



## **Momelotinib Pivotal Phase 3 Data Receives Oral Presentation at American Society of Clinical Oncology Annual Meeting**

- *MOMENTUM* data demonstrate potential use of momelotinib in myelofibrosis patients who are symptomatic and anemic –
- Additional data highlight improved transfusion independence, symptoms and spleen volume of cytopenic myelofibrosis patients –

**SAN MATEO, CA, May 26, 2022** - Sierra Oncology, Inc. (NASDAQ: SRRR), a late-stage biopharmaceutical company on a mission to deliver transformative therapies for rare cancers, today announced two abstracts have been accepted into the program for the Annual Meeting of the American Society of Clinical Oncology (ASCO) being held June 3-7, 2022, in Chicago and online. An abstract presenting the full data from the pivotal phase 3 MOMENTUM study in myelofibrosis patients who are symptomatic and anemic has been selected for an oral presentation on June 7. An additional subset analysis from the trial evaluating safety and efficacy for patients with low platelet counts has been selected for poster presentation.

*“Receiving an oral presentation at ASCO for our pivotal Phase 3 study data—which demonstrated that momelotinib achieved statistically significant and clinically important efficacy across all prespecified and key secondary endpoints—is truly a momentous occasion for Sierra Oncology. Further, we are excited to present a subset analysis in a poster presentation examining the use of momelotinib in thrombocytopenic patients with platelet counts as low as  $25 \times 10^9/L$ ,”* said Barbara Klencke, MD, Chief Medical Officer at Sierra Oncology. *“Together, these abstracts demonstrate the true potential use of momelotinib as the treatment of choice across a range of myelofibrosis patients who are symptomatic and cytopenic, including those with anemia and thrombocytopenia.”*

### **Abstract: 7002: MOMENTUM: Phase 3 Randomized Study of Momelotinib (MMB) versus Danazol (DAN) in Symptomatic and Anemic Myelofibrosis (MF) Patients Previously Treated with a JAK Inhibitor**

The primary and all key secondary results, as well as safety data, from the MOMENTUM pivotal Phase 3 trial of momelotinib will be presented in an oral presentation by Ruben Mesa, MD, co-Principal Investigator of the study. Key data to be presented include:

- Primary Endpoint of Total Symptom Score (TSS) of  $\geq 50\%$ : 25% in the MMB arm vs. 9% in the control arm ( $p=0.0095$ )
- Secondary Endpoint of Transfusion Independence (TI): 31% in the MMB arm vs. 20% in the control arm (one-sided  $p=0.0064$ ; non-inferiority)
- Secondary Endpoint of Splenic Response Rate (SRR)  $\geq 35\%$ : 23% in the MMB arm vs. 3% in the control arm ( $p=0.0006$ )
  - SRR of  $\geq 25\%$  was 40% in the MMB arm and 6% in the control arm
- A trend toward improved overall survival is demonstrated in the MMB arm based on data up to Week 24 ( $p=0.0719$ ) and overall ( $p=0.3510$ )



- The rate of Grade 3 or worse adverse events in the randomized treatment period was 54% in the MMB arm and 65% in the control arm. Serious treatment emergent adverse events were 35% in the MMB arm and 40% in the control arm. The most frequent non-hematologic adverse events were diarrhea, nausea, asthenia, pruritis and increased blood creatinine
- Mean baseline characteristics for all patients were TSS of 27, Hemoglobin (Hgb) of 8 g/dL and platelet count of  $145 \times 10^9/L$

***Abstract 7061: Thrombocytopenic Myelofibrosis (MF) Patients Previously Treated with a JAK Inhibitor in a Phase 3 Randomized Study of Momelotinib (MMB) versus Danazol (DAN) [MOMENTUM]***

Abstract 7061 will highlight an analysis of MOMENTUM patients with baseline platelet counts as low as  $25 \times 10^9/L$  on study endpoints, including Week 24 TSS reduction of  $\geq 50\%$  from baseline, transfusion independence rates, and SRR of  $\geq 35\%$  from baseline. Results to be presented include:

- Of the 195 patients enrolled in the MOMENTUM study, 124, 100 and 31 patients had baseline platelet counts of less than 150, 100, and  $50 \times 10^9/L$ , respectively.
- In patients with baseline platelets  $<100 \times 10^9/L$  (MMB: n=66; DAN: n=34): TSS responder proportion was 29% in the MMB arm and 15% in the control arm; TI response proportion was 27% in the MMB arm and 21% in the control arm; SRR was 20% in the MMB arm and 6% in the control arm
- In patients with baseline platelets  $<50 \times 10^9/L$  (MMB: n=18; DAN: n=13): TSS responder proportion was 22% in the MMB arm and 8% in the control arm; TI response proportion was 17% in the MMB arm and 15% in the control arm; SRR was 22% in the MMB arm and 0% in the control arm
- The broader thrombocytopenic subgroup with baseline platelets  $<150 \times 10^9/L$  demonstrated similar efficacy and safety as described in the published abstract
- In patients with baseline platelets below  $50 \times 10^9/L$ , mean platelet levels remained stable over time in both the MMB and control arms
- Overall Survival directionally favored the MMB arm, consistent with the survival results in the intent-to-treat population
- The proportion of patients who experience Grade 3 or higher treatment-emergent adverse events were comparable between the study arms
- Mean baseline characteristics for patients with baseline platelets  $<100 \times 10^9/L$  included TSS of 28 and 25 and Hgb of 8.1 and 7.8 g/dL for the MMB and control arms, respectively.

