PROTOCOL TITLE: *Provider Practice Patterns and Barriers in Prescribing Tarlatamab for Extensive Stage Small Cell Lung Cancer*

PI: Name: Noura Choudhury, MD
Telephone: 773-834-3105
E-mail: noura.choudhury@bsd.uchicago.edu

CO-I(S): Name: *[Include Co-Is as applicable]*
Telephone:
E-mail:

FUNDING: INTERNAL,
DEPARTMENT OF MEDICINE, SECTION OF HEMATOLOGY/ONCOLOGY

SPONSOR: Name: Noura Choudhury, MD
Address: Department of Medicine, Section of Hematology/Oncology
Telephone: noura.choudhury@bsd.uchicago.edu
Address: Department of Medicine, Section of Hematology/Oncology
Telephone: 773-834-3105

TYPE OF RESEARCH: Observational, survey

PROTOCOL NUMBER: IRB26-0150

PROTOCOL VERSION: 1

PROTOCOL VERSION DATE: 01/26/2026

TABLE OF CONTENTS PAGE

1. INTRODUCTION

1.1 BACKGROUND AND RATIONALE

1.1.1 Background: Disease and current understanding of disease

Small cell lung cancer (SCLC) is an aggressive malignancy that represents about 15% of lung cancers. Given the aggressive nature of its disease, it is common for patients to present with widespread metastasis early in diagnosis. About 60-70% of patients are diagnosed with extensive stage SCLC (ES-SCLC).[1] For these patients, response rates to standard chemotherapy are around 60%, but median progression free survival (PFS) is between 6-12 months.[2] Adding PD-L1 inhibitors, such as atezolizumab or durvalumab, to standard chemotherapy improves PFS and OS; however, median OS in pivotal front-line trials remains around 12-14 months and most progress within 6 months.[3]

The bispecific T-cell engager (BiTE) tarlatamab is approved for third-line therapy and beyond ES-SCLC. Based on the results of the phase 2 DeLLphi-301 trial, patients with ES-SCLC who had received at least two lines of systemic therapy received either 10 mg or 100 mg tarlatamab until disease progression. Patients in the 10mg arm (i.e., the dose that subsequently received FDA approval) had objective response rates of 40%, median PFS of 4.9 months, and median OS of 14.3 months.[4]

One of the most notable side effects of Tarlatamab treatment per the DeLLphi-301 trial was cytokine release syndrome (CRS) or immune effector-associated neurotoxicity (ICANS). CRS affected about 50-60% of patients in this trial and ICANS affected between 8-28%.[6] In other real-world studies, CRS and ICANS contributed to about 40% and 48% respectively of adverse effects in patients taking Tarlatamab.[5] Because of this increased risk of CRS in patients, the FDA recommends 24-hour hospital observation for patients treated with the first two doses of Tarlatamab in cycle 1 (day 1 and day 8).

1.1.2 Rationale for Conducting this Research

Due to the required 24-hour monitoring period, we hypothesize that providers not associated with a tertiary academic center may have decreased rates of Tarlatamab prescribing, in part from lack of access to the drug and due to inability to monitor inpatient.

We propose an observational study surveying providers who treat patients with ESCLC to examine their practice patterns and comfortability by prescribing Tarlatamab. The results of this survey will allow us to identify barriers with prescribing Tarlatamab and to inform interventions that may improve access to Tarlatamab.

1.2 OBJECTIVES

Primary Objective

The primary objective of this observational study is to evaluate provider practice patterns and comfort levels by prescribing Tarlatamab and identify any barriers to prescribing Tarlatamab.

Secondary Objective(s)

Identify geographic patterns related to tarlatamab prescribing.

METHODS

We have created an online survey which will be distributed to medical oncologists in the United States. Oncologists will be identified via the ASCO members society and pre-formed email list servers. There are 7 sections and 25 questions in total.

We will distribute our survey via email to those oncologists who treat patients with small lung cancer cells with the assistance of ASCO society. In the e-mail, we will describe the purpose of the study and provide a link to the questionnaire. Oncologists will be asked if they agree to participate in this study. They will be informed that the private identifiable information that we will be collecting includes their e-mail address. If they consent to participate, they can click on the link to the questionnaire and fill it out. If they do not consent to the study, they do not need to fill out the questionnaire. If oncologists do not respond to the first e-mail, they will be contacted 2 more times about the study, again to optimize response rates.

