# GSK reaches agreement to acquire late-stage biopharmaceutical company Sierra Oncology for \$1.9bn

GSK

PUBLISHED APR 13, 2022 BY GSK

For media and investors only

Issued: 13 April 2022, London UK

- Sierra Oncology's differentiated momelotinib has the potential to address the critical unmet medical needs of myelofibrosis patients with anaemia
- Momelotinib complements GSK's existing expertise in haematology, with Sierra Oncology anticipating US regulatory submission in Q2 this year and EU submission in the second half of 2022
- Sales contribution expected to start in 2023 with significant growth potential thereafter
- Supports development of strong portfolio of new specialty medicines and vaccines

GlaxoSmithKline plc (LSE/NYSE: GSK) and Sierra Oncology, Inc (Nasdaq: SRRA) today announced that the companies have entered into an agreement under which GSK will acquire Sierra Oncology, a California-based, late-stage biopharmaceutical company focused on targeted therapies for the treatment of rare forms of cancer, for \$55 per share of common stock in cash representing an approximate total equity value of \$1.9 billion (£1.5 billion).

Myelofibrosis is a fatal cancer of the bone marrow impacting the normal production of blood cells. Anaemia represents a high unmet medical need in patients with myelofibrosis. At diagnosis, approximately 40% of patients are already anaemic, and it is estimated that nearly all patients will eventually develop anaemia.,

Patients treated with the most commonly used JAK inhibitor will often require transfusions, and more than 30% will discontinue treatment due to anaemia. Anaemia and transfusion dependence are strongly correlated with poor prognosis and decreased overall survival.

Momelotinib has a differentiated mode of action with inhibitory activity along key signalling pathways. This activity may lead to beneficial treatment effects on anaemia and reduce the need for transfusions while also treating symptoms. In January 2022, Sierra Oncology announced positive topline results from the MOMENTUM phase III trial. The study met all its primary and key secondary endpoints, demonstrating that momelotinib achieved a statistically significant and clinically meaningful benefit on symptoms, splenic response, and anaemia.

Luke Miels, Chief Commercial Officer, GSK said:

Sierra Oncology complements our commercial and medical expertise in haematology. Momelotinib offers a differentiated treatment option that could address the significant unmet medical needs of myelofibrosis patients with anaemia, the major reason patients discontinue treatment. With this proposed acquisition, we have the opportunity to potentially bring meaningful new benefits to patients and further strengthen our portfolio of specialty medicines.

Stephen Dilly, MBBS, PhD, President and Chief Executive Officer, Sierra Oncology said:

Uniting with GSK creates the best opportunity for Sierra Oncology to realise its mission of delivering targeted therapies that treat rare forms of cancer while also delivering compelling and certain value for our stockholders. Now we have a partner with a global infrastructure and oncology expertise that enables us to deliver momelotinib to patients as quickly as possible and on a global scale.

Momelotinib complements GSK's Blenrep (belantamab mafodotin), building on GSK's commercial and medical expertise in haematology. The proposed acquisition aligns with GSK's strategy of building a strong portfolio of new specialty medicines and vaccines. If the transaction is completed and momelotinib is approved by regulatory authorities, GSK expects momelotinib will contribute to GSK's growing

specialty medicines business, with sales expected to begin in 2023, with significant growth potential and a positive benefit to the Group's adjusted operating margin in the medium term.

Under the terms of the agreement, the acquisition will be effected through a one-step merger in which the shares of Sierra Oncology outstanding will be cancelled and converted into the right to receive \$55 per share in cash. Subject to customary conditions, including the approval of the merger by at least a majority of the issued and outstanding shares of Sierra Oncology, and the expiration or earlier termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, the transaction is expected to close in the third quarter of 2022 or before.

The per share price represents a premium of approximately 39 per cent to Sierra Oncology's closing stock price on 12 April 2022 and a premium of approximately 63 per cent to Sierra's volume-weighted average price (VWAP) over the last 30 trading days. Sierra Oncology's Board of Directors has unanimously recommended that Sierra's stockholders vote in favour of the approval of the merger. Additionally, stockholders of Sierra Oncology holding approximately 28 per cent of Sierra's outstanding shares, have agreed to vote their shares in favour of approval of the merger.

GSK will account for the transaction as a business combination and expects it to be accretive to adjusted EPS in 2024, the expected first full year of momelotinib's sales. New GSK reaffirms its full-year 2022 guidance, the medium-term outlook for 2021-2026 of more than 5% sales and 10% adjusted operating profit CAGR\* at CER\*\*, and long-term sales ambition.

The value of the gross assets of Sierra Oncology to be acquired (as of 31 December 2021) is \$109 million (£83 million at the rate of £1 = \$1.312, being the 31 March 2022 spot rate). The net losses of the business were \$95 million for the 12 months ended 31 December 2021 (£70 million, at the rate of £1 = \$1.38, being the average rate for the period).

\* CAGR: Compound Annual Growth Rate; \*\*CER: Constant Exchange Rate

PJT Partners is acting as financial advisor and Cleary Gottlieb Steen & Hamilton LLP is serving as legal counsel to GSK in connection with

the transaction. Lazard is acting as financial advisor and Wilson Sonsini Goodrich & Rosati, is serving as legal counsel to Sierra Oncology.

