

EQRx Announces Acceptance of Marketing Authorization Application by the European Medicines Agency for Aumolertinib in EGFR-Mutated Non-small Cell Lung Cancer

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- Submission is EQRx's first to European Medicines Agency
- Application is based on data from the pivotal Phase 3 AENEAS trial evaluating aumolertinib as first-line treatment of patients with EGFR-mutated non-small cell lung cancer

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 European Medicines Agency (EMA) has accepted for review its marketing authorization application (MAA) for aumolertinib, a third-generation epidermal growth factor receptor (EGFR)-tyrosine kinase inhibitor (TKI) in development for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGFR mutations, and for adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC.

“This acceptance is an important milestone for aumolertinib, and for EQRx, as we focus on improving and broadening patient access to today’s therapeutic innovations within this class of medicines,” said Melanie Nallicheri, president and chief executive officer of EQRx. “The European Medicines Agency engages with 27 member states to ensure that the needs and concerns of a wide range of patients, including approximately 60,000 European patients who may be diagnosed with EGFR-mutated non-small cell lung cancer annually, are represented. We believe that, if approved, aumolertinib can provide an additional and potentially differentiated option for patients in Europe with this form of lung cancer, and we look forward to working with the EMA as it conducts its review.”

In 2020, lung cancer was the third most diagnosed cancer in Europe and the leading cause of cancer-related mortality, accounting for one fifth of cancer deaths.^[1] Globally, it is estimated that almost a third of patients with NSCLC, which accounts for approximately 85% of all lung cancers, have EGFR mutations.^[2]

“For patients with locally advanced or metastatic non-small cell lung cancer with EGFR mutations, third generation EGFR-tyrosine kinase inhibitors have become the standard of

care in many places worldwide,” said Vince Miller, MD, physician-in-chief at EQRx. “However, these treatments are often not easily attainable for patients, and there remains a need for additional third-generation EGFR TKIs to increase treatment options and improve access to therapies for people with non-small cell lung cancer.”

The MAA is primarily supported by data from the pivotal Phase 3 AENEAS trial evaluating aumolertinib in the first-line treatment of locally advanced or metastatic EGFR-mutated NSCLC. [3]

This is EQRx’s second submission to a regulatory agency for aumolertinib. Aumolertinib’s MAA for use in EGFR-mutated non-small cell lung cancer is currently under review by the UK’s Medicines and Healthcare products Regulatory Agency.

About Aumolertinib

Aumolertinib is a third-generation, irreversible epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor (TKI) that targets both EGFR-sensitizing and T790M resistance mutations with high selectivity over wild-type EGFR. [4] Aumolertinib is being investigated in several ongoing clinical trials, including studies in first- and second-line EGFR-mutated non-small cell lung cancer (NSCLC). Aumolertinib is approved by the National Medical Products Administration (NMPA) of China for both first-line and second-line treatment of patients with locally advanced or metastatic EGFR-mutated NSCLC. Aumolertinib was discovered by Hansoh Pharmaceutical Group Company Limited (Hansoh Pharma), and EQRx has partnered with Hansoh Pharma on global development of aumolertinib with the goal of expanding access worldwide. EQRx holds the development and commercialization rights to aumolertinib outside of Greater China.

About the AENEAS Trial

AENEAS ([NCT03849768](#)) is a randomized, double-blind, multicenter, Phase 3 study designed to evaluate the efficacy and safety of aumolertinib versus gefitinib as first-line treatment for adults with locally advanced or metastatic EGFR-mutated non-small cell lung cancer (NSCLC). The study was conducted by Hansoh Pharma and enrolled 429 patients who were randomized to receive either aumolertinib (n=214) or gefitinib (n=215). The study met its primary endpoint, demonstrating statistically significant improvement in progression-free survival as compared to gefitinib. Secondary endpoints include overall survival, overall response rate and safety. Results from AENEAS were published in the *Journal of Clinical Oncology* in May 2022. [3]

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](#).

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 EMA approval of aumolertinib, aumolertinib’s potential as a treatment for NSCLC, UK approval of aumolertinib, and EQRx’s ability to expand access to innovative medicines, among others. 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 risks associated with successfully demonstrating the efficacy, safety and tolerability of aumolertinib and obtaining regulatory approvals therefor; risks related to the conduct of clinical trials, including delays of any current and future clinical trials; risks related to continued development of aumolertinib or EQRx’s other drug candidates; risks that the results of prior clinical trials may not be predictive of future results; EQRx’s ability to obtain, maintain and protect its intellectual property; expectations regarding EQRx’s existing collaborations with Hansoh Pharma and its other existing and future collaboration partners; risks associated with EQRx’s ability to otherwise implement its business plans; changes in the competitive and highly regulated industries in which EQRx operates, including laws and regulations affecting EQRx’s business; 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.

EQRx Contacts:

Media:

Dan Budwick

1AB

dan@1abmedia.com

Investors:

investors@eqr.com

[1]. Dyba T, et al. The European cancer burden in 2020: Incidence and mortality estimates for 40 countries and 25 major cancers. *Eur J Cancer*. 2021;157:308-347.

[2]. Zhang, et al. The prevalence of EGFR mutation in patients with non-small cell lung cancer: a systematic review and meta-analysis. *Oncotarget*. 2016;7:78985-78993.

[3]. Lu S, et al. AENEAS: A randomized phase III trial of aumolertinib versus gefitinib as first-line therapy for locally advanced or metastatic non-small-cell lung cancer with EGFR exon 19 deletion or L858R mutations. *J Clin Oncol*. 2022;40(27):3162-3171.

[4]. Lu S, et al. Efficacy of aumolertinib (HS-10296) in patients with advanced EGFR T790M+ NSCLC: updated post-national medical products administration approval results from the APOLLO registrational trial. *J Thorac Oncol*. 2022;17(3):411-422.