



Brown/LUNGevity Award to Understand Mechanisms of Resistance to Immunotherapy 2024 Request for Application

IMPORTANT NOTES TO READ BEFORE PROCEEDING

LUNGevity Foundation (“LUNGevity”) is issuing an RFA for the 2024 Brown/LUNGevity Award to Understand Mechanisms of Resistance to Immunotherapy to study how metastatic non-small cell lung cancer (mNSCLC) becomes resistant to first-line immunotherapy and how this resistance can be targeted.

LUNGevity Foundation advises applicants to read the entire RFA, including eligibility requirements and other terms and conditions, before starting an application. Any applicant who is deemed ineligible for this award and/or does not follow the instructions for preparing the application will be disqualified and the application not reviewed.

The Brown/LUNGevity Award Program to Understand Mechanisms of Resistance to Immunotherapy uses a **two-step application process**. An applicant must first submit a letter of intent (LOI). Only a subset of applicants will be invited to submit a full application after the LOIs are reviewed. The application process will be managed through proposalCENTRAL.

Important Dates:

- February 9, 2024: Letter of Intent (LOI) deadline
- May 8, 2024: Full application deadline
- Late Summer 2024: Award notifications made
- November 1, 2024: Awards begin

Detailed instructions for applying for this award begin on page 10.

LUNGevity FOUNDATION

LUNGevity Foundation is a 501(c)(3) philanthropy specifically focused on funding research for the early detection and effective treatment of lung cancer. LUNGevity’s mission is to improve mortality rates of lung cancer patients through the development of protocols and tools for early detection of lung cancer, early intervention in the disease progression, and treatments, including targeted therapy and immunotherapy. LUNGevity focuses on translational science. For more information about LUNGevity Foundation, please visit www.LUNGevity.org.

FUNDING OPPORTUNITY DESCRIPTION

Goal of the program

To fund high-impact research that seeks to understand resistance to first-line immunotherapy and develop therapeutic strategies targeting this resistance.

Overview

Background

Lung cancer treatment has dramatically changed with the introduction of targeted therapies for biomarker-driven lung adenocarcinomas¹ and immunotherapies for squamous cell lung cancer and adenocarcinomas (two types of non-small cell lung cancer or NSCLC) that do not have a



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biomarker with an FDA-approved targeted therapy.^{1,2} In 2022, immunotherapy as a single agent or in combination with chemotherapy was prescribed to approximately 116,000 patients diagnosed with advanced-stage NSCLC (adenocarcinoma without biomarkers + squamous cell lung cancer)³, of which only 20%-30% will show a durable response.⁴ In addition, immunotherapy has now been approved for early-stage NSCLC and is offered either as neoadjuvant (before surgery) therapy in combination with chemotherapy or as adjuvant (after surgery) therapy in combination with chemotherapy. Therefore, the impact of immunotherapy research is broader-reaching than just patients with advanced-stage NSCLC. Current immunotherapy modalities include drugs that block the PD-L(1) or the CTLA-4 immune checkpoint pathways.⁴

LUNGevity conducted a landscape analysis of the current lung cancer treatment landscape and found that while there are several new drugs currently in clinical development, only a small proportion of immunotherapy assets are specifically targeted toward treating resistance to PD-L(1) or CTLA-4 blockade.⁵

Through this RFA mechanism, LUNGevity is interested in answering these questions:

- How do cells escape immunotherapy after an initial response, i.e., what is/are the mechanism(s) causing **acquired resistance** to immunotherapy?
- What's next for patients whose tumors have progressed after first-line immunotherapy regimens?

AWARD PROGRAM REQUIREMENTS

The research funded through this award is expected to have a direct clinical impact on patients with NSCLC whose tumors have progressed on currently approved immunotherapy regimens.

The award, totaling up to \$500,000 will be funded for a duration up to 2 years. We anticipate funding at least one award through this program.

Awardees are required during the duration of the award term to share their research progress with LUNGevity staff, members of the LUNGevity Scientific Advisory Board, and study section reviewers, as necessary.

