and market conditions. Rintodestrant and lerociclib are not approved by the FDA. The safety or effectiveness of rintodestrant and lerociclib have not been established by the FDA. Except as required by law, the company assumes no obligation to update any forward-looking statements contained herein to reflect any change in expectations, even as new information becomes available.

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# Transformed Company; Pivotal 2021

2020

COSELA™ (trilaciclib)

Rintodestrant

Lerociclib

CDK2  
Discovery Platform

EQ 嘉和 GENOR  
OUT-LICENSED

ARC THERAPEUTICS  
OUT-LICENSED

2021

COSELA is a cornerstone therapy:

The first and only therapy to help protect against chemotherapy-induced myelosuppression for ES-SCLC patients receiving certain chemotherapy treatments

Pipeline-in-a-molecule development opportunity

Rintodestrant + palbociclib Phase 2 data expected 2Q

**\$207M cash on hand**  
(as of December 31, 2020)

NOW APPROVED  
**COSELA™**  
trilaciclib for injection  
300 mg

**Streamlined company focused on maximizing  
the development and commercialization of COSELA**

# Chemo to Remain Mainstay Therapy Despite Shortcomings



## Over 1 million cancer patients receive chemo in North America each year

- Cost-efficient and effective treatment option expected to remain backbone of SoC
- Established high water-mark that has proven difficult to exceed head-to-head
- Immunotherapy with chemo has demonstrated the best results in many tumors

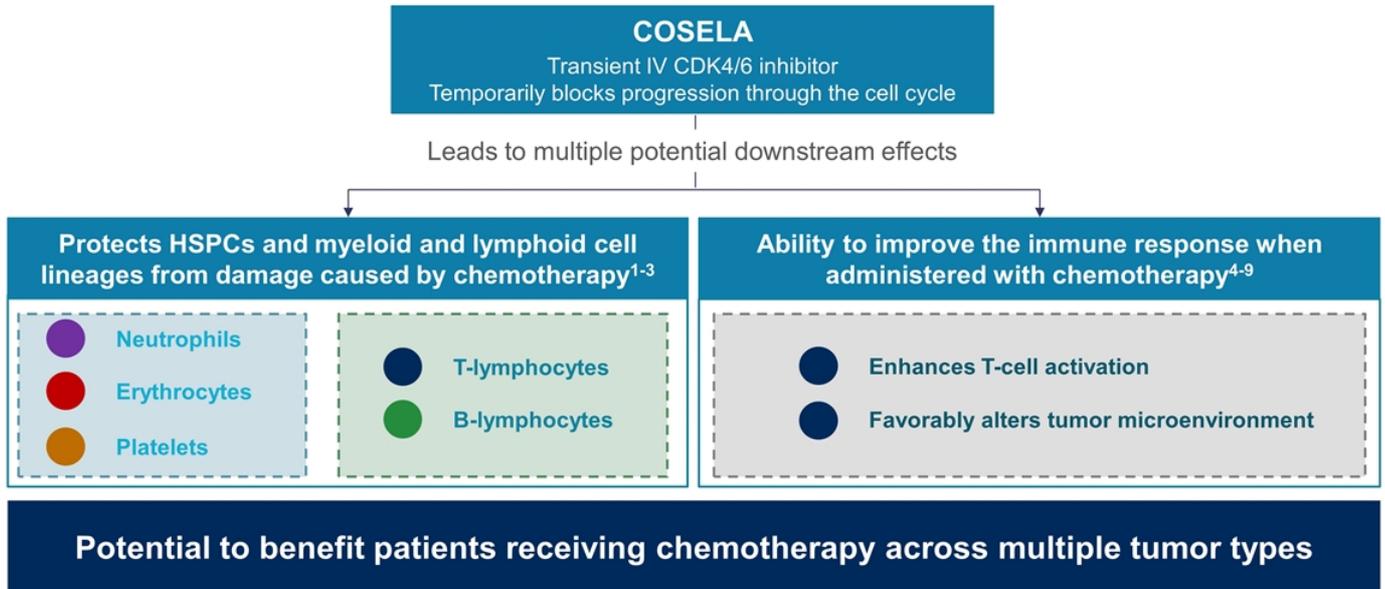
## Two Critical Areas of Unmet Need

**1** Proactively reducing the damaging consequences of chemotherapy

**2** Meaningfully improving overall survival in broad populations

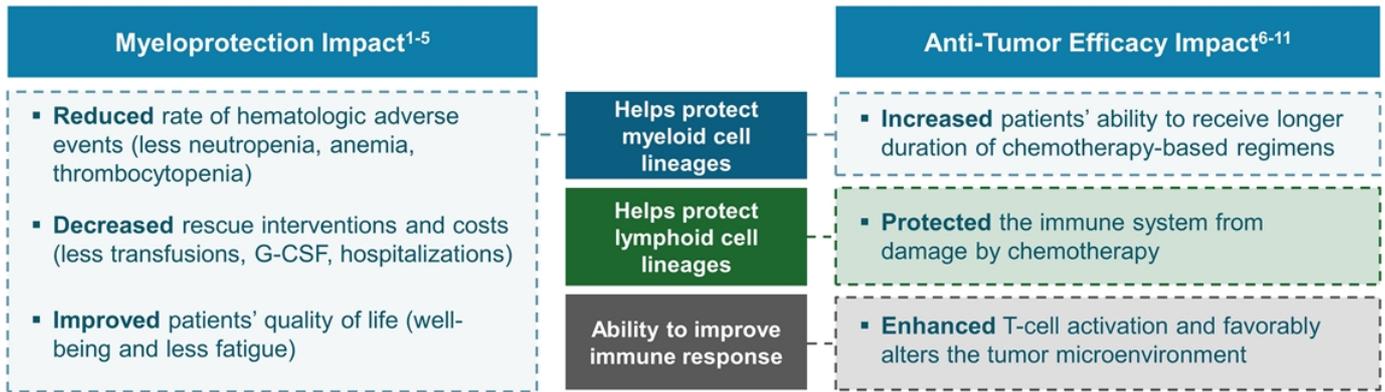
**High unmet need for new therapies that can significantly reduce myelosuppression and meaningfully improve efficacy across patient populations**