Sierra Oncology is a late-stage biopharmaceutical company based in San Mateo, California, on a mission to deliver targeted therapies that treat rare forms of cancer. In addition to momelotinib, the pipeline consists of two assets in phase I SRA515 and SRA737. SRA515 is a selective bromodomain-containing protein 4 (BRD4) bromodomain and extra-terminal domain (BET) inhibitor with a novel bivalent binding mode that inhibits both protein bromodomains, and SRA737 is a novel checkpoint kinase 1 (CHK1) inhibitor.

Myelofibrosis is a fatal disorder of the bone marrow where fibrous scar tissue gradually replaces normal bone marrow, limiting its ability to make blood cells (haematopoiesis). This may cause anaemia (reduced red blood cells), leading to shortness of breath or fatigue; increased risk of infection due to decreased white blood cells; or increased risk of bleeding or bruising due to reduced platelet counts. Organs such as the spleen or liver may start to produce blood cells. This is known as extramedullary haematopoiesis, which causes splenomegaly or hepatomegaly (enlarged spleen or liver). Myelofibrosis affects approximately 20,000 patients in the US.

Momelotinib has a differentiated mode of action with inhibitory ability along three key signalling pathways: activin A receptor, type I (ACVR1)/activin receptor-like kinase-2 (ALK2), Janus kinase (JAK) 1, and JAK2. This activity may lead to beneficial treatment effects on anaemia and reduce transfusion dependence while treating myelofibrosis symptoms and splenic response.

## About the MOMENTUM phase III trial

MOMENTUM is a global, randomised, double-blind phase III clinical trial of momelotinib versus danazol in patients with myelofibrosis. Patients were symptomatic and anaemic 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 the disease: symptoms, blood transfusions (due to anaemia) and splenomegaly.

The primary endpoint of the study was a Total Symptom Score (TSS) reduction of ≥50% over the 28 days immediately before the end of

Week 24 compared to baseline TSS, using the Myelofibrosis Symptom Assessment Form (MFSAF). Secondary endpoints included Transfusion Independence (TI) rate for ≥12 weeks immediately before the end of Week 24 with maintained haemoglobin levels ≥ 8 g/dL and Splenic Response Rate (SRR) based on splenic volume reduction of ≥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 anaemia in patients with myelofibrosis, as recommended by the National Comprehensive Cancer Network (NCCN) and the European Society of Medical Oncology (ESMO) guidelines. Patients were randomized 2:1 (momelotinib n = 130 and DAN n = 65) to receive either momelotinib or danazol. After 24 weeks of treatment, patients on danazol were allowed to cross over to receive momelotinib. Early cross over to momelotinib was available for confirmed symptomatic splenic progression.

In January 2022, Sierra Oncology reported top-line results from the MOMENTUM phase III trial showing that the study met the primary endpoint of TSS reduction of ≥50% with 25% in the momelotinib arm versus 9% in the control arm (p=0.0095). Additionally, the trial met its secondary endpoints of TI with 31% in the momelotinib arm versus 20% in the control arm (one-sided p=0.0064; non-inferiority) and SRR based on splenic volume reduction of ≥35% with 23% in the momelotinib arm versus 3% in the control arm (p=0.0006). Grade 3 or worse adverse events in the randomised treatment period were 54% in the momelotinib arm and 65% in the control arm. Serious treatment-emergent adverse events were 35% in the momelotinib arm and 40% in the control arm.

These data will support Sierra Oncology's planned regulatory submissions with health authorities. The complete data from the MOMENTUM phase III trial will be presented at a forthcoming medical conference.

Additional information and where to find it

This communication is being made in respect of the proposed acquisition of Sierra Oncology, Inc. ("Sierra") by GlaxoSmithKline plc ("GSK"). In connection with the proposed acquisition, Sierra intends to file with the Securities and Exchange Commission (the "SEC") and mail to its stockholders a proxy statement (the "Proxy Statement") in

connection with the solicitation of proxies to approve the transaction. Sierra's stockholders are urged to read the Proxy Statement and any other relevant documents filed with the SEC or delivered to Sierra's stockholders in connection with the transaction when such materials become available because they will contain important information about the transaction and the parties to the transaction. The Proxy Statement and all other documents filed by or caused to be filed by Sierra with the SEC will be available at no charge on the SEC's website at <a href="https://www.sec.gov">www.sec.gov</a>. You may read and copy those documents or other information filed by Sierra at the SEC public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-0330 for further information on the public reference room. A free copy of the Proxy Statement and all other documents filed by or caused to be filed by Sierra with the SEC will also be available by visiting Sierra's website (<a href="https://www.sierraoncology.com">https://www.sierraoncology.com</a>).

