Edison Oncology Completes Target Enrollment in Phase 1/2a Orotecan™ Clinical Trial

Menlo Park, CA – March 20, 2026 – Edison Oncology Holding Corp. ("Edison Oncology" or the "Company") today announced that it has completed target enrollment in its ongoing Phase 1/2a clinical trial (NCT04337177) evaluating Orotecan™, the Company's proprietary oral formulation of irinotecan designed for at-home administration, in adults and children recurrent or relapsed cancers.

Achievement of the enrollment target enables the Company to proceed with the pre-specified statistical evaluation of the study's safety and pharmacokinetic ("PK") endpoints. Treatment and enrollment under the current protocol may continue while the Company completes data analysis and evaluates next steps in development.

Orotecan is being developed as a patient-friendly oral alternative to intravenous ("IV") irinotecan, which has demonstrated clinical activity across multiple tumor types. IV irinotecan is typically administered to pediatric patients during clinical visits and requires treatment for five to ten consecutive days every two weeks and can significant quality of life for patients and their families. Similar to IV irinotecan, Orotecan is intended to be used across multiple tumor types, but via oral at home administration.

Published clinical experience has demonstrated that the IV formulation of irinotecan can be administered orally with promising efficacy; however, poor palatability and formulation limitations have restricted widespread adoption. Orotecan has been specifically formulated to address these limitations and enable convenient, once-daily dosing in the home setting.

Advancing Toward Registration-Directed Development

The current clinical trial, being conducted in collaboration with Valent Technologies LLC, is designed to prospectively evaluate the safety, tolerability, and pharmacokinetic profile of Orotecan and to support selection of a recommended oral dose for advancement into registration-directed studies. Patients in the trial receive once-daily oral dosing designed for administration in the home setting, consistent with the intended outpatient use of the product. To date, the regimen has demonstrated tolerability consistent with expectations for irinotecan-based therapy, although full analysis is ongoing.

The Company previously presented preliminary, interim data suggesting that the systemic exposure achieved by the oral Orotecan formulation may be comparable to exposure observed with unformulated intravenous irinotecan administered orally. Published third-party clinical studies of oral irinotecan have reported anti-tumor activity with objective responses and disease control, supporting the clinical relevance of systemic exposure to irinotecan and its active metabolites.

"We are pleased to have reached the enrollment threshold required to support statistical analysis of the primary and secondary endpoints in this study," said Jeffrey Bacha, Chief Executive Officer of Edison Oncology. "Based on our observations to date, including the tolerability profile and the ability to administer Orotecan as a predictable, once-daily oral regimen in the home setting, we believe Orotecan has the potential to offer a compelling alternative to multi-day intravenous irinotecan dosing administered in an infusion center."

Edison Oncology intends to seek a development and commercialization partner to advance Orotecan into registration-directed clinical studies. This strategy is intended to support the continued development of Orotecan while allowing the Company to allocate capital efficiently across its development portfolio and focus the majority of its internal resources on advancing its EO3001 and EO4426 programs, which represent the Company's primary development focus. In parallel, the Company plans to pursue continued patient access to Orotecan under the current protocol and potentially through expanded access pathways, where appropriate, while partnership discussions are ongoing.

"The opportunity to deliver therapy outside of the infusion setting and avoid repeated clinic visits for pediatric patients represents an important aspect of our development strategy for Orotecan. While enrollment to date is sufficient to complete the planned analyses, the protocol permits enrollment of additional patients. Given the ongoing treatment of eligible patients, the tolerability observed to date, and the continued interest in this outpatient regimen, we believe it is appropriate to continue enrollment and treatment as we complete our data review."

Improving the Treatment Experience

By enabling once-daily, at-home oral administration, Orotecan is designed to:

- Reduce the burden of repeated infusion clinical visits;
- Improve convenience for pediatric patients and caregivers;
- Maintain systemic exposure consistent with established irinotecan regimens; and
- Support potential integration into established treatment paradigms.

The Company believes that successful development of Orotecan could meaningfully improve the therapeutic experience for patients receiving irinotecan-based regimens while preserving clinical utility.

Further details regarding the pharmacokinetic analysis and development plans will be provided following completion of data review.

About Edison Oncology Holding Corp.

Edison Oncology Holding Corp. is a clinical-stage biopharmaceutical company developing a pipeline of first-in-class, small-molecule, biomarker-driven therapies designed to overcome key resistance mechanisms and address critical unmet needs in aggressive and underserved cancers. Leveraging existing clinical data and a modern understanding of cancer biology, the Edison Oncology focuses on genetically defined cancers, advancing its programs through a capital-efficient combination of internal development and strategic partnerships while retaining meaningful development and commercial rights. To learn more, please visit https://www.edisononcology.com/ and follow us for updates on LinkedIn.

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