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 30, 2019

DECIPHERA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38219**	**30-1003521**
(State or other jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification Number)**

500 Totten Pond Road **Waltham, MA**	**02451**
(Address of registrant's principal executive office)	**(Zip code)**

(781) 209-6400
(Registrant's telephone number, including area code)

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

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 203.425)

☐ 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 exchange on which registered
Common Stock, $0.01 Par Value	**DCPH**	**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 or Rule 12b-2 of the Securities Exchange Act of 1934.

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 September 30, 2019, Deciphera Pharmaceuticals, Inc. (the "Company") announced the presentation of results from its INVICTUS pivotal Phase 3 study in patients with advanced gastrointestinal stromal tumors presented in an oral presentation at the European Society of Medical Oncology 2019 Congress. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K, and a copy of the presentation is furnished as Exhibit 99.2 to this Current Report on Form 8-K.

The furnishing of the attached press release and presentation is not an admission as to the materiality of any information therein. The information contained in the press release and the presentation is summary information that is intended to be considered in the context of more complete information included in the Company's filings with the U.S. Securities and Exchange Commission, or the SEC, and other public announcements that the Company has made and may make from time to time by press release or otherwise. The Company undertakes no duty or obligation to update or revise the information contained in this report, although it may do so from time to time as its management believes is appropriate. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or through other public disclosures. For important information about forward looking statements, see the "Cautionary Note Regarding Forward-Looking Statements" section of the press release in Exhibit 99.1 attached hereto.

The information in this Item 7.01 of this Current Report on Form 8-K and Exhibit 99.1 and Exhibit 99.2 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 7.01 and in the press release attached as Exhibit 99.1 to this Current Report and in the presentation attached as Exhibit 99.2 to this Current Report shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by Deciphera Pharmaceuticals, Inc. on September 30, 2019, furnished herewith.
99.2	Presentation from September 30, 2019, furnished herewith.

EXHIBIT INDEX

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99.2	Presentation from September 30, 2019, furnished herewith.

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: September 30, 2019

DECIPHERA PHARMACEUTICALS, INC.

By: /s/ Steven L. Hoerter
Steven L. Hoerter
President and Chief Executive Officer

Deciphera Pharmaceuticals Announces Late-Breaking Oral Presentation at the European Society for Medical Oncology (ESMO) 2019 Congress Demonstrating Positive Results from INVICTUS Pivotal Phase 3 Study of Ripretinib in Patients with Advanced Gastrointestinal Stromal Tumors

Waltham, MA – September 30, 2019 – Deciphera Pharmaceuticals, Inc. (Nasdaq:DCPH), a clinical-stage biopharmaceutical company addressing key mechanisms of tumor drug resistance, today announced the late-breaking presentation of results from the INVICTUS pivotal Phase 3 clinical study of ripretinib in patients with advanced gastrointestinal stromal tumors (GIST) in an oral session at the European Society for Medical Oncology (ESMO) 2019 Congress.

“For GIST patients who have failed currently approved agents, there exists an urgent need for effective and well-tolerated treatment options,” said Margaret von Mehren, MD, Department of Medical Oncology, Fox Chase Cancer Center, Philadelphia, Pennsylvania. “With a statistically significant improvement observed in progression free survival compared with placebo, and a clinically meaningful increase in overall survival compared with placebo, ripretinib represents a potential standard of care for patients harboring a broad spectrum of mutations known to drive GIST in patients who have no approved treatment options.”

“Results from the INVICTUS study support our belief that ripretinib has the potential to transform the current treatment landscape for advanced GIST,” said Steve Hoerter, President and Chief Executive Officer of Deciphera. “We are now working with the FDA as we prepare the NDA submission for ripretinib, which we expect in the first quarter of 2020.”

Today’s presentation featured new data as well as top-line results previously announced by the Company in August 2019. A copy of the presentation will be available following the session at www.deciphera.com.

INVICTUS Study Results

The INVICTUS Phase 3 clinical study is a randomized (2:1), double-blind, placebo-controlled, international, multicenter study to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in 129 patients with advanced GIST whose previous therapies have included at least imatinib, sunitinib, and regorafenib. As previously reported, the study achieved the primary endpoint of improved progression free survival (PFS) compared to placebo in patients with fourth-line and fourth-line plus GIST, as determined by blinded independent central radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1.

Progression Free Survival (PFS)

Ripretinib significantly reduced the risk of disease progression or death by 85% compared to placebo and demonstrated a median PFS of 6.3 months compared to 1.0 month in the placebo arm (HR=0.15, 95% CI (0.09,0.25), p<0.0001). This PFS benefit was consistent across all assessed patient subgroups.

Objective Response Rate (ORR) and Duration of Response

Eight patients (9.4%) had a confirmed objective response with ripretinib (p=0.0504) compared to no confirmed responses in the placebo arm, as measured by blinded independent central review, which was not statistically significant. As of the cutoff date of May 31, 2019, the median duration of response had not been reached with seven of the eight patients still responding to treatment. All responders had partial responses.

Overall Survival (OS)

Ripretinib reduced the risk of death by 64% compared to placebo and demonstrated a median OS of 15.1 months vs. 6.6 months in the placebo arm (HR=0.36, 95% CI (0.20,0.62), nominal p=0.0004). Since statistical significance was not achieved for the secondary endpoint of ORR, the hypothesis testing of OS was not formally performed. According to the pre-specified hierarchical testing procedure of the endpoints, the hypothesis testing of OS cannot be formally conducted unless the test for ORR is statistically significant.