In thrombocytopenic, symptomatic and anemic patients with myelofibrosis, including those with platelets as low as  $25 \times 10^9/L$ , momelotinib was administered safely and demonstrated improvements in symptom responses, transfusion independence rates and spleen responses as compared to danazol. Consistent with the overall intent-to-treat MOMENTUM population, platelets levels remained stable over time, survival favored momelotinib versus danazol, and the safety profile was generally maintained in thrombocytopenic myelofibrosis patients receiving momelotinib.

*Presentation Details*



### **Abstract 7002**

*Title:* MOMENTUM: Phase 3 Randomized Study of Momelotinib (MMB) versus Danazol (DAN) in Symptomatic and Anemic Myelofibrosis (MF) Patients Previously Treated with a JAK Inhibitor

*Presenter:* Ruben Mesa, MD, FACP, Executive Director of the Mays Cancer Center, home to UT Health San Antonio, MD Anderson Cancer Center

*Session Title:* Oral Abstract Session: Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allograft

*Presentation Date and Time:* Tuesday, June 7, 2022, 10:33 am CT

### **Abstract 7061**

*Title:* Thrombocytopenic Myelofibrosis (MF) Patients Previously Treated with a JAK Inhibitor in a Phase 3 Randomized Study of Momelotinib (MMB) versus Danazol (DAN) [MOMENTUM]

*Presenter:* Aaron Gerds, MD, MS, Taussig Cancer Institute, Cleveland Clinic

*Session Title:* Hematologic Malignancies—Leukemia, Myelodysplastic Syndromes, and Allograft

*Session Date and Time:* Saturday, June 4, 2022, 8:00 am – 11:00 am CT

### **About Momelotinib**

Momelotinib is a potent, selective and orally bioavailable ACVR1 / ALK2, JAK1, JAK2 inhibitor under investigation for the treatment of myelofibrosis in symptomatic, anemic patients previously treated with an approved JAK inhibitor. More than 1,200 subjects have received momelotinib since clinical studies began in 2009, including approximately 1,000 patients treated for myelofibrosis, several of whom remain on treatment for over 11 years. Momelotinib is the first and only JAK inhibitor to demonstrate positive data for all key hallmarks of the disease—symptoms, splenic response and anemia.

### **About Myelofibrosis**

Myelofibrosis is a rare blood cancer that results from dysregulated JAK-STAT signaling and is characterized by constitutional symptoms, splenomegaly (enlarged spleen) and progressive anemia. From prior studies with momelotinib, we know approximately half of myelofibrosis patients are moderately to severely anemic when eligible for JAK inhibitor treatment. Furthermore, currently approved JAK inhibitors only address symptoms and splenomegaly and are myelosuppressive. This can lead to worsening anemia, resulting in dose reductions that potentially reduce treatment effect.

### **About the Pivotal MOMENTUM Clinical Trial**

MOMENTUM is a global, randomized, double-blind Phase 3 clinical trial of momelotinib versus danazol in patients with myelofibrosis who were symptomatic and anemic, and had been previously treated with an FDA-approved JAK inhibitor. The study was designed to evaluate the safety and efficacy of momelotinib for the treatment and reduction of the key hallmarks of disease: symptoms, blood transfusions (due to anemia) and splenomegaly (enlarged spleen).

The primary endpoint of the study is Total Symptom Score (TSS) reduction of  $\geq 50\%$  over the 28 days immediately prior to the end of Week 24 compared to baseline TSS, using the Myelofibrosis Symptom Assessment Form (MFSAF). Secondary endpoints included Transfusion Independence (TI) rate for  $\geq 12$  weeks immediately prior to the end of Week 24 with Hgb levels  $\geq 8$  g/dL, and



Splenic Response Rate (SRR) based on splenic volume reduction of  $\geq 35\%$  at Week 24. The study enrolled 195 patients based on a planned 180 patients across 21 countries.

Danazol was selected as the treatment comparator given its use to ameliorate anemia in patients with myelofibrosis, as recommended by National Comprehensive Cancer Network (NCCN) and European Society of Medical Oncology (ESMO) guidelines. Patients were randomized 2:1 (MMB n = 130 and DAN n = 65) to receive either momelotinib or danazol. After 24 weeks of treatment, patients on danazol were allowed to crossover to receive momelotinib. Early cross-over to momelotinib was available for confirmed symptomatic splenic progression.

### **About Sierra Oncology**

Sierra Oncology is a late-stage biopharmaceutical company on a mission to deliver targeted therapies that treat rare forms of cancer. We harness our deep scientific expertise to identify compounds that target the root cause of disease to advance targeted therapies with assets on the leading edge of cancer biology. Our team takes an evidence-based approach to understand the limitations of current treatments and explore new ways to change the cancer treatment paradigm. Together we are transforming promise into patient impact.

For more information, visit [www.SierraOncology.com](http://www.SierraOncology.com).

### **Cautionary Note on Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements regarding Sierra Oncology's expectations regarding the potential and future success of momelotinib. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These statements are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those described in the forward-looking statements. Such forward-looking statements are subject to risks and uncertainties, including, among others, the risk that Sierra Oncology may be unable to successfully commercialize momelotinib, Sierra Oncology's third-party manufacturers may cause its supply of materials to become limited or interrupted or fail to be of satisfactory quantity or quality, Sierra Oncology may be unable to obtain and enforce intellectual property protection for its technologies and momelotinib and the other factors described under the heading "Risk Factors" set forth in Sierra Oncology's filings with the Securities and Exchange Commission from time to time. Sierra Oncology undertakes no obligation to update the forward-looking statements contained herein or to reflect events or circumstances occurring after the date hereof, other than as may be required by applicable law.

### **For further information:**

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