# COSELA: Novel Approach to Address Shortcomings of Chemo



1. Weiss J, et al. Ann Oncol. 2019 Oct; 30(10): 1613–1621. 2. He S, et al. Sci Transl Med. 2017;9:eaal3986. 3. Bisi JE, et al. Mol Cancer Ther. 2016;15:783-93. 4. Tan A, et al. Lancet Oncol. 2019 Sep 28. 5. Zhang J, et al. Nature. 2018;553:91-95. 6. Jerby-Arnon L, et al. Cell. 2018;175:984-997. 7. Goel S, et al. Nature. 2017;548:471-475. 8. Deng J, et al. Cancer Discov. 2018;;216-233. 9. O'Shaughnessy et al., 2020 San Antonio Breast Cancer Symposium (SABCS), Poster #PD1-06.

# COSELA Demonstrated Meaningful Benefits Across Studies

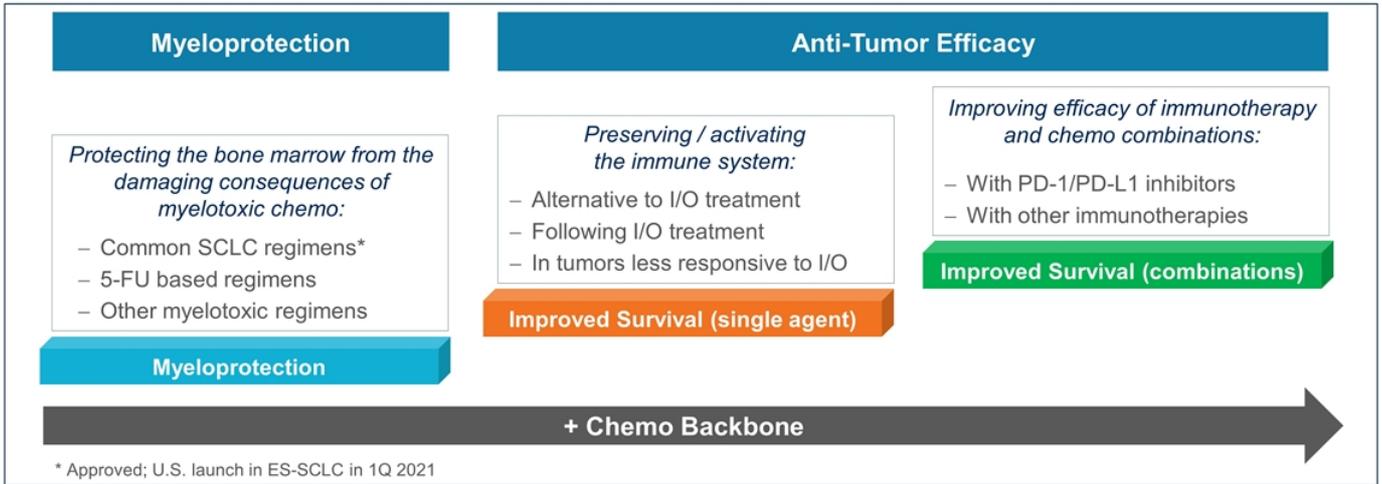


**Approved as myeloprotective therapy in ES-SCLC with certain chemotherapy regimens; increased anti-tumor efficacy being evaluated in additional trials**



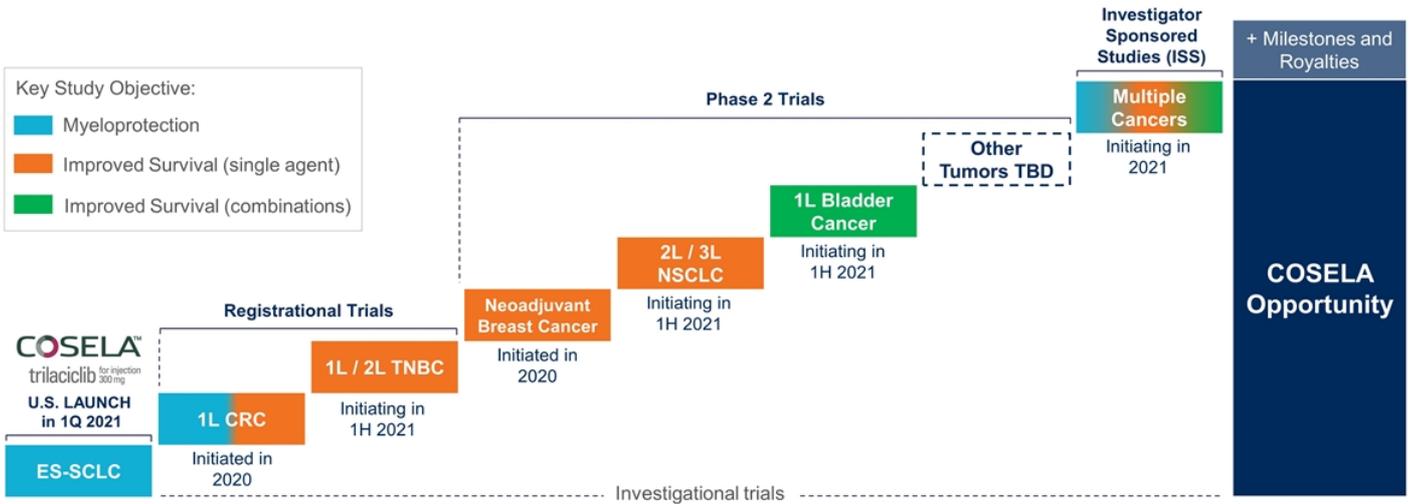
1. Weiss J, et al. Ann Oncol. 2019 Oct; 30(10): 1613–1621. 2. He S, et al. Sci Transl Med. 2017;9:eaal3986. 3. Bisi JE, et al. Mol Cancer Ther. 2016;15:783-93. 4. Weiss et al. MASCC Oral Presentation, Abstract #MASCC9-0845. 5. Tan A, et al. Lancet Oncol. 2019 Sep 28. 6. Ferrarotto et al., 2020 North America Conference on Lung Cancer (NACLC), Abstract # OA03.08. 7. Zhang J, et al. Nature. 2018;553:91-95. 8. Jerby-Arnon L, et al. Cell. 2018;175:984-997. 9. Goel S, et al. Nature. 2017;548:471-475. 10. Deng J, et al. Cancer Discov. 2018;216-233. 11. O'Shaughnessy et al., 2020 San Antonio Breast Cancer Symposium (SABCS), Poster #PD1-06.