Safety

Ripretinib was generally well tolerated and the adverse events observed in INVICTUS were consistent with data from previously presented Phase 1 study results. Treatment-emergent adverse events (TEAEs) occurred in 99% of patients on the ripretinib arm compared to 98% on the placebo arm. Grade 3 or 4 TEAEs occurred in 49% of patients on the ripretinib arm compared to 44% on the placebo arm. Grade 3 or 4 TEAEs greater than 5% of patients on the ripretinib arm were anemia (9%), abdominal pain (7%) and hypertension (7%). Grade 3 or 4 TEAEs greater than 5% of patients on the placebo arm were anemia (14%). TEAEs leading to dose reduction occurred in 7% of patients on the ripretinib arm compared to 2% on the placebo arm. TEAEs leading to dose interruption occurred in 24% of patients on the ripretinib arm compared to 21% on the placebo arm. TEAEs leading to study treatment discontinuation occurred in 8% of patients on the ripretinib arm compared to 12% of patients on the placebo arm. TEAEs leading to death occurred in 6% of patients on the ripretinib arm compared to 23% on the placebo arm.

New Drug Application (NDA) Submission

Based on the positive INVICTUS data, the Company expects to submit an NDA to the U.S. Food and Drug Administration (FDA) for ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib and regorafenib in the first quarter of 2020.

About the INVICTUS Phase 3 Study

The INVICTUS Phase 3 clinical study is a randomized, double-blind, placebo-controlled, international, multicenter study to evaluate the safety, tolerability, and efficacy of ripretinib compared to placebo in patients with advanced GIST whose previous therapies have included imatinib, sunitinib, and regorafenib. This study was designed to provide evidence of clinical benefit in fourth-line and fourth-line plus patients with GIST that would be required to secure a regulatory approval. Patients were randomized 2:1 to either 150 mg of ripretinib or placebo once daily. The primary efficacy endpoint is progression-free survival (PFS) as determined by independent radiologic review using modified Response Evaluation Criteria in Solid Tumors (RECIST). Secondary endpoints as determined by independent radiologic review using modified RECIST include Objective Response Rate (ORR), Time to Tumor Progression (TTP) and Overall Survival (OS). See www.clinicaltrials.gov for further information (NCT03353753).

About Ripretinib

Ripretinib is an investigational tyrosine kinase switch control inhibitor that was engineered to broadly inhibit KIT and PDGFRα mutated kinases by using a unique dual mechanism of action that regulates the kinase switch pocket and activation loop. Ripretinib is currently in clinical development for the treatment of KIT and/or PDGFRα-driven cancers, including gastrointestinal stromal tumors, or GIST, systemic

mastocytosis, or SM, and other cancers. Ripretinib inhibits initiating and secondary KIT mutations in exons 9, 11, 13, 14, 17, and 18, involved in GIST, as well as the primary D816V exon 17 mutation involved in SM. Ripretinib also inhibits primary PDGFRα mutations in exons 12, 14 and 18, including the exon 18 D842V mutation, involved in a subset of GIST. In June 2019, the U.S. FDA granted Fast Track Designation to ripretinib for the treatment of patients with advanced GIST who have received prior treatment with imatinib, sunitinib and regorafenib.

Deciphera Pharmaceuticals has an exclusive license agreement with Zai Lab (Shanghai) Co., Ltd. for the development and commercialization of ripretinib in Greater China (Mainland China, Hong Kong, Macau and Taiwan). Deciphera Pharmaceuticals retains development and commercial rights for ripretinib in the rest of the world.

About Deciphera Pharmaceuticals

Deciphera Pharmaceuticals is a clinical-stage biopharmaceutical company focused on improving the lives of cancer patients by addressing key mechanisms of drug resistance that limit the rate and/or durability of response to existing cancer therapies. Our small molecule drug candidates are directed against an important family of enzymes called kinases, known to be directly involved in the growth and spread of many cancers. We use our deep understanding of kinase biology together with a proprietary chemistry library to purposefully design compounds that maintain kinases in a "switched off" or inactivated conformation. These investigational therapies comprise tumor-targeted agents designed to address therapeutic resistance causing mutations and immuno-targeted agents designed to control the activation of immunokinases that suppress critical immune system regulators, such as macrophages. We have used our platform to develop a diverse pipeline of tumor-targeted and immuno-targeted drug candidates designed to improve outcomes for patients with cancer by improving the quality, rate and/or durability of their responses to treatment.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including, without limitation, statements regarding the potential for the results of our INVICTUS pivotal Phase 3 clinical study to support an NDA submission, the timing of our planned NDA submission for fourth and fourth-line plus GIST, the potential for ripretinib and our other drug candidates based on our kinase switch control inhibitor platform to provide clinical benefit, impact current treatment paradigms and landscape and treat cancers such as GIST and other possible indications, and preparations for seeking regulatory approval for and making ripretinib available to patients with fourth-line and fourth-line plus GIST, if approved. The words "may," "will," "could," "would," "should," "expect," "plan," "anticipate," "intend," "believe," "estimate," "predict," "project," "potential," "continue," "target" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. 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 and uncertainties related to the delay of any current or planned clinical studies or the development of our drug candidates, including ripretinib, our ability to successfully demonstrate the efficacy and safety of our drug candidates including in later-stage studies, the preclinical and clinical results for our drug candidates, which may not support further development of such drug candidates, our ability to timely complete and prepare the information required for and file an NDA for ripretinib, our ability to manage and our reliance on third parties such as our third party drug substance and drug product contract manufacturers, actions of regulatory agencies, any or all of which may affect the initiation, timing and progress of clinical studies and the timing of and our ability to obtain regulatory approval, if at all, and make our investigational drugs available to patients, and other risks identified in our