Scientific Scope of Projects

Awarded project(s) is/are expected to further our knowledge of **acquired resistance** mechanisms to first-line immunotherapy in mNSCLC and how they can be targeted. They can be translational or clinical in nature. **Preclinical studies will not be funded.**

Preference will be given to specific approaches based on post-treatment biomarkers rather than approaches that intensify therapy in patients with negative prognostic/predictive biomarkers.



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Final selection will be contingent on scientific review and availability of funds.

Eligibility

Education and Experience: At the start of the award term, the applicant, who must be a principal investigator for the proposed research, must:

- 1) hold a doctoral degree and faculty appointment (or equivalent) with an academic institution, including research institutions that are not formally associated with a university
- 2) have completed a postdoctoral training fellowship.

An applicant may be at any level of research experience and must be an independent, self-directed researcher for whom their institution must provide space and other resources customary for independent investigators. The application must convey the commitment of the institution to the applicant and the proposed research activities. An applicant with an existing LUNGevity award (except a Career Development Award) may apply.

Team Preference: While not a requirement, we encourage a team approach with the inclusion of at least two institutions right from the LOI stage. One institution may serve as the primary institution. Please reach out to us if you have any questions about the team preference.

Geographical Restriction: International teams are **highly recommended**. The award program does not have any geographical restrictions.

Applicants are **not** required to be U.S. citizens or to be employed by a U.S. institution. **At the time of application, if an applicant is employed by a U.S. institution**, they must be a United States citizen or a foreign national holding one of the following visa immigration statuses: permanent resident (Green Card), exchange visitor (J-1), temporary worker in a specialty occupation (H-1, H-1B), Canadian or Mexican citizen engaging in professional activities (TC or TN), or temporary worker with extraordinary abilities in the sciences (O-1).

The application must be submitted in English.

AWARD INFORMATION

Award Structure

Investigators may receive up to \$500,000 over two years. No more than 25% of the requested budget may be used for an investigator's/co-investigators' salary and/or fringe benefits. No more than 10% of the requested budget may be used for overhead/indirect costs.

Award funds may be used for the salary and fringe benefit costs of personnel other than the applicant. Fringe benefit costs may only be expended upon the stipulation that they cannot be obtained from another source.

Allowable costs for clinical trials include: expenses related to subject recruitment (such as participation incentives, subject remuneration, phlebotomy charges, etc.), clinical laboratory



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analyses of human subjects or their samples (such as clinical laboratory assays, imaging charges, etc.), and correlative studies. While the award may be used to help with operational costs, the investigator is required to procure funding to cover the remaining cost of the trial.

Drug costs will not be covered.

This award is subject to annual review and funding for the next year will be contingent upon a review of progress.

Award Payment Schedule

LUNGevity will issue the first-year award payment no earlier than November 1, 2024, following receipt of fully executed agreement documents. LUNGevity will issue the payment for Year 2 following satisfactory review of Year 1 progress and financial reports. Payment for Year 2 will be made only after the awardee's funding balance has decreased to \$25,000 or less.

Award Selection

Final selection of the project to be funded will be made by the Brown Family following discussion with and recommendations by LUNGevity.

Some of the factors considered when reviewing applications include:

- Innovation: Does the project address acquired resistance to immunotherapy using approaches that have not been considered?
- Scientific merit and feasibility of the research plan, including partnerships
- Impact: How will the research findings from the project move to the clinic within a reasonable time frame and impact patients? What plans does/do the applicant(s) have for the clinical application of the findings of the project?
- Research environment: Does the applicant have access to institutional resources required for the successful completion of the proposed project?
- Appropriateness of the requested budget to complete the proposed research project/Other sources of funding, including potential overlap with proposed project.

OTHER TERMS AND CONDITIONS

Following are other terms and conditions that apply to the Brown/LUNGevity Award Program to Understand Mechanisms of Resistance to Immunotherapy. A more detailed set of terms and conditions will be included in the agreement document for funded projects.