# Significant Expansion Opportunities for COSELA



**Optimizing development plan across three core growth platforms will enable COSELA to benefit as many patients as possible**

# Pipeline-in-a-Molecule Opportunity Beyond ES-SCLC Launch



**Aggressively pursuing development in areas of high strategic importance where COSELA is most likely to provide meaningful benefits to patients**



## 2021 Key Objectives

1. Obtain U.S. approval for ES-SCLC and successfully launch COSELA in 1Q
2. Establish COSELA as Standard of Care for ES-SCLC patients in the U.S.
3. Maximize long-term value of COSELA by executing robust development plan
4. Evaluate partnership options for rintodestrant following combination data readout in 2Q
5. Continue managing investor capital efficiently

**Focused on successfully launching COSELA in ES-SCLC and accelerating development into other areas where chemotherapy is used**

# 2021 Key Objectives

- 1. Obtain U.S. approval for ES-SCLC and successfully launch COSELA in 1Q**
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**NOW APPROVED**

**COSELA™**

**trilaciclib** for injection  
300 mg

Approved by U.S. Food and Drug Administration to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer



# COSELA Prescribing Information Highlights<sup>1</sup>

## Study 1: COSELA Prior to Etoposide, Carboplatin, and Atezolizumab

Patients with newly diagnosed ES-SCLC not previously treated with chemotherapy

Endpoint	COSELA 240 mg/m <sup>2</sup> (N=54)	Placebo (N=53)	Adjusted 1-Sided p-value
<b>Primary Endpoint</b>			
DSN <sup>2</sup> in Cycle 1 - days Mean (SD)	0 (1.0)	4 (4.7)	<0.0001
Number (%) of patients with severe neutropenia	1 (1.9%)	26 (49.1%)	<0.0001
<b>Key Secondary Endpoints</b>			
Number of all-cause dose reductions, event rate per cycle	0.021	0.085	0.0195
Number (%) of patients with RBC transfusion on/after 5 weeks	7 (13.0%)	11 (20.8%)	--
Number (%) of patients with G-CSF administration	16 (29.6%)	25 (47.2%)	--

<sup>1</sup>See important safety information and detail on additional studies in the U.S. Package Insert and at COSELA.com

<sup>2</sup>DSN = Duration of Severe Neutropenia



### Pharmacodynamics

Trilaciclib increased the percentage of cells arrested in G1 up to 32 hours post-infusion for all bone marrow progenitor subsets evaluated... this transient G1 arrest of hematopoietic stem cells contributed to the **myeloprotective effect** of trilaciclib.

### Safety (pooled, n=240)

The most common adverse reactions occurring in ≥10% of patients were fatigue, hypocalcemia, hypokalemia, hypophosphatemia, aspartate aminotransferase increased, headache and pneumonia.

Grade 3/4 hematological adverse reactions occurring in patients treated with COSELA and placebo, respectively, included:

- neutropenia (32% and 69%)
- febrile neutropenia (3% and 9%)
- anemia (16% and 34%)
- thrombocytopenia (18% and 33%)
- leukopenia (4% and 17%)

# COSELA Approved: U.S. Launch in 1Q21

## Broad Coverage of ES-SCLC

- Label covers a majority of patients
  - Including those treated with I/O
  - Indicated for broad myelosuppression (vs just neutropenia)
- Multilineage myeloprotection mechanism
- All three studies with key endpoints represented
- 30-minute infusion within 4 hours of chemotherapy; will fit into oncologist practice workflow

## Pre-Launch Activities Complete

- Identified HCP targets
- Profiled key accounts
- Engaged payors
- Educated leading patient advocacy organizations
- Executed strategic pricing strategy

## Product Launch Ongoing

- G1 launch comms plan underway
  - ✓ National accounts team reaching key provider networks
  - ✓ Communicating approval with targeted payer customers
  - ✓ Boehringer Ingelheim field sales team<sup>1</sup> notifying priority accounts, initiating customer interaction
  - ✓ Clinical nurse educators scheduling in-service meetings
  - ✓ MSLS responding to customers
  - ✓ G1-to-One pt. support hub launched

**This important new treatment is available to the majority of patients with ES-SCLC undergoing chemotherapy in the U.S.**