SEC filings, including our Quarterly Report on Form 10-Q for the quarter ended June 30, 2019, and subsequent filings with the SEC. We caution you not to place undue reliance on any forward-looking statements, which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements. Any forward-looking statements contained in this press release represent our views only as of the date hereof and should not be relied upon as representing its views as of any subsequent date. We explicitly disclaim any obligation to update any forward-looking statements.

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INVICTUS:
A Phase 3, *IN*ter*V*entional, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Ripretinib as ≥4th Line Therapy *I*n Patients with Advan*C*ed Gastrointestinal Stromal *TU*mor*S* (GIST) Who Have Received Treatment with Prior Anticancer Therapies (NCT03353753)

Margaret von Mehren, Steven Attia, Sebastian Bauer, Ping Chi, Gina D'Amato, Suzanne George, Hans Gelderblom, Michael C. Heinrich, Robin L. Jones, Peter Reichardt, Patrick Schoffski, Cesar Serrano, John Zalcberg, Julie Meade, Kelvin Shi, Rodrigo Ruiz-Soto, Jean-Yves Blay

esmo.org

Acknowledgements

We would like to thank the patients and their families and caregivers, the investigators, and the investigational site staff of the INVICTUS study.

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Each flag corresponds to the participating country and the number of participating centers within that country.

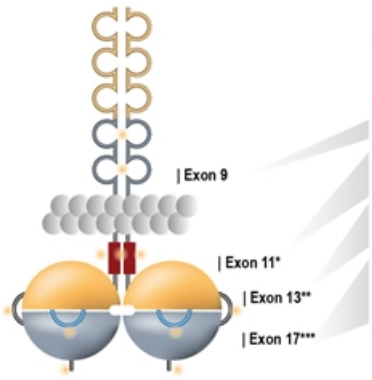
Disclosures

Margaret von Mehren: advisory/consultancy role with Deciphera Pharmaceuticals, LLC, Blueprint Medicines™ Corporation, and Exelixis, Inc.; travel accommodations from Deciphera Pharmaceuticals, LLC and the National Comprehensive Cancer Network®; institutional supportive research funding from ASCO, Deciphera Pharmaceuticals, LLC, Blueprint Medicines™ Corporation, AROG Pharmaceuticals, Inc., Novartis, Gradalis®, Inc., and Genmab.

The INVICTUS study was sponsored by Deciphera Pharmaceuticals, LLC, Waltham, MA, USA.

KIT Mutations Drive ~80% of GIST

- GIST is a rare sarcoma accounting for 1% to 2% of GI malignancies[1]
- Primary mutations in KIT or PDGFRA occur in >85% of patients with GIST[2]
- Mutations lead to activation of the kinase[3]



Domain	Gene	1° Mutation Frequency	2° Mutation Frequency
D5	*KIT*	10%	
JM	*KIT* *PDGFRA*	67* 1	
TK1 (ATP-binding pocket)	*KIT* *PDGFRA*	1 1	56**
Activation loop	*KIT* *PDGFRA D842* *PDGFRA*	1 5 1	41*** 3

*Exon 11 mutations of the JM domain result in loss of function of the KIT inhibitory switch[4]

**Mutations in the TK1 region of KIT reflect mutations in the ATP-binding pocket ("switch pocket region")[4,5]

***Mutations in the activation loop of KIT reflect mutations in the KIT activating switch region[4]

From Hemming M, et al. *Ann Oncol*. 2018;29:2037-2045 by permission of Oxford University Press on behalf of the European Society for Medical Oncology.

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1. Parab TM, et al. *J Gastrointest Oncol*. 2019;10:144-154. **2.** Hsueh YS, et al. *PLOS One*.2013;e65762. **3.** Smith BD, et al. *Cancer Cell*. 2019;35:738-751 **4.** Bai Y, et al. *Leukemia*.2013;27:278-285. **5.** Oppelt PJ, et al. *J Gastrointest Oncol*. 2017;8:466-473.

GIST Current Treatment Landscape

No approved 4th line therapies are available

	Line of Therapy			
	1st line	**2nd line**	**3rd line**	**4th line**
Current approved therapy	Imatinib	Sunitinib	Regorafenib	No approved therapy
Median PFS	Imatinib 400 mg: 20.4 mo[1a] Imatinib 800 mg: 24.0 mo[1a] *P*=0.18	Sunitinib: 5.6 mo[2b] Placebo: 1.4 mo[2b] *P*<0.0001	Regorafenib: 4.8 mo[3] Placebo: 0.9 mo[3] *P*<0.0001	
Overall response rate (CR + PR)	Imatinib 400 mg: 51.0%[1] Imatinib 800 mg: 56.7%[1] *P*=0.08	Sunitinib: 6.8%[2] Placebo: 0% *P*=0.006	Regorafenib: 4.5%[4] Placebo: 1.5% *P*=NR	
Median OS	Imatinib 400 mg: 46.8 mo[1a] Imatinib 800 mg: 46.8 mo[1a] *P*=0.31	Sunitinib: 17.0 mo[5b] Placebo: 14.9 mo[5b] *P*=0.161	Regorafenib: 17.4 mo[3] Placebo: 17.4 mo[3] *P*=0.5716	

[a] PFS / OS converted from years to months. [b] PFS converted from weeks to months.
NR, not reported.