Animal Use

LUNGevity allows animal use in biomedical research only when no other means of obtaining scientifically sound, valid, and useful results are available. Applicants must ensure that only the minimum number of appropriate animals required to obtain and validate results shall be used. In cases requiring the death of an animal, only the most appropriate and humane form of euthanasia shall be used consistent with the purpose of the research.



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If animals will be used in the proposed research project, applicants must provide institutional endorsements that the research facility, its research, and its employees adhere to the appropriate animal welfare regulations in their country. In the U.S., these include:

- Animal Welfare Act
- USDA rules
- National Research Council *Guide for the Care and Use of Laboratory Animals*
- Public Health Service Policy on Humane Care and Use of Laboratory Animals

In addition to the above, applications must also include the following documents:

- Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation.
- Institutional Animal Care and Use of Committee (IACUC) approval.

A project is **not** eligible for an award if the research proposal involves animals and the institution does not have accreditation from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC), **or** does not hold a current Public Health Service (PHS) Animal Welfare Assurance, **or** does not have accreditation from the United States Department of Agriculture, **or** does not have accreditation from the Institutional Animal Care and Use Committee (IACUC).

Authorized Award Holders

The award will be granted only to an individual; awards are not awarded to institutions. No award may be held by or transferred to another individual.

Biohazards

Biohazards are broadly defined to be recombinant and/or infectious and tumor materials that may be deleterious to normal organisms upon controlled exposure. Research involving biohazards requires one paper copy of the appropriate institutional committee approval at the time a full application is submitted.

Carryover of Funding

Carryover of funding into the next year requires prior approval by LUNGevity. All requests must be in writing and received by LUNGevity 60 days prior to the end of that funding year. When making the request, the awardee must indicate the amount and from what budget-line and to what budget-line the carryover monies are being applied. In the case of supplies or equipment, all items must be itemized.

Change in Budget

Requests for a change in budget that is 10% or more for a budget line requires prior approval by LUNGevity. All requests must be in writing and received by LUNGevity at least 60 days prior to the end of the current funding year. When requesting a change in budget, the awardee must indicate the amount to be transferred, the budget line the funds are currently included in and to



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where they would be transferred. In the case of supplies or equipment, all items must be itemized.

Change of Institution

Transfer of this award from one institution to another because of the relocation of the awardee requires prior approval by LUNGevity. All requests must be in writing and made as soon as the awardee officially knows of the relocation. A grant may not be transferred to a laboratory, clinic, hospital, or other research institution that is not affiliated with a tax-exempt not-for-profit institution. All unexpended funds must be returned to LUNGevity within 45 days of transfer approval. A grant agreement must then be executed by the new institution. After LUNGevity receives the unexpended funds from the original institution and the grant agreement has been executed with the new institution, the funds will be reissued to the new institution.

Equal Employment Opportunity

LUNGevity awards will be made to individuals working in institutions identified as Equal Opportunity Employers (or equivalent in non-US institutions).

Equipment and Supply Purchases

Upon conclusion of the award, equipment and supplies purchased with award funds become the property of the institution at which the work was done.

Equipment Expenditures

No more than 30% of the total award budget over the award term may go to fund the purchase of permanent equipment. Equipment is defined as an item that costs \$500 or more, has a primary function related to the research project, and ordinarily has a usable life expectancy of one year or greater.

Equipment Repair & Service Contracts

No portion of the award budget may be used for repair or service contract costs for institutional equipment.

Human Subjects

If human subjects are a part of the proposed research project, the following documents must be received before any award monies are released:

- A copy of the Institutional Review Board (IRB) approval and approved patient consent forms
- A copy of the appropriate institutional committee approval for research involving human adult stem cells or use of human fetal tissue.

If the proposed research project involves human subjects, the population sampled shall be inclusive of the general population of relevance to the scientific question posed, without restriction in regard to gender, race, age, and socioeconomic status. Proposals that intentionally restrict the population sampled must include a compelling scientific rationale for such design.

LUNGevity encourages applicants to submit their projects to the appropriate human subjects Institutional Review Board at the time of application.