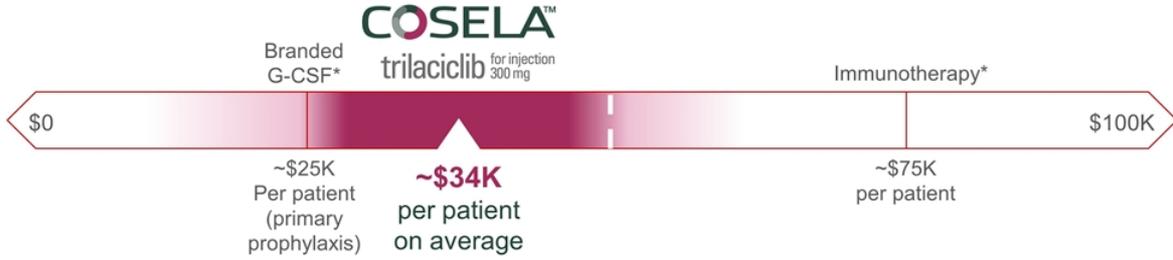


<sup>1</sup>Three-year agreement where Boehringer Ingelheim leads sales force engagement initiatives for COSELA in the U.S. for the initial ES-SCLC indication. The agreement does not extend to additional indications.

# COSELA is Strategically Priced

**WAC per vial = \$1,417**

Based on clinical trial experience, most 1L ES-SCLC patients on average will receive 2 vials per dose, 3 doses per chemotherapy cycle, and 4 chemotherapy cycles (24 vials total)



**G1 analyses suggest COSELA pricepoint will enable access in ES-SCLC; expected to be budget-neutral to savings-positive**



\*G-CSF helps white blood cells recover from chemotherapy; immunotherapies help the immune system fight cancer.  
COSELA is approved to help protect against chemotherapy-induced myelosuppression for ES-SCLC patients receiving certain chemotherapy treatments.

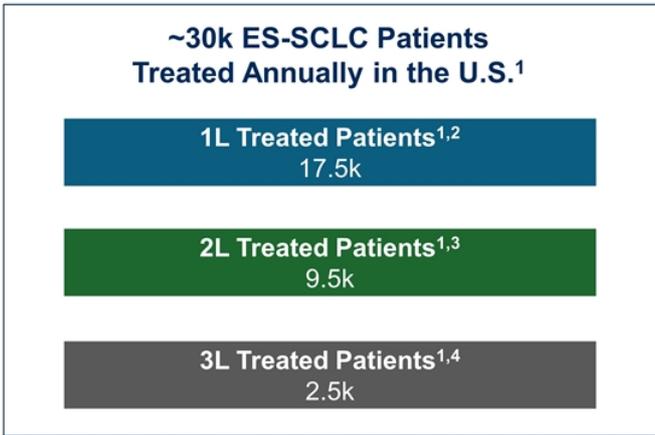
## G1 to One: Single Source for Access & Affordability

### One-stop hub to ensure excellence in COSELA patient support



- Benefits investigation
- Prior authorization and appeals support
- Out of pocket assistance
- Access to PAP for therapy for eligible patients
- Support for patients getting started on COSELA

# Opportunity to Meaningfully Impact Many Lives



## ES-SCLC patients predominately treated with highly myelosuppressive chemo regimens

- Limited successful innovation given aggressiveness of disease (1L median OS ~1 year<sup>5</sup>)
- Standard treatment includes 4 to 6 cycles of chemo

## Payor research and discussions indicate potential broad patient access to COSELA

- ~60% of ES-SCLC patients covered by Medicare (expect Medicare to cover label at launch)

**COSELA provides a meaningful improvement for ES-SCLC patients and has potential to generate near-term revenue to further support ongoing development**



1. Based on incidence of 25k for all SCLC with 81% of patients being diagnosed at Extensive Stage; *Decision Resources Group, Small Cell Lung Cancer Disease Landscape & Forecast, March 2020*.  
 2. Based on 22k 1L SCLC total patients (20K de novo ES-SCLC and 2K late relapse LS-SCLC) treated at an assumed 80% treatment rate (from 2020 internal primary market research).  
 3. Based on 12.5k 2L SCLC total patients (11k progressed 1L SCLC and 1.5k early relapse LS-SCLC) treated at an assumed 72% treatment rate (from 2020 internal primary market research).  
 4. Based on 5k 3L SCLC total patients treated at an assumed 50% treatment rate (from 2020 internal primary market research).  
 5. Demonstrated in COSELA G1T28-02 and G1T28-05 study control arms.

# Three Core Goals for a Successful U.S. ES-SCLC Launch

## 1 Increase Awareness of Myelosuppression

Increase awareness of the significant multi-lineage impact of myelosuppression on clinical outcomes, costs, and patients' QoL