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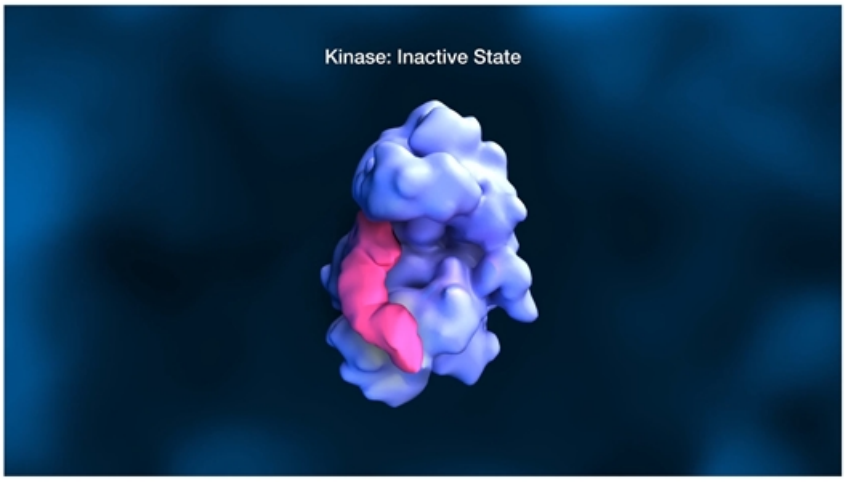
1. Casali PG, et al. *J Clin Oncol*. 2017;35:1713-1720. **2.** Sutent [package insert]. New York, NY: Pfizer Labs; 2017. **3.** Stivarga [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; 2017. **4.** Demetri GD, et al. *Lancet*. 2013;381:295-302. **5.** Garrett CR, et al. Poster presented at: Connective Tissue Oncology Society: November 13-15, 2008; London, UK. Abstract 35049.

Ripretinib Mechanism of Action



- Ripretinib is a novel tyrosine kinase **switch control** inhibitor engineered to broadly inhibit KIT and PDGFRA mutated kinases by using a unique **dual mechanism of action** that regulates the kinase switch pocket and activation loop

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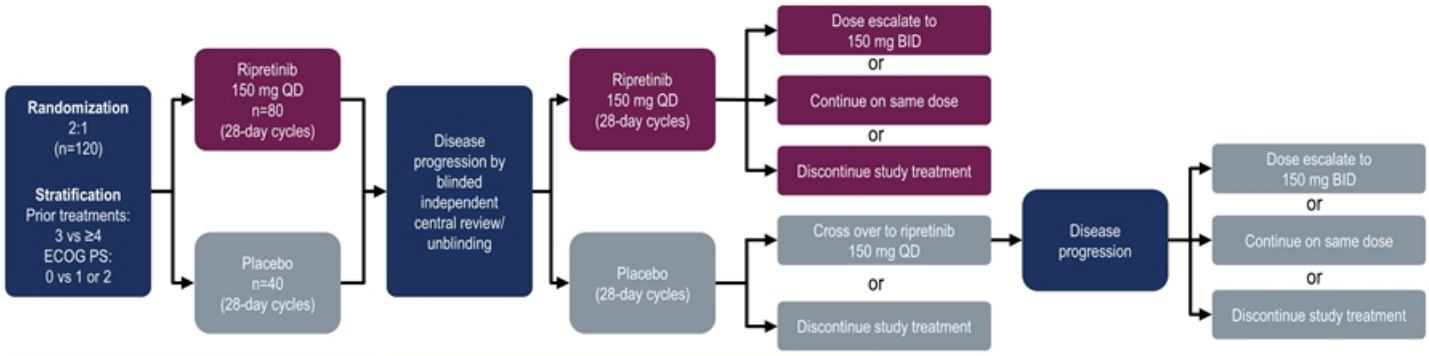
Smith BD, et al. *Cancer Cell*. 2019;35:738-751.

INVICTUS: Randomized Phase 3 Study Design

Evaluated ripretinib as ≥4th line therapy in patients with advanced GIST



Primary endpoint

PFS

(per modified RECIST based on **B**linded **I**ndependent **C**entral **R**eview [BICR])

Select Secondary endpoints

- **Objective response rate (ORR)** assessed by BICR (Key endpoint)
- **Overall survival (OS)**

