



Sugemalimab Demonstrates Statistically Significant Overall Survival Benefit in Patients with Stage IV Non-Small Cell Lung Cancer

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- Pivotal Phase 3 GEMSTONE-302 trial met key secondary endpoint of prolongation of overall survival with sugemalimab plus chemotherapy versus placebo plus chemotherapy
- Overall survival benefit demonstrated regardless of tumor pathologic subtype or PD-L1 expression levels

CAMBRIDGE, Mass., Jan. 18, 2022 (GLOBE NEWSWIRE) -- [EQRx, Inc.](#) (Nasdaq: EQRX), a new type of pharmaceutical company committed to developing and delivering important new medicines to patients at radically lower prices, along with its partner CStone Pharmaceuticals, today announced that sugemalimab plus chemotherapy demonstrated a statistically significant improvement in overall survival (OS) compared to placebo plus chemotherapy as a first-line treatment for patients with Stage IV non-small cell lung cancer (NSCLC) in the randomized, double-blind Phase 3 GEMSTONE-302 study. These data were reported after a planned interim analysis for OS, a key secondary endpoint of the study. These results build on previously presented positive data from the GEMSTONE-302 study, which met the primary endpoint of progression-free survival (PFS) and were recently published in [The Lancet Oncology](#).¹

Clinical benefit was observed across subgroups, including patients with squamous and non-squamous subtypes, and regardless of PD-L1 expression levels. As previously reported, the safety profile of sugemalimab was consistent with that of the PD-1/PD-L1 class.¹

"We are highly encouraged to see that sugemalimab in combination with chemotherapy demonstrates significant clinical benefit, including improvement in both PFS and OS, when compared to placebo plus chemotherapy across a broad spectrum of patients with Stage IV non-small cell lung cancer in this Phase 3 study," said Vince Miller, MD, physician-in-chief at EQRx. "Price remains a barrier to accessing innovative therapies for many people with lung cancer around the world, despite the availability of multiple anti-PD-(L)1 therapies. We look forward to engaging with global regulatory authorities with the aim of delivering a lower-cost treatment option to patients upon approval."

Detailed results will be submitted for presentation at a future medical congress.

In addition to the ongoing GEMSTONE-302 study, the companies are investigating sugemalimab as a consolidation therapy in patients with locally advanced, unresectable Stage III NSCLC without disease progression after either concurrent or sequential chemoradiotherapy in the pivotal Phase 3 GEMSTONE-301 study. Positive PFS data from GEMSTONE-301 were also presented at ESMO 2021 and recently published in [The Lancet Oncology](#).^{2,3,4}

About Lung Cancer

Every 15 seconds, a person across the world is diagnosed with lung cancer, and every 18 seconds, a person dies of the disease, making it the second most commonly diagnosed cancer and leading cause of cancer deaths worldwide. In 2020, an estimated 2.2 million people were diagnosed with lung cancer.⁵ NSCLC is the most common type of lung cancer, accounting for 84% of all lung cancer diagnoses.⁶

About GEMSTONE-302

GEMSTONE-302 (NCT03789604) is a randomized, double-blind, Phase 3 study designed to evaluate the efficacy and safety of sugemalimab or placebo in combination with carboplatin-based chemotherapy as a first-line treatment in patients with Stage IV squamous or non-squamous NSCLC. The study was conducted in China by CStone Pharmaceuticals and included 479 patients, who were randomized to either the sugemalimab group (n=320) or the placebo group (n=159). The primary endpoint was investigator-assessed PFS. Secondary endpoints include blinded independent central review (BICR)-assessed PFS, safety and OS. CStone Pharmaceuticals previously shared positive results of the final analysis of PFS, the primary endpoint of the study, from GEMSTONE-302 at the IASLC 2021 World Conference on Lung Cancer and results were recently published in [The Lancet Oncology](#).^{7,8}