2. STUDY DESIGN

2.1 Type of Study

This is a non-interventional, observational, cross-sectional survey study of practicing medical oncologists in the United States who treat patients with small cell lung cancer (SCLC). The study is designed to characterize real-world provider practice patterns, comfort levels, and perceived barriers related to prescribing tarlatamab for patients with extensive-stage SCLC.

No investigational interventions, treatments, or changes to clinical care will be introduced as part of this study. Data will be collected at a single time point through a voluntary, self-administered electronic questionnaire. The study is descriptive in nature and intended to generate hypothesis-informing insights regarding access to and utilization of tarlatamab in routine clinical practice.

2.2 Study Population

Oncologists who treat patients with SCLC will be identified through the ASCO members society directory and through preformed email list servers.

2.3 Duration of Study

Our research project will start on February 15th, 2026 and will last for 1 year, including 2 phases: 1) Data collection and 2) Data analyses. The data collection will begin with survey dissemination to eligible oncologists, which will extend over 6 months. The data analyses period is anticipated to span approximately another 3-6 months.

3. TARGET STUDY POPULATION

3.1 Number of Subjects

We anticipate sending the survey to approximately 300 oncologists, hoping for at least a 50% response rate, or 150 responders.

3.2 Gender, Age, Racial and Ethnic Origin of Subjects

Both men and women of all racial and ethnic groups are eligible for the study.

3.3 Inclusion Criteria

Oncologists who treat lung cancer.

3.4 Exclusion Criteria

N/A

3.5 Vulnerable Subjects

Vulnerable or special populations (children, pregnant women and fetuses, prisoners, mentally disabled persons, economically disadvantaged persons and/or educationally disadvantaged persons) will not be included in this study.

3.6 Subject Identification & Recruitment

Participants will be oncologists practicing within the United States will be identified via the ASCO database and pre-established email list servers.

3.7 Location

This study will be conducted at the UCMC in the Section of Hematology and Oncology (5841 S Maryland Ave., MC 2115).

4. DATA HANDLING AND RECORD KEEPING

4.1 Data Capture, Management, & Collection Procedures

The data collected from the questionnaires will be stored on an encrypted RedCap database. Only the study investigators and other key research personnel will have access to this database. If there is a data breach, we will report the event to the IRB through the electronic portal. We will also report this breach to subjects by e-mailing them and informing them about the type of PHI that was disclosed (email). After publication of the results, we will destroy the identifiable data collected for this study (e-mail addresses).

4.2 Secure Storage of Data

Collected data will be compiled in an encrypted REDCap database through UCMC. Only the study investigators and other key research personnel will have access to this database. The REDCap Database will be maintained by the UCMC co-principal investigators and their designated research teams for 5 years. REDCap is a widely used database, that is compatible with the Healthcare Information Portability and Accountability Act (HIPAA). This database will have restricted access, will be password protected, and be routinely backed-up. At the end of study, collected data will be destroyed and the REDCap database will be terminated.

4.3 Confidentiality

There will be no PHI collected from subjects in this study. All identifiable information will be treated as private and confidential. Survey data collected from study will be stored in a REDCap database available in an encrypted manner for 5 years. At the end of study, collected data will be destroyed and the REDCap database will be terminated.

4.4 Unanticipated Problems (UP) Reporting

All UPs will be reported to the Institutional Review Board (IRB) as determined by IRB policy.

5. RISKS AND BENEFITS

5.1 Risks

There are no anticipated risks to this study as no health information will be collected and the survey will be anonymous.

5.2 Benefits to Subject/Others

There are no direct benefits to participants in this study. Subjects will not receive any compensation or individual feedback as a result of their participation.

However, this study may provide indirect benefits to the broader medical and oncology community. By characterizing real-world practice patterns, provider comfort levels, and perceived barriers to prescribing tarlatamab for patients with extensive-stage small cell lung cancer (ES-SCLC), the findings may help identify structural, institutional, and logistical factors that limit access to this therapy. These insights may inform future educational initiatives, policy changes, or system-level interventions aimed at improving equitable access to tarlatamab and optimizing care delivery for patients with ES-SCLC.

The knowledge gained from this study may also contribute to the existing literature on adoption of novel immunotherapies in routine clinical practice and help guide future research focused on implementation and access to emerging cancer treatments.

6. INFORMED CONSENT

Informed consent and pertinent information for participation in this study will be obtained and documented within the survey itself by the participants' willingness to complete the survey.