Data cutoff
May 31, 2019

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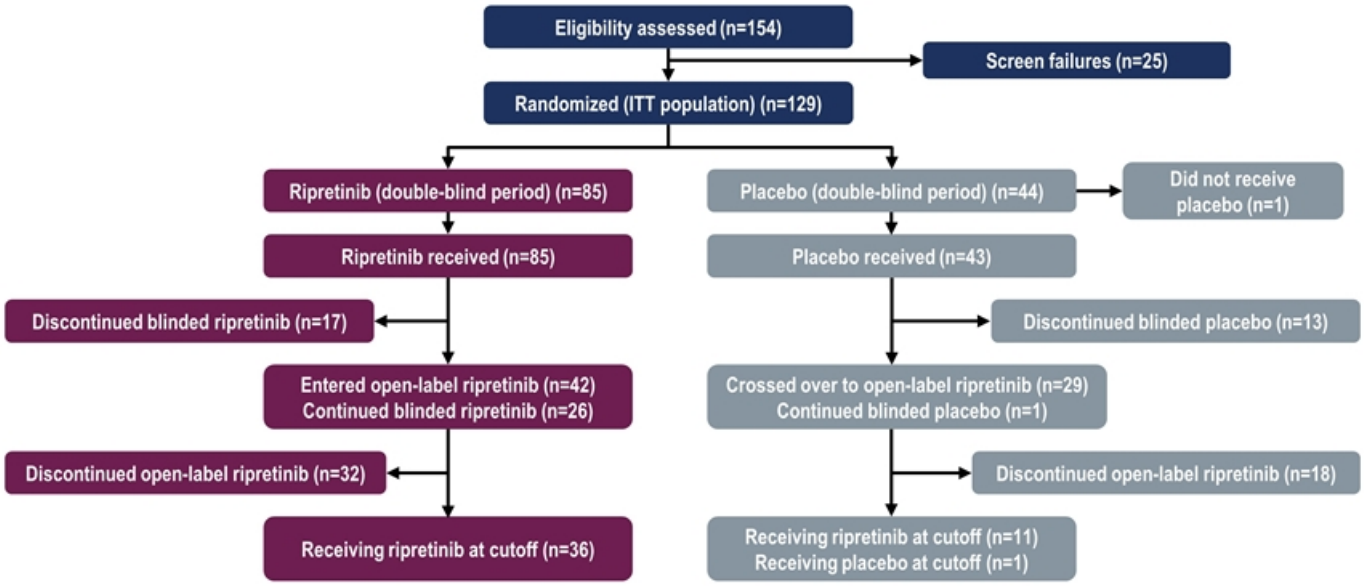
Patient Disposition

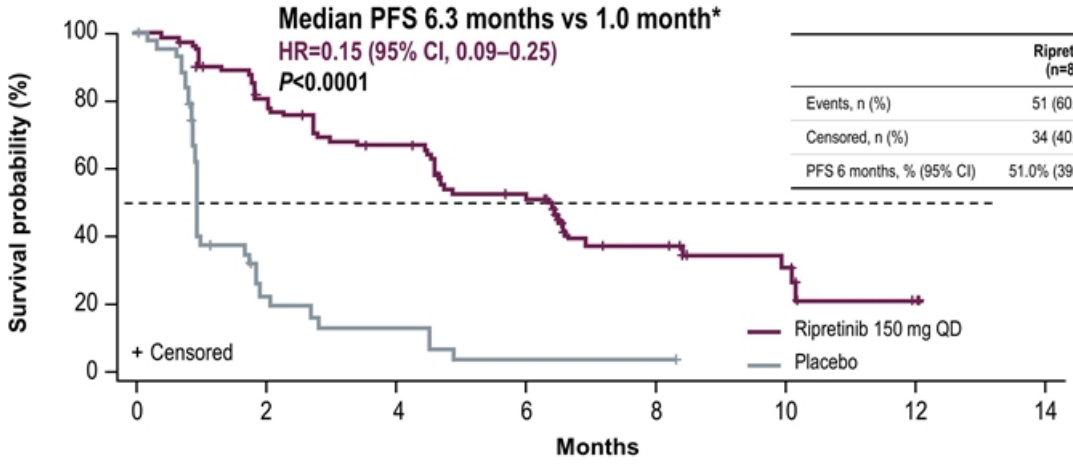


Baseline Characteristics

	Ripretinib (n=85)	Placebo (n=44)	Total (n=129)
Age (years) Median (min, max)	59 (29, 82)	65 (33, 83)	60 (29, 83)
18–64 years	57 (67%)	22 (50%)	79 (61%)
65–74 years	20 (24%)	12 (27%)	32 (25%)
≥ 75 years	8 (9%)	10 (23%)	18 (14%)
Gender			
Male (%)	47 (55%)	26 (59%)	73 (57%)
Race			
White (%)	64 (75%)	33 (75%)	97 (75%)
Region			
US (%)	40 (47%)	20 (46%)	60 (47%)
ECOG PS (%)			
ECOG PS 0	37 (44%)	17 (39%)	54 (42%)
ECOG PS 1/2	48 (56%)	27 (61%)	75 (58%)
Number of prior therapies (%)			
3	54 (64%)	27 (61%)	81 (63%)
≥4 (range, 4-7)	31 (36%)	17 (39%)	48 (37%)
Primary mutation (central testing of tumor tissue) n (%)			
KIT exon 9	14 (17%)	6 (14%)	20 (16%)
KIT exon 11	47 (55%)	28 (64%)	75 (58%)
Other KIT	2 (2%)	2 (5%)	4 (3%)
PDGFRA	3 (4%)	0	3 (2%)
KIT/PDGFRA wild type	7 (8%)	3 (7%)	10 (8%)
Not available / not done*	12 (14%)	5 (11%)	17 (13%)

*Not available=tumor tissue analyzed for baseline mutations but analysis failed; Not done=biopsy completed per protocol but sample not received for analysis.