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IRB approval and approved patient consent forms must be provided to LUNGevity before award funds will be disbursed.

Malpractice Liability

LUNGevity will not assume responsibility for and the institution will indemnify and hold LUNGevity harmless from any lawsuit, claim, judgment, damages, awards, or malpractice arising from research or investigations related to an award.

No-cost Extension

A no-cost award extension requires prior approval by LUNGevity. All requests must be in writing and received by LUNGevity at least 90 days prior to the award's official termination date. When making the request, the awardee must provide a detailed rationale for the extension, project expenses to date, and a detailed revised budget. Awardees may request a no-cost extension only once per award. Approval of the no-cost extension is not automatic and will only be granted in exceptional circumstances.

Other Funding

LUNGevity research funds will not be awarded to duplicate any work that is being supported by other funding agencies.

Overhead/Indirect Costs

Overhead or indirect costs are permitted up to 10% of the award but are not incremental to the award. Duplication of indirect costs on subcontracts is not allowed.

Patent and Intellectual Property Policy

Inventions and discoveries from research performed during the term of a LUNGevity award will be subject to the current LUNGevity patent policy as well as to the patent policies of the institution where the work is performed. The LUNGevity policy is described in full on page 9.

Preprints and Public Access Policy

Grantees are required to deposit their submitted manuscripts, and subsequent versions, via a publicly accessible preprint server (e.g., arXiv, bioRxiv, medRxiv, or another trusted disciplinary server). Preprints must be shared under an open license (CC BY). LUNGevity Foundation recognizes preprints as evidence of productivity for purposes of grant applications, reviews, and reporting.

Upon acceptance, we require electronic copies of research papers, accepted for publication in a peer-reviewed journal and supported in whole or in part by LUNGevity Foundation, to be made freely available upon publication. Grantees may comply with this policy by publishing in an open access journal, publishing in a hybrid journal with an open access option, or by making a copy of their Author Accepted Manuscript available via a trusted open repository (e.g., PubMed Central). All peer-reviewed articles must be freely available under a suitable open license, preferably the Creative Commons Attribution (CC BY) license, which permits reuse without restriction.



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Progress Reports and Renewal of Funding

Annual written progress and financial reports (as well as presentations at the annual LUNGevity Science Meeting) are required. Interim progress reports are the basis for the decision to award subsequent years of funding. A final progress report is also required at the conclusion of the project along with a complete financial disbursement report covering the entire award period. The financial report must reflect the award expenditures as approved by LUNGevity. All unused funds must be returned to LUNGevity. In addition, any funds used for unauthorized expenditures or unexpended funds must be returned to LUNGevity.

Project Support Expenditures

No award shall be used for the purchase of furniture or computers, repair or service contracts, institutional equipment, the construction or renovation of facilities, payment of honoraria or membership dues, tuition for either the awardee or other project personnel, the purchase of textbooks or periodicals, or payment for secretarial support.

Publication Expenditures

The maximum amount of funds expendable for publication costs is \$2,000. All publication costs must directly relate to the LUNGevity project.

Publications and Conference Presentations

All publications and/or presentations at scientific conferences and meetings based on research conducted from this award must include a citation of Brown/LUNGevity as a supporting entity as follows: "This study was supported by a 2024 Brown/LUNGevity Award to Understand Mechanisms of Resistance to Immunotherapy." Reprints of abstracts, manuscripts, or other articles that reflect research done after award acceptance must be submitted to LUNGevity.

Tobacco-Funded Research

LUNGevity will not provide research or other funding to investigators who have received direct funding or funding from agencies of the tobacco industry.

Travel Expenditures

The maximum funds expendable for awardee travel are \$1,500 per year. Travel to LUNGevity meetings is paid directly by the Foundation and is not included in the allowable \$1,500.



