September 13, 2022

Syros Receives FDA Orphan Drug Designation for SY-5609 for the Treatment of Pancreatic Cancer

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- Syros Pharmaceuticals, Inc. (NASDAQ:SYRS), a leader in the development of medicines that control the expression of genes, today announced that the U.S. Food and Drug Administration (FDA) has granted orphan drug designation (ODD) to SY-5609 for the treatment of pancreatic cancer. SY-5609, a highly selective and potent oral cyclin-dependent kinase 7 (CDK7) inhibitor, is currently being evaluated in combination with chemotherapy for the treatment of patients with relapsed metastatic pancreatic cancer.

“This orphan drug designation underscores the urgency of our efforts to develop SY-5609 for patients with pancreatic cancer, one of the most devastating and difficult to treat malignancies,” said David A. Roth, M.D., Chief Medical Officer of Syros. “Based on the early data we reported last year, which demonstrated single-agent activity in heavily pre-treated patients, as well as compelling preclinical data and a strong mechanistic rationale, we believe SY-5609 could deliver meaningful benefit to people with pancreatic cancer, whose tumors have otherwise eluded therapeutic intervention. We look forward to sharing initial data from the safety lead-in portion of our ongoing Phase 1 study later this year.”

The FDA's Office of Orphan Drug Products grants orphan status to support development of medicines for the treatment of rare diseases that affect fewer than 200,000 people in the United States. Orphan drug designation may provide certain benefits, including a seven-year period of market exclusivity if the drug is approved, tax credits for qualified clinical trials and an exemption from FDA application fees.

Syros’ ongoing Phase 1 trial is evaluating SY-5609 in combination with chemotherapy in pancreatic cancer patients who have progressed following treatment with FOLFIRINOX. Patients were randomized to receive either SY-5609 in combination with gemcitabine, or SY-5609 in combination with gemcitabine and nab-paclitaxel, at the approved doses of the combination agents. The study is assessing safety and tolerability, as well as efficacy measures such as disease control rate and progression free survival. Safety and clinical activity data from the safety lead-in portion of the trial are expected in the second half of 2022.

Under an existing clinical supply agreement with Roche, Syros is also supplying SY-5609 for a combination dosing cohort in Roche’s ongoing Phase 1/1b INTRINSIC trial. This cohort is evaluating the combination of SY-5609 and atezolizumab in patients with BRAF-mutant colorectal cancer. Roche is the sponsor of the INTRINSIC trial.

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 SY-5609, the potential of SY-5609 to deliver meaningful benefit to people with pancreatic cancer, 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. 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 June 30, 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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