85% Risk Reduction of Disease Progression or Death With Ripretinib Compared With Placebo



	Ripretinib (n=85)	Placebo (n=44)
Events, n (%)	51 (60.0%)	37 (84.1%)
Censored, n (%)	34 (40.0%)	7 (15.9%)
PFS 6 months, % (95% CI)	51.0% (39.4–61.4)	3.2% (0.2–13.8)

Number of patients at risk:

Ripretinib 150 mg QD	85	64	52	37	18	8	1	0
Placebo	44	7	4	1	1	0		

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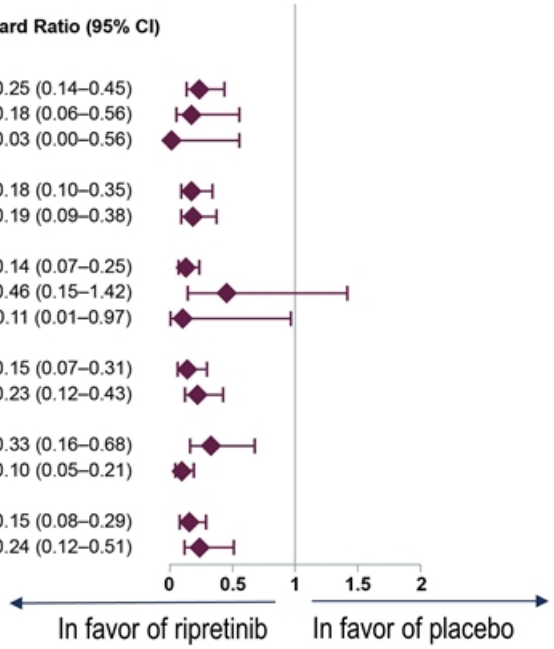
*Double-blind period.

Ripretinib Showed PFS Benefit in All Assessed Patient Subgroups

Subgroup	Ripretinib 150 mg QD (n)	Placebo (n)	Hazard Ratio (95% CI)
Age			
18–64 years	57	22	0.25 (0.14–0.45)
65–74 years	20	12	0.18 (0.06–0.56)
≥ 75 years	8	10	0.03 (0.00–0.56)
Gender			
Male	47	26	0.18 (0.10–0.35)
Female	38	18	0.19 (0.09–0.38)
Race			
White	64	33	0.14 (0.07–0.25)
Non-white	13	7	0.46 (0.15–1.42)
Not reported	8	4	0.11 (0.01–0.97)
Region			
US	40	20	0.15 (0.07–0.31)
Non-US	45	24	0.23 (0.12–0.43)
Screening ECOG PS			
0	38	19	0.33 (0.16–0.68)
1 or 2	47	25	0.10 (0.05–0.21)
Number of prior therapies			
3	54	27	0.15 (0.08–0.29)
≥ 4	31	17	0.24 (0.12–0.51)



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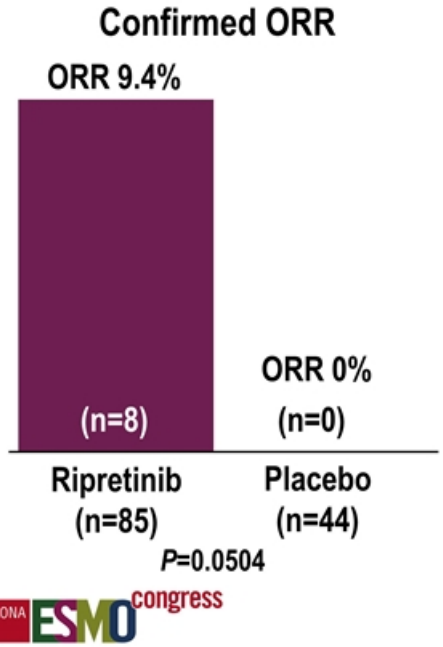
Durable Response With Ripretinib