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LUNGEVITY PATENT AND INTELLECTUAL PROPERTY POLICY

- a. All inventions or intellectual property made with support in whole or in part by research or training grants or awards from LUNGEVITY must be reported at the earliest practical time to the Research and Program Services Division. The grantee institution or individual awardee agrees to notify LUNGEVITY immediately of the decision to apply for letters patent or other legal protection for intellectual property, and to consider seriously and in good faith any comments or objections LUNGEVITY may have concerning such applications. LUNGEVITY agrees to keep all information confidential and to not release any information relating to such inventions, intellectual property or applications. All patenting expenses shall be borne by the grantee institution or individual awardee unless the intellectual property is ceded to LUNGEVITY (see paragraphs b and c).
- b. Title to any invention or intellectual property shall reside in the grantee institution to the extent that such title is claimed by the institution under its patent policy or procedure and paragraphs c-e shall apply. If a grantee institution has no established patent policy or procedure for administering inventions or intellectual property, or if the institutional patent policy or procedure does not claim rights for the institution or individual inventor, then LUNGEVITY shall have the right to determine the disposition of invention or intellectual property rights and paragraphs c-d shall not apply.
- c. No patent, patent application or other type of protection shall be abandoned without first notifying the Research and Program Services Division. At such time, the grantee institution and individual awardee shall give LUNGEVITY the opportunity to take title to the invention or other intellectual property.
- d. The grantee institution shall agree that when it licenses any invention or intellectual property it will obligate the licensee as follows: The licensee agrees to exert its best efforts to commercialize or cause to be commercialized the invention or intellectual property as rapidly as practical, consistent with sound and reasonable business practices and judgment. In the event that the licensee has failed to commercialize the invention or intellectual property within the number of years determined to be reasonable for the invention or intellectual property, the grantee institution upon conferring with LUNGEVITY shall have the right to convert an exclusive license to a non-exclusive license or to terminate a non-exclusive license. If the licensee or grantee institution has an ongoing and active research, development, manufacturing, marketing or licensing program as appropriately directed toward the production and sale of the invention or intellectual property, the same would be deemed to be sufficient evidence that the licensee or grantee institution has commercialized the invention or intellectual property.
- e. LUNGEVITY reserves the right to public acknowledgment for inventions or intellectual property resulting from support by LUNGEVITY; however, LUNGEVITY name and logo may not be used in association with an invention or intellectual property without prior approval of LUNGEVITY.



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APPLICATION INSTRUCTIONS AND TIMELINE

Templates and detailed instructions for required information/materials can be found at <https://proposalcentral.com>. Be sure to read those instructions in case any instructions were changed, added, or deleted after this RFA was issued.

Letter of Intent (LOI)

The letter of intent **must** include a narrative that contains:

1. **Rationale** for the project with details on how the project will impact clinical care of patients whose tumors have developed resistance to first-line immunotherapy
2. Planned **specific aims** (may be modified slightly in the full application)
3. Brief statement of the **overall experimental approach**
4. Brief statement describing the **clinical context** in which the therapeutic strategy will be used
5. Brief statement of the **quantitative metrics/performance** that the approach should achieve to show clinical utility
6. **References**

The narrative should be typed in Arial 11-point type, single-spaced, with .5" margins. It should not exceed a total of **three pages**, including the references. **Your LOI will not be considered if these instructions are not followed.**

The following items should be included as part of the LOI:

- An NIH **biosketch** (OMB No. 0925-0001 and 0925-0002) for the applicant and co-applicant (if applicable). For non-US applicants, please include a 2 page CV with your application. Double-check that the information included is current and thorough. **We will not be contacting you to clarify any information.**
- If a non-citizen, **proof of visa immigration status**, as described under "Award Eligibility." This should be attached to the end of the biosketch.

No budget information or other supporting materials should be included with the LOI. A sponsoring institution signature is not required.

Letters of Intent are due **by February 9, 2024 (11:59 pm EST)**, via proposalCENTRAL. Extensions will not be given. Once an LOI has been submitted it cannot be changed.



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Applicants will be notified by email no earlier than **March 25, 2024**, whether they will be invited to submit a full application. LUNGevity will **not** provide feedback regarding results of the review of any Letter of Intent submitted.

