

EQRx Announces Acceptance of Marketing Authorization Application by the UK's Medicines and Healthcare Products Regulatory Agency for Sugemalimab in Metastatic Non-small Cell Lung Cancer

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- Application is based on data from the pivotal Phase 3 GEMSTONE-302 trial assessing sugemalimab in combination with chemotherapy as first-line treatment of metastatic non-small cell lung cancer
- Acceptance of the marketing authorization application (MAA) is EQRx's second from the United Kingdom's Medicines and Healthcare products Regulatory Agency after acceptance of aumolertinib MAA earlier this year

[EQRx, Inc.](#) (Nasdaq: EQRX), a new type of pharmaceutical company committed to developing and expanding access to innovative medicines for some of the most prevalent disease areas, including cancer and immune-inflammatory conditions, today announced that the United Kingdom's (U.K.) Medicines and Healthcare products Regulatory Agency (MHRA) has accepted for review its marketing authorization application (MAA) for sugemalimab, an anti-programmed death-ligand 1 (PD-L1) antibody, in combination with chemotherapy for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC).

“With the acceptance of this application, we now have two investigational therapies under review with the MHRA in non-small cell lung cancer, which affects about 40,000 people annually in the U.K. and is a leading cause of cancer death,” said Melanie Nallicheri, president and chief executive officer of EQRx. “This significant milestone is a step toward our goal of getting our medicines to patients and delivering on our mission of increasing access to impactful treatments.”

The MAA is primarily supported by data from the pivotal Phase 3 GEMSTONE-302 trial, conducted by EQRx's partner CStone Pharmaceuticals, that evaluated treatment with sugemalimab in combination with chemotherapy in patients with metastatic NSCLC.

In 2021, sugemalimab was granted the Innovation Passport designation in the U.K. through the Innovative Licensing and Access Pathway (ILAP) from the ILAP partner organizations including the MHRA. The ILAP was established in early 2021 to accelerate the development of and access to medicines in the U.K.

About Sugemalimab

Sugemalimab is a monoclonal antibody targeting programmed death-ligand 1 (PD-L1) that is under investigation in several ongoing clinical trials, including studies in relapsed or refractory extranodal natural killer/T cell lymphoma (ENKTL), Stage III non-small cell lung cancer (NSCLC), Stage IV NSCLC, gastric cancer and esophageal cancer. In October of 2020, the U.S. Food and Drug Administration (FDA) granted sugemalimab Breakthrough Therapy designation for the treatment of adult patients with relapsed or refractory ENKTL.

Sugemalimab is approved by the National Medical Products Administration (NMPA) of China for the treatment of patients with unresectable Stage III NSCLC whose disease has not progressed following concurrent or sequential platinum-based chemoradiotherapy and in combination with chemotherapy for the first-line treatment of patients with metastatic squamous and non-squamous NSCLC. Sugemalimab was discovered by CStone Pharmaceuticals, and EQRx has partnered with CStone Pharmaceuticals on the global development of sugemalimab with the goal of expanding access worldwide. EQRx holds the development and commercialization rights to sugemalimab outside of Greater China.

About GEMSTONE-302

GEMSTONE-302 ([NCT03789604](#)) is a randomized, double-blind, Phase 3 study designed to evaluate the efficacy and safety of sugemalimab versus placebo in combination with carboplatin-based chemotherapy as a first-line treatment for patients with Stage IV squamous or non-squamous non-small cell lung cancer (NSCLC). The study was conducted by CStone Pharmaceuticals and included 479 patients who were randomized to either the sugemalimab group (n=320) or the placebo group (n=159). The study met its primary endpoint, demonstrating statistically significant improvement in investigator-assessed progression-free survival (PFS) with sugemalimab plus chemotherapy compared to placebo plus chemotherapy.¹ Secondary endpoints include overall survival, PFS in patients with PD-L1 ≥1% (assessed by the investigators), PFS as assessed by blinded independent central review (BICR), objective response rate (assessed by the investigators), duration of response and safety. In 2022, results from GEMSTONE-302 were published in *The Lancet Oncology* and favorable data on overall survival, a pre-specified secondary endpoint, were presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting.[\[1\]](#),[\[2\]](#)

-About EQRx

EQRx is a new type of pharmaceutical company committed to developing and expanding access to innovative medicines for some of the most prevalent disease areas, including cancer and immune-inflammatory conditions. Launched in January 2020, EQRx is leveraging cutting-edge science, technology and strategic partnerships with stakeholders from across the healthcare system toward the goal of increasing access for patients around the world. To learn more, visit www.eqr.com and follow us on social media: Twitter: [@EQRx_GLOBAL](#), [LinkedIn](#), Instagram: [@eqrxinc](#).

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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,” “goal,” “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 obtaining regulatory approval for sugemalimab, the potential of sugemalimab as a treatment option for NSCLC and other diseases, EQRx’s ability to expand access to sugemalimab worldwide with its partner CStone Pharmaceuticals, and EQRx’s ability to develop and deliver innovative medicines to patients and increase access to impactful treatments. 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 the inherent risks in pharmaceutical development, including with respect to the conduct of clinical trials and risk of delays; risks that the results of prior clinical trials may not be predictive of future results or that additional clinical trials become necessary due to changes in standard of care; risks associated with successfully demonstrating the safety and efficacy of sugemalimab and its other drug candidates and obtaining regulatory approvals; EQRx’s ability to obtain, maintain and protect its intellectual property; expectations regarding EQRx’s existing collaborations 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 and expanding and maintaining the Global Buyers Club, particularly in light of its recent determination to adopt a market based pricing strategy in the U.S. for certain pipeline candidates; variations in operating performance across competitors; changes in the competitive and highly regulated industries in which EQRx operates, including laws and regulations affecting EQRx’s business, such as the recently enacted Inflation Reduction Act; and other risks associated with its plans to create a new kind of pharmaceutical company, among others. 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 in EQRx’s most recent Annual Report on Form 10-K as well as any other filings 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.

Investors and others should note that we communicate with our investors and the public using our website www.eqr.com, including, but not limited to, company disclosures, investor presentations and FAQs, SEC filings, press releases, public conference call transcripts and webcast transcripts. The information that we post on our website could be deemed to be material information. As a result, we encourage investors, the media and other interested parties to review the information that we post there on a regular basis. The contents of our website shall not be deemed incorporated by reference in any filing with the SEC.

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[1] Zhou, Caicun et al. Sugemalimab versus placebo, in combination with platinum-based chemotherapy, as first-line treatment of metastatic non-small-cell lung cancer (GEMSTONE-302): interim and final analyses of a double-blind, randomised, phase 3 clinical trial. *The Lancet Oncology*. 2022;23:220-233.

[2] Zhou, Caicun et al. A protocol pre-specified interim overall survival (OS) analysis of GEMSTONE-302: A phase 3 study of sugemalimab (suge) versus placebo plus platinum-based chemotherapy (chemo) as first-line (1L) treatment for patients (pts) with metastatic non-small cell lung cancer. Poster presentation at ASCO 2022. Abstract #9027, ASCO 2022.