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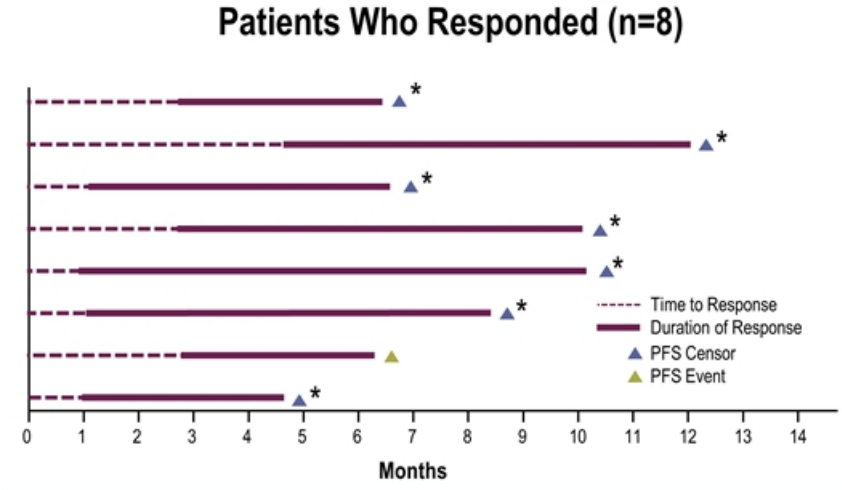
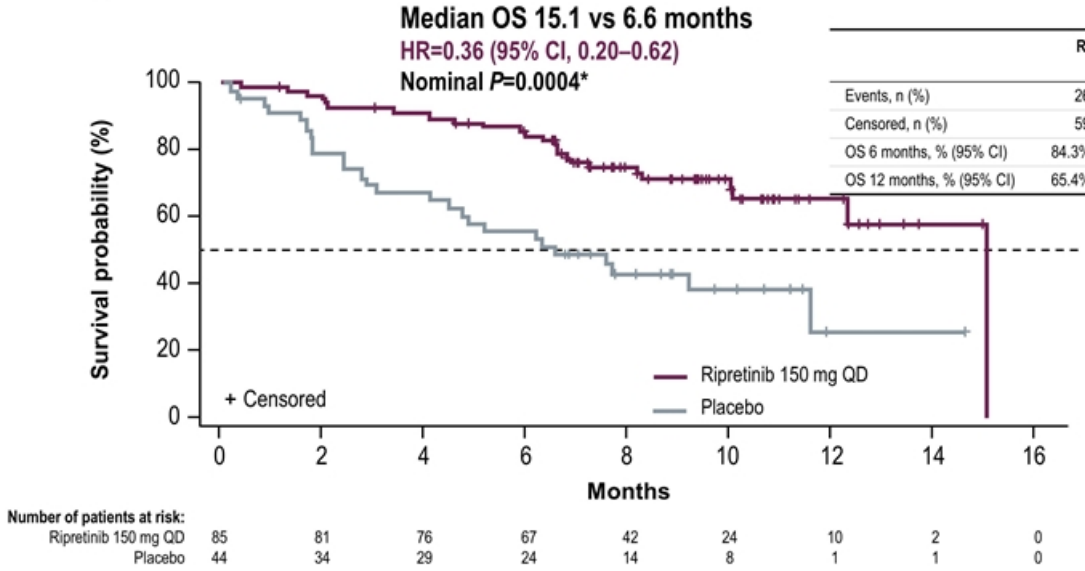


- Median duration of response has not been reached yet
- *7 of 8 ripretinib responders are still responding as of data cutoff
- All responders had partial responses

OS Benefit: 64% Risk Reduction of Death Compared With Placebo



	Ripretinib (n=85)	Placebo (n=44)
Events, n (%)	26 (30.6%)	26 (59.1%)
Censored, n (%)	59 (69.4%)	18 (40.9%)
OS 6 months, % (95% CI)	84.3% (74.5–90.6)	55.9% (39.9–69.2)
OS 12 months, % (95% CI)	65.4% (51.6–76.1)	25.9% (7.2–49.9)

Number of patients at risk:

Ripretinib 150 mg QD	85	81	76	67	42	24	10	2	0
Placebo	44	34	29	24	14	8	1	1	0

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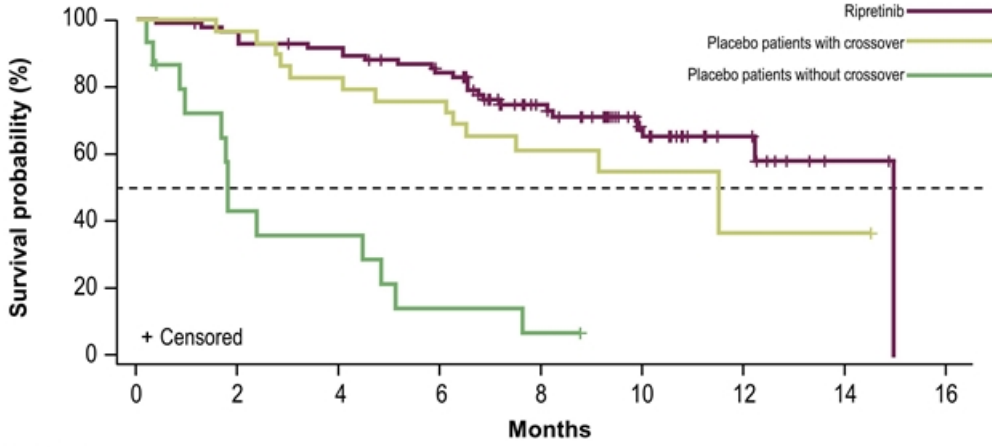
*Due to hierarchal testing procedures of the end points, the OS end point could not be formally tested because the ORR was not statistically significant.

Crossover Provided OS Benefit



Number of patients at risk:									
Ripretinib	85	81	76	67	42	24	10	2	0
Placebo patients with crossover	29	28	24	22	13	8	1	1	0
Placebo patients without crossover	15	6	5	2	1	0			

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NE, not estimable.