7. STATISTICAL PLAN AND CONSIDERATIONS

7.1 Sample Size Determination

This is a descriptive, observational survey study of medical oncologists who treat patients with small cell lung cancer. As the study is not designed to test a formal hypothesis or evaluate an intervention, no priori statistical power calculation was performed to determine sample size.

The target sample size is based on feasibility and expected response rates. The survey will be distributed to approximately 300 eligible oncologists identified through the

American Society of Clinical Oncology (ASCO) membership directory and pre-established email list servers. Based on anticipated response rates for physician surveys, an estimated 50% response rate is expected, yielding approximately 150 completed surveys. This sample size is expected to be sufficient to describe provider practice patterns, comfort levels, and perceived barriers to prescribing tarlatamab using descriptive statistical analyses and exploratory subgroup comparisons.

7.2 Statistical Methods

Survey responses will be analyzed using descriptive statistical methods. Categorical variables will be summarized using frequencies and percentages, and continuous variables will be summarized using means and standard deviations or medians and interquartile ranges, as appropriate.

Exploratory analyses may be conducted to examine associations between provider characteristics (e.g., practice setting, geographic region, years in practice) and self-reported prescribing patterns or perceived barriers to tarlatamab use. Comparisons between groups will be performed using chi-square or Fisher's exact tests for categorical variables and t-tests or non-parametric equivalents for continuous variables, as appropriate.

All analyses will be exploratory in nature and intended to generate hypotheses rather than test predefined causal relationships. No adjustments for multiple comparisons are planned. Statistical analyses will be conducted using standard statistical software (e.g., R, SAS, or SPSS).

8. ETHICAL CONSIDERATIONS

This study is to be conducted according to US and international standards of Good Clinical Practice, applicable government regulations and Institutional research policies and procedures.

This protocol and any amendments will be submitted to the Institutional Review Board (IRB), in agreement with local legal prescriptions, for formal approval of the study conduct. The decision of the IRB concerning the approval of the study will be made in writing to the investigator and a copy of this decision will be provided to the sponsor and funding agency before commencement of this study.

8.1 Conflict of Interest

All UCMC investigators have a COI disclosure on file.

9. PUBLICATION PLAN

The primary responsibility for publication of the results of this study is held by the UCMC team. There will be no other investigators involved with the study.

10. REFERENCES

1. Fabian J. Bolte, Sean C. Dougherty, Abigail O. Danos, Alia C. Lynch, Yaroslav Shvorak, Sarah Statler, Ryan D. Gentzler, Richard D. Hall, Real-World Outcomes of Tarlatamab in Small Cell Lung Cancer, Including Patients With Untreated Brain

Metastases, Clinical Lung Cancer, Volume 26, Issue 5, 2025, Pages 347-353.e1, ISSN 1525-7304, https://doi.org/10.1016/j.cllc.2025.03.006.

2. Small-cell lung cancer. Jackman, David M et al. The Lancet, Volume 366, Issue 9494, 1385 – 1396
3. José Trigo, Vivek Subbiah, Benjamin Besse, et al., Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial, The Lancet Oncology, Volume 21, Issue 5, 2020, Pages 645-654, ISSN 1470-2045, https://doi.org/10.1016/S1470-2045(20)30068-1.
4. Rehman RU, Anjum AF, Fatima R. Tarlatamab and the Future of Immunotherapy: A New Approach to Small Cell Lung Cancer. Curr Ther Res Clin Exp. 2024 Dec 21;102:100773. doi: 10.1016/j.curtheres.2024.100773. PMID: 39877675; PMCID: PMC11772990.
5. Nikhil Vojjala et al. Tarlatamab-induced immune-related adverse events: Retrospective real-world pharmacovigilance study using FAERS database.. *J Clin Oncol* **43**, e24106-e24106(2025). DOI:10.1200/JCO.2025.43.16_suppl.e.24106
6. Sands JM, Champiat S, Hummel HD, Paulson KG, Borghaei H, Alvarez JB, Carbone DP, Carlisle JW, Choudhury NJ, Clarke JM, Gadgeel SM, Izumi H, Navarro A, Lau SCM, Lammers PE, Huang S, Hamidi A, Mukherjee S, Owonikoko TK. Practical management of adverse events in patients receiving tarlatamab, a delta-like ligand 3-targeted bispecific T-cell engager immunotherapy, for previously treated small cell lung cancer. Cancer. 2025 Feb 1;131(3):e35738. doi: 10.1002/cncr.35738. PMID: 39876075; PMCID: PMC11775405.