August 3, 2022

Syros Receives Positive Opinion on Orphan Drug Designation from the European Medicines Agency for Tamibarotene for the Treatment of MDS

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Syros Pharmaceuticals (NASDAQ:SYRS), a leader in the development of medicines that control the expression of genes, today announced that the European Medicines Agency (EMA) issued a positive opinion on the Company's application for orphan drug designation for tamibarotene for the treatment of myelodysplastic syndrome (MDS). Tamibarotene, an oral first-in-class selective retinoic acid receptor alpha (RARα) agonist, is currently being evaluated in combination with azacitidine in the SELECT-MDS-1 Phase 3 trial for RARA-positive patients with newly diagnosed higher-risk MDS (HR-MDS).

Previously, the U.S. Food and Drug Administration (FDA) granted orphan drug designation to tamibarotene in MDS in February 2022.

"We are pleased that the EMA has issued a positive opinion for orphan drug designation for tamibarotene as it represents an important milestone for MDS patients, who have an urgent need for effective, tolerable, and convenient treatment options," said David A. Roth, M.D., Syros' Chief Medical Officer. "We believe tamibarotene has the potential to change the current standard of care and become the first therapy for a targeted population in HR-MDS. We continue to advance our SELECT-MDS-1 trial and are looking forward to announcing pivotal data in late 2023 or early 2024."

Orphan drug designation in the European Union (EU) is granted by the European Commission based on a positive opinion issued by the EMA Committee for Orphan Medicinal Products. The EMA's orphan designation is available to companies developing treatments for life-threatening or chronically debilitating conditions that affect fewer than five in 10,000 persons in the EU. Medicines that meet the EMA's orphan designation criteria qualify for financial and regulatory incentives that include a 10-year period of marketing exclusivity in the EU after product approval, protocol assistance from the EMA at reduced fees during the product development phase and access to centralized marketing authorization.

The ongoing SELECT-MDS-1 Phase 3 clinical trial is evaluating the safety and efficacy of tamibarotene in combination with azacitidine for RARA-positive patients with newly diagnosed HR-MDS. Data from the pivotal trial are expected in the fourth quarter of 2023 or the first quarter of 2024, with a potential new drug application filing expected in 2024.

Syros is also evaluating tamibarotene in combination with azacitidine and venetoclax for RARA-positive patients with newly diagnosed unfit acute myeloid leukemia (AML), for which

tamibarotene had previously received orphan drug designation from both the FDA and EMA. Data from the safety lead-in portion of the SELECT-AML-1 Phase 2 trial is expected in the second half of this year.

About Syros Pharmaceuticals

Syros is redefining the power of small molecules to control the expression of genes. Based on its unique ability to elucidate regulatory regions of the genome, Syros aims to develop medicines that provide a profound benefit for patients with diseases that have eluded other genomics-based approaches. Syros is advancing a robust clinical-stage pipeline, including: tamibarotene, a first-in-class oral selective RARα agonist in RARA-positive patients with higher-risk myelodysplastic syndrome and acute myeloid leukemia; SY-2101, a novel oral form of arsenic trioxide in patients with acute promyelocytic leukemia; and SY-5609, a highly selective and potent oral CDK7 inhibitor in patients with select solid tumors. Syros also has multiple preclinical and discovery programs in oncology and monogenic diseases. For more information, visit www.syros.com and follow us on Twitter (@SyrosPharma) and LinkedIn.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995, including without limitation statements regarding Syros' clinical development plans with respect to tamibarotene, the potential of tamibarotene to benefit RARA-positive HR-MDS patients and to become the first approved therapy in a targeted population in HR-MDS, the timing of anticipated data readouts and potential regulatory submissions from Syros' clinical trials, and the potential for Syros's product candidates to obtain regulatory approval. In addition, a positive opinion from the EMA on Syros' application for orphan drug designation for tamibarotene for the treatment of MDS is not a guarantee of approval of an orphan drug designation. The words ''anticipate,'' ''believe,'' ''continue,'' ''could,'' ''estimate,'' ''expect,'' "hope," ''intend,'' ''may,'' ''plan,'' ''potential,'' ''predict,'' ''project,'' ''target,'' ''should,'' ''would,'' and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Actual results or events could differ materially from the plans, intentions and expectations disclosed in these forward-looking statements as a result of various important factors, including Syros' ability to: advance the development of its programs, including tamibarotene, under the timelines it projects in current and future clinical trials; demonstrate in any current and future clinical trials the requisite safety, efficacy and combinability of its drug candidates; sustain the response rates and durability of response seen to date with its drug candidates; successfully develop a companion diagnostic test to identify patients with the RARA biomarker; obtain and maintain patent protection for its drug candidates and the freedom to operate under third party intellectual property; obtain and maintain necessary regulatory approvals; identify, enter into and maintain collaboration agreements with third parties; manage competition; manage expenses; raise the substantial additional capital needed to achieve its business objectives; attract and retain qualified personnel; and successfully execute on its business strategies; risks described under the caption "Risk Factors" in Syros' Annual Report on Form 10-K for the year ended December 31, 2021 and Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, each of which is on file with the Securities and Exchange Commission; and risks described in other filings that Syros makes with the Securities and Exchange Commission in the future. In addition, the extent to which the COVID-19 pandemic continues to impact Syros' workforce

and its clinical trial operations activities, and the operations of the third parties on which Syros relies, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration and severity of the pandemic, additional or modified government actions, and the actions that may be required to contain the virus or treat its impact. Any forward-looking statements contained in this press release speak only as of the date hereof, and Syros expressly disclaims any obligation to update any forward-looking statements, whether because of new information, future events or otherwise.

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