TEAEs in >10% of Patients

Preferred Term	Ripretinib any grade (n=85)	Placebo any grade (n=43)*
Any TEAE or grade 3/4 TEAE**	**84 (98.8%)**	**42 (97.7%)**
Alopecia	44 (51.8%)	2 (4.7%)
Fatigue	36 (42.4%)	10 (23.3%)
Nausea	33 (38.8%)	5 (11.6%)
Abdominal pain	31 (36.5%)	13 (30.2%)
Constipation	29 (34.1%)	8 (18.6%)
Myalgia	27 (31.8%)	5 (11.6%)
Diarrhea	24 (28.2%)	6 (14%)
Decreased appetite	23 (27.1%)	9 (20.9%)
Palmar-plantar erythrodysesthesia syndrome	18 (21.2%)	0
Vomiting	18 (21.2%)	3 (7%)
Headache	16 (18.8%)	2 (4.7%)
Weight decreased	16 (18.8%)	5 (11.6%)

Preferred Term	Ripretinib any grade (n=85)	Placebo any grade (n=43)*
Arthralgia	15 (17.6%)	2 (4.7%)
Blood bilirubin increased	14 (16.5%)	0 (0%)
Edema peripheral	14 (16.5%)	3 (7%)
Muscle spasms	13 (15.3%)	2 (4.7%)
Anemia	12 (14.1%)	8 (18.6%)
Hypertension	12 (14.1%)	2 (4.7%)
Asthenia	11 (12.9%)	6 (14%)
Dry skin	11 (12.9%)	3 (7%)
Dyspnea	11 (12.9%)	0
Hypophosphatemia	9 (10.6%)	0
Lipase increased	9 (10.6%)	0
Pruritus	9 (10.6%)	2 (4.7%)
Stomatitis	9 (10.6%)	0

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*44 patients were randomized to placebo, but 1 did not receive treatment.
**Regardless of causality

TEAEs in >10% of Patients
Grade 3/4 TEAEs

Preferred Term	Ripretinib any grade (n=85)	Ripretinib grade 3/4 (n=85)†	Placebo any grade (n=43)*	Placebo grade 3/4 (n=43)*†
Any TEAE or grade 3/4 TEAE**	84 (98.8%)	**42 (49.4%)**	42 (97.7%)	**19 (44.2%)**
Alopecia	44 (51.8%)	0	2 (4.7%)	0
Fatigue	36 (42.4%)	3 (3.5%)	10 (23.3%)	1 (2.3%)
Nausea	33 (38.8%)	3 (3.5%)	5 (11.6%)	0
Abdominal pain	31 (36.5%)	6 (7.1%)	13 (30.2%)	2 (4.7%)
Constipation	29 (34.1%)	1 (1.2%)	8 (18.6%)	0
Myalgia	27 (31.8%)	1 (1.2%)	5 (11.6%)	0
Diarrhea	24 (28.2%)	1 (1.2%)	6 (14%)	1 (2.3%)
Decreased appetite	23 (27.1%)	1 (1.2%)	9 (20.9%)	1 (2.3%)
Palmar-plantar erythrodysesthesia syndrome	18 (21.2%)	0	0	0
Vomiting	18 (21.2%)	3 (3.5%)	3 (7%)	0
Headache	16 (18.8%)	0	2 (4.7%)	0
Weight decreased	16 (18.8%)	0	5 (11.6%)	0
Arthralgia	15 (17.6%)	0	2 (4.7%)	0
Blood bilirubin increased	14 (16.5%)	1 (1.2%)	0 (0%)	0
Edema peripheral	14 (16.5%)	1 (1.2%)	3 (7%)	0
Muscle spasms	13 (15.3%)	0	2 (4.7%)	0
Anemia	12 (14.1%)	8 (9.4%)	8 (18.6%)	6 (14%)
Hypertension	12 (14.1%)	6 (7.1%)	2 (4.7%)	0
Asthenia	11 (12.9%)	1 (1.2%)	6 (14%)	2 (4.7%)
Dry skin	11 (12.9%)	0	3 (7%)	0
Dyspnea	11 (12.9%)	0	0	0
Hypophosphatemia	9 (10.6%)	4 (4.7%)	0	0
Lipase increased	9 (10.6%)	4 (4.7%)	0	0
Pruritus	9 (10.6%)	0	2 (4.7%)	0
Stomatitis	9 (10.6%)	0	0	0

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*44 patients were randomized to placebo, but 1 did not receive treatment.
**Regardless of causality

†Corresponding grade 3/4 TEAEs to TEAEs in >10% of patients receiving ripretinib.

TEAE Leading to Dose Modification

Categories n (%)	Ripretinib (n=85)	Placebo (n=43)*
Any TEAE leading to dose reduction	6 (7.1%)	1 (2.3%)
Any TEAE leading to dose interruption	20 (23.5%)	9 (20.9%)
Any TEAE leading to treatment discontinuation	7 (8.2%)	5 (11.6%)
Any TEAE leading to death**	5 (5.9%)	10 (23.3%)

*44 patients were randomized to placebo, but one did not receive treatment.
**One patient in each arm considered possibly related to blinded study drug

INVICTUS: Conclusions

- **Median PFS** was significantly improved with ripretinib compared with placebo (6.3 vs 1.0 months; HR=0.15 [95% CI, 0.09–0.25])
  - **Risk of progression or death reduced by 85%** compared with placebo
- **Median OS** with ripretinib was 15.1 months vs 6.6 months in the placebo arm (HR=0.36 [95% CI, 0.20–0.63])
  - **Risk of death reduced by 64%** compared with placebo
- Ripretinib was associated with a **favorable tolerability profile**
- Ripretinib represents a **potential new standard of care** with broad activity in ≥4th line GIST, a patient population with advanced refractory disease and no other approved options

Enrollment is ongoing in **intrigue**, a Phase 3, interventional, randomized, multicenter, open-label study of ripretinib vs sunitinib in patients with advanced GIST after treatment with imatinib (NCT03673501)