## 2 Communicate the Unique Benefits of COSELA

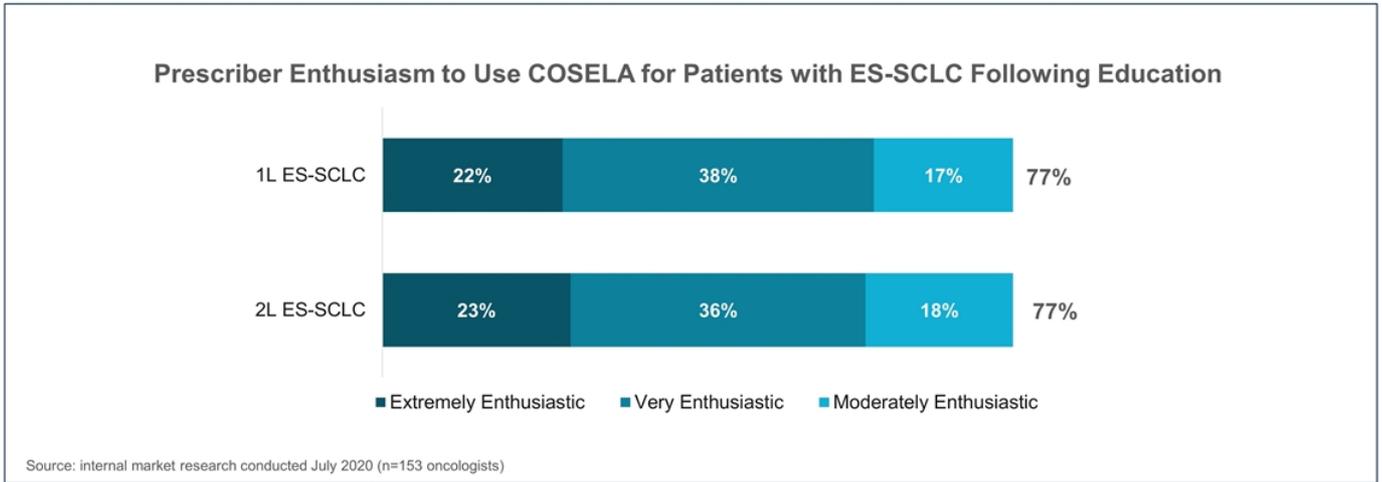
Educate prescribers, payers, and patients on the benefits of COSELA's proactive multi-lineage protection

## 3 Optimize Early Experience

Gain inclusion into relevant guidelines / pathways; enable broad patient access; and ensure ease of use for prescribers / nurses / staff

**Focused on ensuring patients with ES-SCLC can benefit from COSELA first time and every time they are treated with chemotherapy**

# Prescribers are Enthusiastic to Use COSELA



**Education will be key to establish COSELA as a Standard of Care for patients with ES-SCLC receiving chemotherapy**

## 2021 Key Objectives

1. Obtain U.S. approval for ES-SCLC and successfully launch COSELA in 1Q
- 2. Establish COSELA as Standard of Care for ES-SCLC patients in the U.S.**
3. Maximize long-term value of COSELA by executing robust development plan
4. Evaluate partnership options for rintodestrant following combination data readout in 2Q
5. Continue managing investor capital efficiently

# The Burden of Chemotherapy

## MYELOSUPPRESSION

An unavoidable consequence of chemo that impacts patient safety, healthcare system costs and QoL

HEMATOLOGIC EVENT:	NEUTROPENIA	ANEMIA	THROMBOCYTOPENIA
CONSEQUENCE:	Risk of infection	Fatigue	Risk of bleeding
RESPONSE:	G-CSF use (associated bone pain)	RBC transfusions and ESA rescue	Platelet transfusions

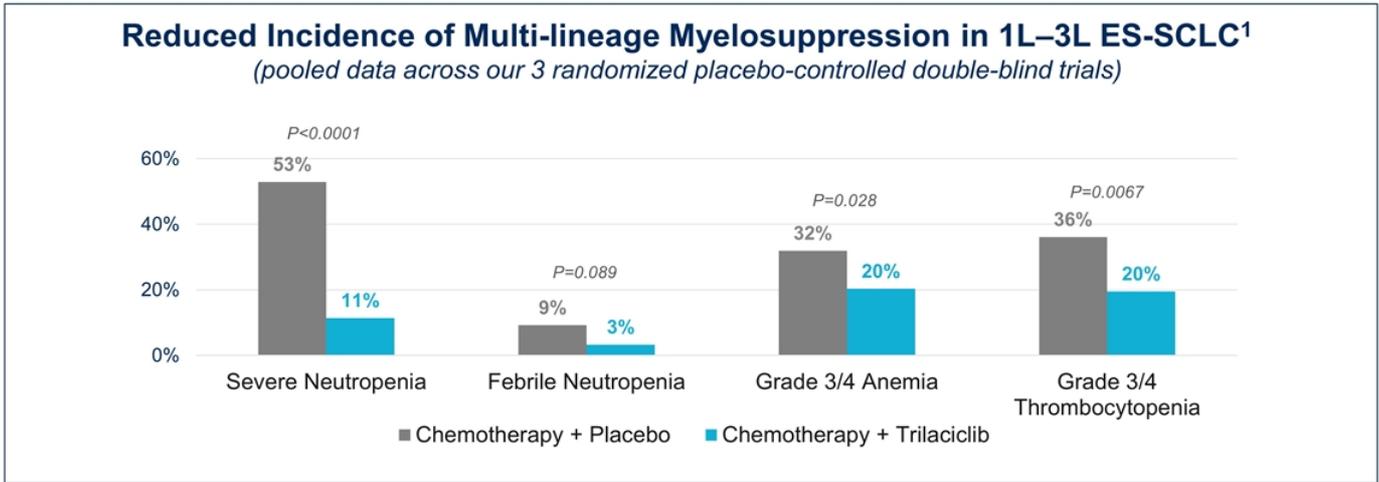
Increased  
healthcare costs

Chemotherapy  
dose reductions  
and delays

Hospitalizations  
and unscheduled  
patient care

**Myelosuppression can have a significant negative impact on clinical outcomes, healthcare costs, and overall patient quality of life**

# COSELA Meaningfully Reduces Myelosuppression in ES-SCLC



**Clinical Results: COSELA consistently demonstrated meaningful reductions in hematologic adverse events across multiple randomized ES-SCLC studies**



1. Weiss et al., 2020 American Society of Clinical Oncology (ASCO), Abstract #384.

# COSELA Can Drive Payor/Hospital Savings

## Average Total Annual Cost Per Patient with a Grade 3/4 Hematologic Event (Jan 2016 – Dec 2019)<sup>1</sup>

Neutropenia	\$131,047
Anemia	\$95,954
Thrombocytopenia	\$90,053

Average total annual cost per patient *without* a grade 3/4 hematologic event:

\$67,802

Cost savings from less hematologic events largely driven by:

- Reduced interventions (e.g., G-CSF, ESA)
- Fewer required transfusions
- Fewer complications and hospitalizations

**Payor Impact: COSELA's ability to reduce the severe hematologic consequences of chemotherapy expected to result in a budget-neutral to savings-positive impact**

# Opportunity to Improve Quality of Life with COSELA

**89%** of cancer patients with myelosuppression rate it as having a moderate to major impact on their life<sup>1</sup>:

**“...the overall fatigue was the worst.**

It stole my energy and joy for both life and family. It made me want to quit chemo numerous times.”