About Sugemalimab

Sugemalimab is an investigational monoclonal antibody targeting programmed death-ligand 1 (PD-L1) discovered by CStone Pharmaceuticals. Authorized by the U.S.-based Ligand Corporation, sugemalimab is developed by the OmniRat[®] transgenic animal platform, which can generate fully human antibodies in one step. Currently, sugemalimab is being investigated in a number of ongoing clinical trials including one Phase 2 registration study in relapsed/refractory extranodal natural killer (NK)/T cell lymphoma (ENKTL) and four Phase 3 registration studies in Stage III NSCLC (GEMSTONE-301), Stage IV NSCLC (GEMSTONE-302), gastric cancer and esophageal cancer. Both the GEMSTONE-301 and GEMSTONE-302 studies met their primary endpoints of prolonged PFS, and results were recently presented at global medical congresses. In December 2021, the National Medical Products Administration (NMPA) of China approved the New Drug Application (NDA) for sugemalimab combined with chemotherapy for the first-line treatment of metastatic squamous and non-squamous NSCLC patients. In September 2021, the NDA for Stage III NSCLC was accepted by the NMPA. EQRx holds the development and commercialization rights to sugemalimab outside of Greater China. EQRx and CStone Pharmaceuticals have partnered to expand global access to sugemalimab, with plans to continue regulatory discussions in multiple countries.

About EQRx

EQRx is a new type of pharmaceutical company committed to developing and delivering innovative medicines to patients at radically lower prices. Launched in January 2020, EQRx is purpose-built, at scale, with a growing catalog of medicines in development in high-cost drug categories and emerging partnerships with leading payers and providers. Leveraging cutting-edge science and technology and strategic partnerships with

stakeholders from across the healthcare system, EQRx aims to provide innovative, patent-protected medicines more efficiently and cost-effectively than ever before. To learn more, visit www.eqr.com and follow us on social media: Twitter: [@EQRxInc](https://twitter.com/EQRxInc), [LinkedIn](https://www.linkedin.com/company/eqr), Instagram: [@eqrinc](https://www.instagram.com/eqrinc).

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Cautionary Statement Regarding Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of the federal securities laws. These forward-looking statements may be identified by the use of words such as “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “design,” “strategy,” “future,” “opportunity,” “continue,” “aim,” “plan,” “may,” “look forward,” “should,” “will,” “would,” “will be,” “will likely result,” and similar expressions. These forward-looking statements include, but are not limited to, express or implied statements regarding EQRx’s ability to develop and deliver innovative medicines at radically lower prices, EQRx’s ability to expand its pipeline, plans and timelines for the clinical development of EQRx’s product candidates, including the therapeutic potential, clinical benefits and tolerability thereof, expectations regarding EQRx’s existing collaboration with CStone Pharmaceuticals, as well as other statements regarding plans and market opportunities of EQRx. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this press release, including but not limited to changes in the competitive and highly regulated industries in which EQRx operates, variations in operating performance across competitors, changes in laws and regulations affecting EQRx’s business, delay of any current and future clinical trials or the development of sugemalimab or EQRx’s other drug candidates, the risk that the results of prior clinical trials may not be predictive of future results in connection with future clinical trials, EQRx’s ability to successfully demonstrate the safety and efficacy of its drug candidates, the timing and outcome of EQRx’s planned interactions with regulatory authorities; obtaining, maintaining and protecting its intellectual property, EQRx’s relationships with CStone Pharmaceuticals and its other existing and future collaboration partners, risks associated with EQRx’s ability to otherwise implement its business plans, including risks associated with its growth strategy, obtaining regulatory approvals, and creating a global payer network, and other risks associated with its plans to create a new kind of pharmaceutical company, the risk of downturns and a changing regulatory landscape in the highly competitive healthcare and biopharmaceutical industries, the size and growth of the markets in which EQRx operates and its ability to offer innovative medicines at reduced prices, and EQRx’s ability to operate as a public company. The foregoing list of factors is not exhaustive. You should carefully consider the foregoing factors and the other risks and uncertainties described in the “Risk Factors” section of the prospectus dated December 23, 2021 and filed with the SEC under Rule 424(b) and other documents filed by EQRx from time to time with the SEC. These filings identify and address other important risks and uncertainties that could cause actual events and results to differ materially from those contained in the forward-looking statements. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and EQRx assumes no obligation and does not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise.