Full Application

Only invited applicants may prepare and submit a full application. Instructions for how to proceed will accompany the invitation. Among other materials, the full application must include:

A narrative to include these components:

1. **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.
2. **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
3. **Specific Aims:** Concisely explain the project's specific aims.
4. **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Address potential problem areas and present alternative methods and approaches. Please include a detailed sample size justification for the proposed clinical trial and any statistical analyses you propose to use.
5. **Patient Impact Statement:** How will the research findings from the project move to the clinic within a reasonable time frame and impact patients? What plans does/do the applicant(s) have for the clinical application of the findings of the project?
6. **Statistical Analysis Plan:** A detailed statistical analysis plan is required for all applications and is limited to one single-spaced page. The analysis plan should define the primary objectives, study design, and planned analyses supporting the study hypotheses. Justification of the proposed sample size or number of patient samples to be analyzed should be stated and include all parameters required for calculation: the type I error rate, power, and target effect size. Detail regarding analysis methods, groups to be compared, and other assumptions made (for example, regarding accrual rates, follow-up, etc.) should also be included. Ideally, the applicant will collaborate with a biostatistician on their grant proposal, including this analysis plan. In the event that methods from other quantitative sciences are planned (for example, bioinformatics or computational biology), it is recommended that the applicant also collaborate with experts from those respective fields to develop their application and analysis plan.
7. **References**

The narrative should be in English, typed in Arial 11-point type, single-spaced, with .5" margins. The narrative should not exceed a total of **11 pages, including references**. When preparing your narrative, please use one page for Narrative Item 6 (Statistical Analysis Plan).

In addition to the narrative, the following items should also be included with the application package:

- **NIH biosketches** (OMB No. 0925-0001 and 0925-0002) of the applicant and key personnel



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- **Budget information** by year, along with a justification
- **Other Support:** For the applicant only: Be sure to include the dollar amount of each award.
- **The following documents**, if relevant:
 - a copy of the documents listed in the “Animal Use” section
 - a copy of the biohazard document named in the “Biohazards” section
 - a copy of proof of visa immigrant status as described in the “Award Eligibility” section of the RFA (this may be attached at the end of the applicant’s biosketch)

Do **not** include reprints of your previous publications.

Templates and more detailed instructions for all of the above materials and any other materials that must be included can be found at <https://proposalCENTRAL.com>.

Full applications must be submitted via proposalCENTRAL **by May 8, 2024 at 11:59pm EST**. Extensions will not be granted. Once a full application has been submitted, it cannot be changed.

Applicants will be notified of award decisions by email in **Late Summer 2024**. Review comments will be provided for full applications only.

Awardees will receive formal agreement documents at the time of or soon after award notification. These must be signed by both the awardee and an authorized representative of the sponsoring institution and then returned to LUNGevity before any funds will be released.

APPLICATION ASSISTANCE

For answers to questions regarding programs, eligibility, policies, terms and conditions, or instructions for the letter of intent or full application, please contact:

Jody Roosevelt
Research Program Coordinator
jroosevelt@LUNGevity.org
847-525-2075

Upal Basu Roy
Executive Director of Research
ubasuroy@LUNGevity.org

For help with the proposalCENTRAL please contact:
Help Desk at proposalCENTRAL
pcsupport@altum.com
1-800-875-2562



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REFERENCES

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2. NCCN. NCCN Guidelines Version 3.2022 Non-Small Cell Lung Cancer. . https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Published 2022. Accessed July 23, 2022.
3. ACS. Cancer Facts and Figures 2022. <https://www.cancer.org/research/cancer-facts-statistics/all-cancer-facts-figures/cancer-facts-figures-2022.html>. Published 2022. Accessed 2023, May 16.
4. Punekar SR, Shum E, Grello CM, Lau SC, Velcheti V. Immunotherapy in non-small cell lung cancer: Past, present, and future directions. *Front Oncol*. 2022;12:877594.
5. Deb D, Moore AC, Roy UB. The 2021 Global Lung Cancer Therapy Landscape. *J Thorac Oncol*. 2022;17(7):931-936.