**“I don’t feel like doing ANYTHING some days.**

It’s like depression but completely physical.”

**“Did not get out as much, not able to work,**  
always feeling tired.”

COSELA may help patient functioning in ES-SCLC patients:

### Median Time to Deterioration<sup>2</sup>

(pooled data from three randomized, placebo-controlled, double-blind trials)

Measure	Placebo (months)	COSELA (months)	Improvement (months)
Fatigue	2.3	7.0	4.7
Anemia –TOI (Trial Outcome Index)	3.8	7.2	3.4
Functional Well Being	3.8	7.6	3.8

**Patient Benefit: Proactive protection enables better quality of life for patients in this palliative treatment setting**



1. Epstein et al, Patient Burden and Real-World Management of Chemotherapy-Induced Myelosuppression: Results from an Online Survey of Patients with Solid Tumors; Advances in Therapy, July 2020  
2. Weiss et al., MASCC Oral Presentation 2019, Abstract #MASCC 9-0845

# Opportunity for COSELA to Become Standard of Care in ES-SCLC

## ***Clinical Results***

Meaningfully reduces myelosuppression in ES-SCLC

## ***Payer Impact***

May provide cost savings for system (COSELA expected to be budget neutral or better)

## ***Patient Benefits***

Meaningfully improves the overall quality of life for patients based on patient-reported data

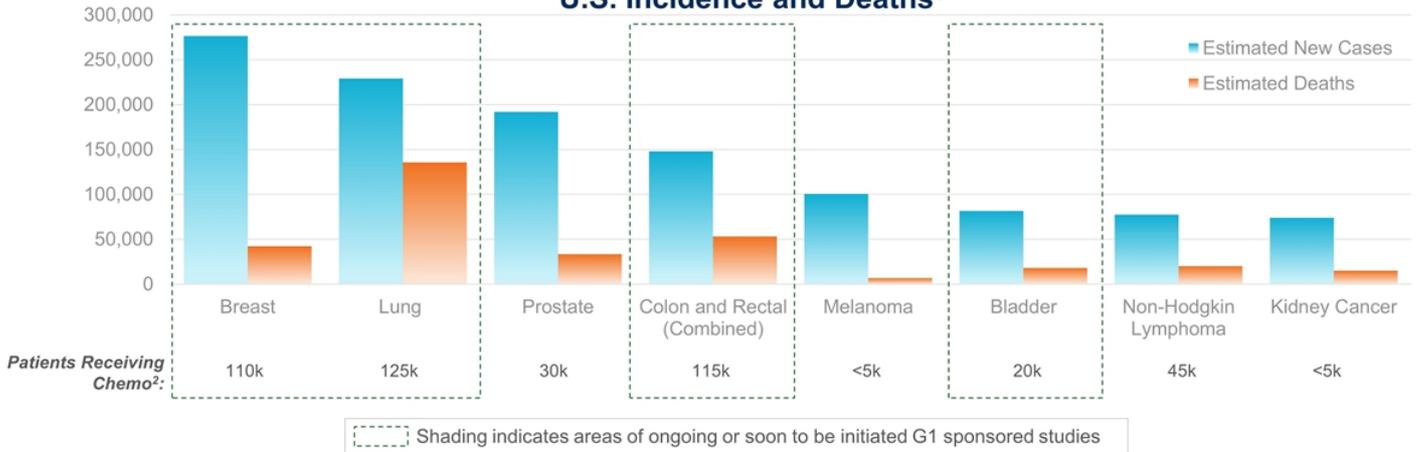
**Heightened awareness of myelosuppression due to the COVID pandemic may further encourage adoption of COSELA as a Standard of Care**

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# Aggressively Pursuing Development in Common Tumor Types

U.S. Incidence and Deaths<sup>1</sup>



**G1 has / will soon initiate sponsored studies in many of the most common and deadly tumor types**



1. Estimated new cases and deaths from National Cancer Institute for 2020.  
 2. Estimated patients receiving chemotherapy from Kantar Health CancerMPact Patient Metrics, 2019 data based on IQVIA BrandImpact regimen shares and Kantar Health Treatment Architecture 2019 survey data for patients receiving chemo (rounded to nearest 5,000 patients).