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References

¹ Zhou C, Wang Z, Sun Y, et al. Sugemalimab versus placebo, in combination with platinum-based chemotherapy, as first-line treatment of metastatic non-small-cell lung cancer (GEMSTONE-302): an interim and final analyses of a double-blind, randomised, phase 3 clinical trial. *The Lancet Oncology*. Published January 14, 2022. DOI: [https://doi.org/10.1016/S1470-2045\(21\)00650-1](https://doi.org/10.1016/S1470-2045(21)00650-1).

² EQRx Announces Presentation of Phase 3 Data Demonstrating a Progression-Free Survival Benefit with Sugemalimab Consolidation Therapy in Patients with Stage III NSCLC at ESMO Congress 2021. Press Release. September 17, 2021. Available here: <https://www.eqr.com/press-release/eqrx-announces-presentation-of-phase-3-data-demonstrating-a-progression-free-survival-benefit-with-sugemalimab-consolidation-therapy-in-patients-with-stage-iii-nsclc-at-esmo-congress-2021/>

³ Wu Y, Zhou Q, Chen M, et al. LBA43 - GEMSTONE-301: A randomized, double-blind, placebo-controlled, phase III study of sugemalimab in patients with unresectable stage III non-small cell lung cancer (NSCLC) who had not progressed after concurrent or sequential chemoradiotherapy (CRT). *ESMO 2021. Annals of Oncology* (2021) 32 (suppl_5): S1283-S1346. 10.1016/annonc/annonc741.

⁴ Zhou Q, Chen M, Jiang O, et al. Sugemalimab versus placebo after concurrent or sequential chemoradiotherapy in patients with locally advanced, unresectable, stage III non-small-cell lung cancer in China (GEMSTONE-301): interim analysis of a randomised, double-blind, multicentre, phase 3 trial. *The Lancet Oncology*. Published January 14, 2022. DOI: [https://doi.org/10.1016/S1470-2045\(21\)00630-6](https://doi.org/10.1016/S1470-2045(21)00630-6).

⁵ World Health Organization, International Agency for Research on Cancer. Globocan 2020: Lung Cancer. International Agency for Research on Cancer. Available here: <https://gco.iarc.fr/today/data/factsheets/cancers/15-Lung-fact-sheet.pdf>. Accessed January 18, 2022.

⁶ American Cancer Society, Key Statistics for Lung Cancer. Available here: <https://www.cancer.org/cancer/lung-cancer/about/key-statistics.html>. Accessed January 18, 2022.

⁷ EQRx Announces Presentation of Updated Data from Pivotal Phase 3 Study of Anti-PD-L1 Antibody Sugemalimab in Combination with Chemotherapy as a First-Line Treatment for Stage IV NSCLC. Press Release. September 13, 2021. Available here: <https://www.eqr.com/press-release/eqrx-announces-presentation-of-updated-data-from-pivotal-phase-3-study-of-anti-pd-l1-antibody-sugemalimab-in-combination-with-chemotherapy-as-a-first-line-treatment-for-stage-iv-nsclc/>

⁸ Zhou C, Wang Z, Sun Y, et al. GEMSTONE-302: Randomized, Double-Blind, Phase 3 Study of Sugemalimab or Placebo Plus Platinum-Based Chemotherapy as First-Line Treatment for Metastatic NSCLC. IASLC 2021 World Conference on Lung Cancer. MA13.07 Mon Sept 13. DOI: <https://doi.org/10.1016/j.jtho.2021.08.180>.