### Participants in the Solicitation

Sierra, GSK, and certain of their respective directors and executive officers may be deemed to be participants in the solicitation of proxies from Sierra's stockholders with respect to the proposed acquisition. Information about Sierra's directors and executive officers is available in Sierra's proxy statement dated April 23, 2021 for its 2021 Annual Meeting of Stockholders. Information about GSK's directors and executive officers can be found in GSK's Annual Report on Form 20-F for 2021. Other information regarding the participants in the proxy solicitation and a description of their direct and indirect interests, by security holdings or otherwise, will be contained in the Proxy Statement and all other relevant materials to be filed with the SEC or delivered to Sierra's stockholders regarding the proposed combination when such materials become available. Sierra's stockholders are urged to read such materials when they become available

Cautionary statement regarding forward-looking statements

GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described in GSK's Annual Report on Form 20-F for 2021 and any impacts of the COVID-19 pandemic.

Definitions of Adjusted results, CER growth, CAGR and new GSK are set out on pages 61 and 62 of GSK's fourth quarter 2021 earnings release and pages 56 and 59 of the GSK 2021 Annual Report. The assumptions and basis for GSK's Guidance and Outlook are set out on page 69 of the GSK 2021 Annual Report.

This communication includes forward-looking statements related to Sierra, momelotinib and the acquisition of Sierra by GSK, that are subject to risks, uncertainties and other factors. All statements other than statements of historical fact are statements that could be deemed forward-looking statements, including all statements regarding the intent, belief or current expectation of Sierra and members of its senior management team and can typically be identified by words such as "believe," "expect," "estimate," "predict," "target," "potential," "likely," "continue," "ongoing," "could," "should," "intend," "may," "might," "plan," "seek," "anticipate," "project" and similar expressions, as well as variations or negatives of these words. Forward-looking statements include, without limitation, statements regarding the business combination, similar transactions, prospective performance, future plans, events, expectations, performance, objectives and opportunities and the outlook for Sierra's business; the commercial success of Sierra's products; the anticipated timing of clinical data and regulatory filings or approvals relating to products; the possibility of favourable or unfavourable results from clinical trials; the anticipated benefits of the acquisition; filings and approvals relating to the transaction; the expected timing of the completion of the transaction; the parties' ability to complete the transaction; and the accuracy of any assumptions underlying any of the foregoing. Investors are cautioned that any such forward-looking statements are not guarantees of future performance and involve risks and uncertainties and are cautioned not to place undue reliance on these forward-looking statements. Actual results may differ materially from those currently anticipated due to a number of risks and uncertainties. Risks and uncertainties that could cause the actual results to differ from expectations contemplated by forward-looking statements include: uncertainties as to the timing of the completion of the merger; the possibility that various closing conditions for the transaction may not be satisfied or waived, including that the required approval of Sierra's stockholders may not be obtained or that required regulatory approvals may not be obtained or are obtained subject to conditions that are not anticipated; the occurrence of any event, change or other circumstance that could give rise to the termination of the merger

agreement; the failure to realize anticipated benefits of the proposed acquisition when expected or at all; potential adverse reactions or changes to business relationships resulting from the proposed acquisition, including the effect of the announcement on the ability of Sierra to retain and hire key personnel; risks that the proposed acquisition disrupts the current plans and operations of Sierra; transaction costs; risks associated with potential litigation related to the transaction; and other risks and uncertainties described from time to time in documents filed with the SEC by Sierra, including current reports on Form 8-K, quarterly reports on Form 10-Q and annual reports on Form 10-K, as well as the proxy statement to be filed by Sierra, or in GSK's Annual Report on Form 20-F for 2021 filed with the SEC by GSK. All forward-looking statements are based on information currently available to GSK and Sierra, and neither GSK nor Sierra assumes any obligation to update any forward-looking statements.

GSK is a science-led global healthcare company. For further information please visit <a href="https://www.gsk.com/about-us">www.gsk.com/about-us</a>.

Naymagon L et al. HemaSphere (2017) 1:1(e1)

Ruxolitinib discontinuation syndrome: incidence, risk factors, and management in 251 patients with myelofibrosis | Blood Cancer Journal (nature.com)

Prognostic relevance of anemia and transfusion dependency in myelodysplastic syndromes and primary myelofibrosis - PMC (nih.gov)

Press release distributed by Wire Association on behalf of GSK, on Apr 13, 2022. For more information subscribe and follow us.

# **Media Assets**

# **Embedded Media**

Visit the online press release to interact with the embedded media.

https://wireassociation.eu/newsroom/gsk/releases/en/gsk-reachesagreement-to-acquire-late-stage-biopharmaceutical-company-sierra-

# **GSK**

Newsroom: <a href="https://wireassociation.eu/newsroom/gsk">https://wireassociation.eu/newsroom/gsk</a>

Website: https://www.gsk.com/

Primary Email: corporate.media@gsk.com

## **Social Media**

Facebook - <a href="https://www.facebook.com/GSK">https://www.facebook.com/GSK</a>

Twitter - <a href="http://twitter.com/GSK">http://twitter.com/GSK</a>

Youtube - <a href="http://www.youtube.com/GSK">http://www.youtube.com/GSK</a>

Linkedin - <a href="http://www.linkedin.com/company/glaxosmithkline">http://www.linkedin.com/company/glaxosmithkline</a>

Instagram - <a href="https://www.instagram.com/gsk/">https://www.instagram.com/gsk/</a>