# Broad Portfolio of Studies Across Common Tumor Types

Cancer Type	Indication	Study Size	Phase 2	Phase 3	Approval
Lung	ES-SCLC	NA	Approved by U.S. Food and Drug Administration		
	2L / 3L NSCLC (Post-checkpoint treatment)	TBD	Starting 1H 2021		
Colorectal	1L CRC	~300	Ongoing		
Breast	1L TNBC <sup>1</sup>	~170	Starting 1H 2021		
	2L TNBC <sup>1</sup> (Post-checkpoint treatment)	~80	Starting 1H 2021		
	Neoadjuvant	Adaptive	Ongoing		
Bladder	1L Bladder (Checkpoint combination)	TBD	Starting 1H 2021		

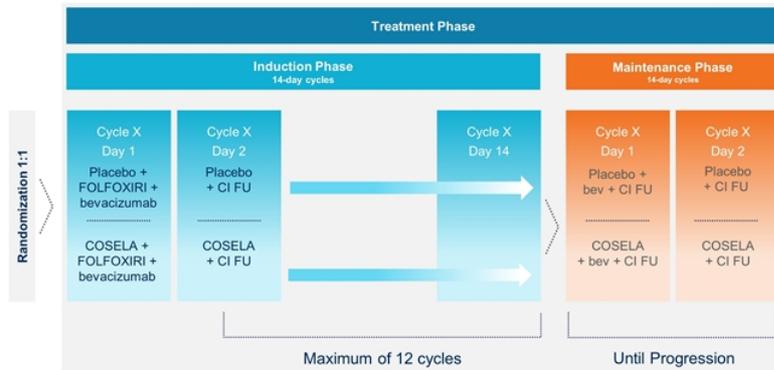
**Two registrational studies will be ongoing by mid 2021 in addition to multiple Phase 2 studies to evaluate COSELA in several treatment settings / tumor types**



1. 1L TNBC and 2L TNBC cohorts being conducted under one study protocol.

# Ongoing First-Line CRC Pivotal Trial

FOLFOXIRI: most efficacious chemo regimen but highly myelosuppressive  
Potential to significantly expand FOLFOXIRI usage supported by market research



**PRIMARY ENDPOINT:**  
Myeloprotection

**SECONDARY ENDPOINTS:**  
PFS/OS, PRO

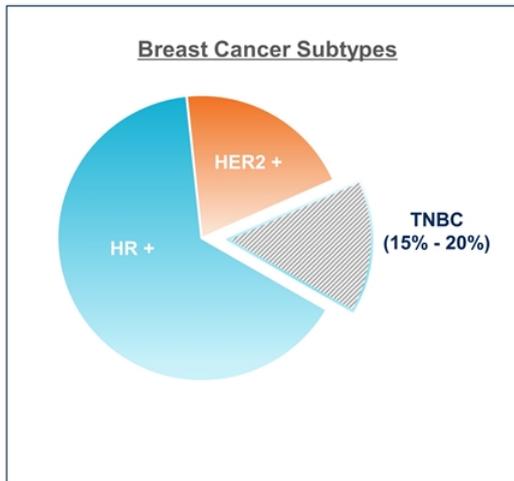
**TARGET ENROLLMENT:**  
~300 participants

**PATIENTS TREATED UNTIL PROGRESSION**

**MULTI-DAY CHEMO REGIMEN**

**Strong support from preclinical models for the benefits of COSELA in combination with 5-FU-based chemo regimens**

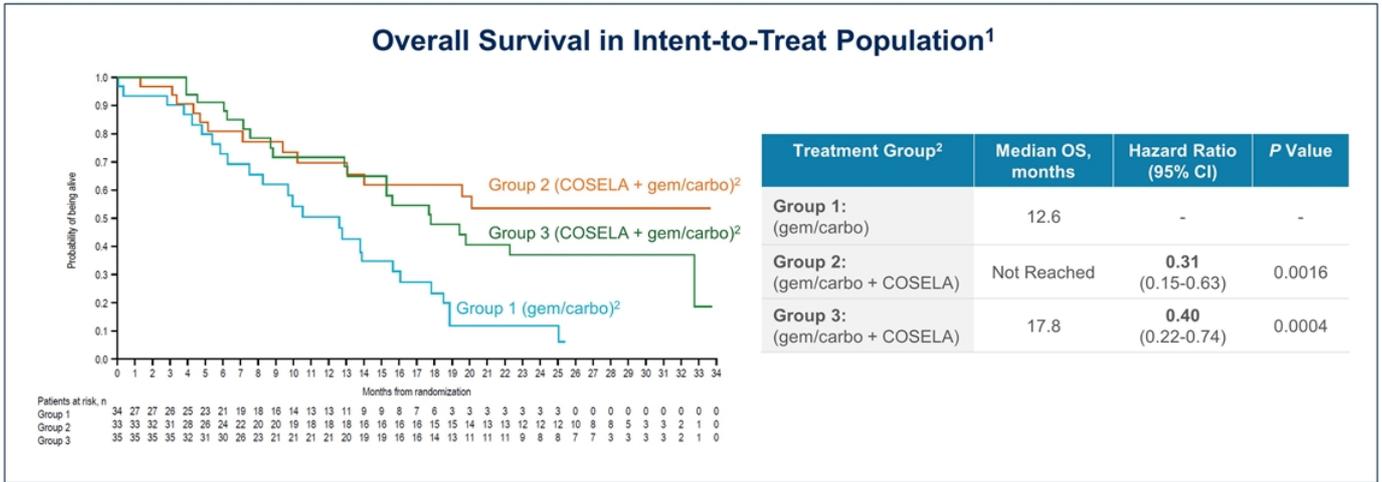
# Metastatic TNBC is an Area of High Unmet Need



- TNBC tumors categorized by lack of HR expression and HER2 gene amplification
- Tumors are aggressive and difficult to treat
- Targeted therapies only demonstrated benefit in subpopulations (e.g., PD-L1 agents, PARPs)
- Antibody Drug Conjugates (ADCs) demonstrated OS improvement in 3L to date, but have associated toxicity

**Urgent need for new therapies that extend Overall Survival with decreased toxicity**

# Observed Robust OS Improvement in mTNBC Phase 2



**Observed a robust statistically significant improvement in Overall Survival for both COSELA schedules**



1. O'Shaughnessy et al., 2020 San Antonio Breast Cancer Symposium (SABCS), Poster #PD1-06. Note: primary endpoints relating to reduction in severe neutropenia not achieved in this study.  
 2. Patients randomized to receive gem/carbo chemotherapy only (Group 1) or gem/carbo plus one of two dosing schedules of COSELA: COSELA administered on the day of chemotherapy (Group 2) or COSELA administered the day prior to and the day of chemotherapy (Group 3).

# OS Improvement Observed, Regardless of PD-L1 Status

## Overall Survival for PD-L1 Positive Tumors<sup>1</sup>

Treatment Group <sup>2</sup>	Patients	Median OS (95% CI), Months	Hazard Ratio (95% CI)	P Value
Group 1: (gem/carbo)	17	10.5 (6.3 – 18.8)	-	-
Group 2 and 3: (gem/carbo + COSELA)	32	32.7 (17.7 – NR)	0.34 (0.2 – 0.7)	0.004

## Overall Survival for PD-L1 Negative Tumors<sup>1</sup>

Treatment Group <sup>2</sup>	Patients	Median OS (95% CI), Months	Hazard Ratio (95% CI)	P Value
Group 1: (gem/carbo)	10	13.9 (12.6 – NR)	-	-
Group 2 and 3: (gem/carbo + COSELA)	26	17.8 (13.1 – NR)	0.48 (0.2 – 1.2)	0.093

**Overall Survival improvement was observed regardless of tumor PD-L1 status (greater effect in PD-L1 positive tumors)**



1. O'Shaughnessy et al., 2020 San Antonio Breast Cancer Symposium (SABCS), Poster #PD1-06. Note: primary endpoints relating to reduction in severe neutropenia not achieved in this study.  
 2. Patients randomized to receive gem/carbo chemotherapy only (Group 1) or gem/carbo plus one of two dosing schedules of COSELA: COSELA administered on the day of chemotherapy (Group 2) or COSELA administered the day prior to and the day of chemotherapy (Group 3).

# Initiating TNBC Phase 3 Trial (1L and 2L Cohorts) in 1H 2021

Strong evidence of efficacy across subsets and line of treatment in Phase 2 trial<sup>1</sup>  
Evaluating 1L checkpoint-naïve and 2L checkpoint-experienced patients



**Pivotal study evaluating COSELA in mTNBC (PD-L1 positive and negative patients) complements ongoing I-SPY 2 Phase 2 Neoadjuvant BC study**



1. O'Shaughnessy et al., 2020 San Antonio Breast Cancer Symposium (SABCS), Poster #PD1-06

# Initiating Two Additional COSELA Phase 2 Trials in 1H 2021

## 1L Bladder Study (anti-PD-L1 combination)

### Strong rationale for COSELA + chemo + I/O in 1L bladder cancer

- Known immunogenic tumor responsive to chemo + I/O
- Data suggests synergistic effect of COSELA + checkpoint<sup>1-3</sup>
- Similar chemo as TNBC study (gemcitabine/platinum)
- Benefits of treating patients until progression

### Interim data expected in late 2022

- Primary aim to evaluate anti-tumor efficacy
- Randomized open-label study design

## 2L / 3L NSCLC Study (post-checkpoint)

### Important area to demonstrate benefits of COSELA in post-checkpoint setting

- Known immunogenic tumor
- COSELA mechanism is distinct from checkpoints
- High unmet need as treatment options limited in 2L / 3L
- Complementary commercial fit with SCLC indication

### Interim data expected in early 2023

- Primary aim to evaluate anti-tumor efficacy
- Randomized double-blind study

## Important future expansion areas for COSELA with data available in next 2 – 3 years



1. Lai et al., Journal for ImmunoTherapy of Cancer 2020; 8:e000847. doi:10.1136/jitc-2020-000847.
2. Deng et al., Cancer Discov. 2018;8(2):216- 33.
3. Daniel et al., 2019 European Society for Medical Oncology (ESMO), Abstract # 1742PD

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5. Continue managing investor capital efficiently

# Rintodestrant Demonstrated a Favorable Oral SERD\* Profile in Clinical Trials

## Fulvestrant is currently only SERD available

- Proven approach but painful intramuscular injections limit use to 2L and preclude use in earlier lines of therapy
- An oral SERD has potential to move into earlier lines of ER-positive breast cancer therapy

## Rintodestrant monotherapy Phase 1b findings to date:

- Favorable tolerability - AEs mostly Grade 1 or Grade 2
- Strong ER target engagement/occupancy with evidence of anti-tumor activity in heavily pre-treated patients

40-patient Phase 2 combination trial with CDK4/6 inhibitor palbociclib ongoing; data in 2Q21

Phase 2 combination data will be important to help secure partner to fund Phase 3 investment

\* SERD = Selective Estrogen Receptor Degradar

**Next steps will be evaluated following data readout expected in 2Q21**



1. Aftimos et al., 2020 San Antonio Breast Cancer Symposium (SABCS), Poster #PS12-04

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## Continue to Efficiently Manage Capital

- **~\$207M cash at year-end 2020 provides runway into second half of 2022**
- **Efficiently executing plan with lean organization of ~125 FTEs**
  - Utilizing capital efficient promotion arrangement with Boehringer Ingelheim for COSELA U.S. launch in SCLC
  - Expect to leverage co-development opportunities with partner Simcere for potential cost and timing efficiencies
- **Access to debt facility up to \$100M total (\$20M drawn to date)**
- **Potential future milestones (up to \$486M) and royalties from licensing agreements**

**Efficiently managing capital with a lean organization  
and benefiting from existing partnership arrangements**

# Maximizing Value of COSELA



**Expect ES-SCLC launch in 1Q 2021 and multiple data readouts to drive expansion and long-term growth**

