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CASE (CemiplimAb-rwlc Survivorship and Epidemiology): a study in advanced basal cell carcinoma

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ABSTRACT

Patients diagnosed with metastatic basal cell carcinoma (BCC) have a poor prognosis. The current standard of care for adults with locally advanced or metastatic BCC who are not candidates for surgery or radiation therapy is treatment with hedgehog pathway inhibitors (HHIs). For patients who progress while on this therapy, further treatment options are limited. There is also a need for real-world clinical practice data on the clinical characteristics, management, disease progression, and survivorship of these patients. The ongoing CemiplimAb-rwlc Survivorship and Epidemiology (CASE) study is a phase IV, multicenter, prospective, non-interventional survivorship and epidemiology cohort study evaluating the effectiveness and safety of cemiplimab, a fully human immunoglobulin G4 monoclonal antibody that blocks the interaction between the programmed cell death-1 (PD-1) receptor and its ligands. This paper describes one cohort of the CASE study of patients with locally advanced or metastatic BCC who have failed or are intolerant of HHIs or for whom HHI therapy is not appropriate. Outcome measures of the study include response to treatment, quality of life, safety, treatment patterns, patient experience, and survival. This study could provide a more complete characterization of this patient population and fill knowledge gaps related to real-world treatment utilization and patient outcomes.

Clinical Trial registration: NCT03836105

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KEYWORDS
Basal cell carcinoma; cemiplimab; clinical trial; protocol; survivorship; epidemiology; PD-1 inhibitor

1. Introduction

1.1. Background and rationale

Basal cell carcinoma (BCC) is the most common form of non-melanoma skin cancer in the USA, with approximately 3.6 million cases each year [1]. Standard treatment for BCC is surgical excision or radiotherapy; however, locally advanced or metastatic BCC may require systemic therapy [2,3]. Metastatic BCC is rare, accounting for less than 1% of all cases. These patients have historically been associated with a very poor prognosis [3,4]. Limited data exist on the clinical characteristics, management, disease progression, and survival of patients with advanced BCC in real-world clinical practice.

BCCs are frequently associated with aberrant signaling of the hedgehog signaling pathway [2]. Hedgehog pathway inhibitors (HHIs) have been shown to be effective in controlling disease [5]. Consequently, current guidelines recommend their use, where indicated, as treatment options for adults with locally advanced or metastatic BCC, who are not candidates for surgery or radiation therapy [2,6].

Prior to the approval of cemiplimab, a fully human immunoglobulin G4 monoclonal antibody that blocks programmed cell death-1 (PD-1) receptor [7,8], patients with advanced BCC who had progressed while on HHIs had limited treatment options [9,10]. In 2021, the US Food and Drug Administration approved cemiplimab as the first treatment indicated for patients with locally advanced or metastatic BCC who had been previously treated with an HHI or for whom an HHI was not appropriate [11,12]. Cemiplimab is a high-affinity, recombinant human IgG4 monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with programmed death-ligand 1 (PD-L1) and programmed death-ligand 2 (PD-L2), restoring the anti-tumor immune response [8,13–16]. BCCs have a high mutational burden which based on data of all cancers renders them good candidates for PD-1 blockade and gives cemiplimab its activity for treating this type of disease [17,18]. The clinical trial data to date have evaluated cemiplimab following HHI [19,20], and there are limited data on how to sequence the systemic therapy options and use in a non-trial population [21].

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Article highlights

Background
- Basal cell carcinoma (BCC) is the most common form of skin cancer. Locally advanced or metastatic BCC may require systemic therapy, but the prognosis for these patients is currently very poor.
- BCCs are frequently associated with aberrant signaling of the hedgehog signaling pathway. Current guidelines recommend hedgehog pathway inhibitors (HHIs) for the treatment of adults with locally advanced or metastatic BCC who are not candidates for surgery or radiation therapy.
- Cemiplimab has been shown to be effective after HHI therapy and represents a new option for patients who are not suitable for HHIs.

Rationale
- There are currently no real-world practice data on clinical characteristics, management, disease progression, and survivorship of patients with advanced BCC treated with cemiplimab.

Methods

CASE (CemiplimAb-rwlc Survivorship and Epidemiology) study
- Key objectives of this real-world study in patients with BCC include:
  - Describing the long-term effectiveness of cemiplimab (cemiplimab-rwlc) 350 mg administered every 3 weeks.
  - Evaluating the safety of cemiplimab and incidence of treatment-related immune-related adverse events.
  - Describing patient experience, quality of life, and functional status.

This paper describes one cohort of the ongoing CASE (CemiplimAb-rwlc Survivorship and Epidemiology; NCT03836105) study, which is evaluating the effectiveness and safety of cemiplimab treatment in, as well as the disease evolution and quality of life (QoL) of, patients with advanced (defined as locally advanced or metastatic [nodal or distant]) BCC. This real-world study allows a more complete characterization of patients with advanced BCC and will increase our understanding of outcomes in this population. Most patients receiving cemiplimab will likely have exhausted all other treatment options and thus represent a distinct patient group for whom limited information is available. Survival of patients with advanced cutaneous squamous cell carcinoma is being studied in a separate cohort of the CASE study.

1.2. Objectives

The main objectives of the study are to describe the long-term effectiveness of cemiplimab (cemiplimab-rwlc) 350 mg administered every 3 weeks (Q3W) for treatment of patients with advanced BCC in real-world clinical settings. Cemiplimab will be administered following failure or intolerance of HHI or in patients where HHI therapy is not appropriate. The study will include patients who are immunosuppressed/immunocompetent, and after prior exposure to radiotherapy. The safety of cemiplimab based on the incidence of treatment-related immune-related adverse events (irAEs), infusion-related reactions (IRRs), and treatment-related serious adverse reactions (SARs) will be evaluated. In addition, the study will describe baseline characteristics and their relation to patient experience, QoL, functional status, and survival.

1.3. Trial design

CASE is a phase IV, multicenter, prospective, noninterventional survivorship and epidemiology cohort study of patients with advanced BCC receiving cemiplimab in the real-world setting (Figure 1).

2. Methods

2.1. Study setting

Patients will be enrolled at up to 55 study sites in the USA; sites in other countries may be initiated after product approval and commercial availability in that country. Participating sites will enroll patients who receive treatment with cemiplimab outside of an interventional clinical trial.

2.2. Eligibility criteria

Table 1 outlines the eligibility criteria for this study. We plan to enroll adults ≥18 years of age who have recently initiated, or

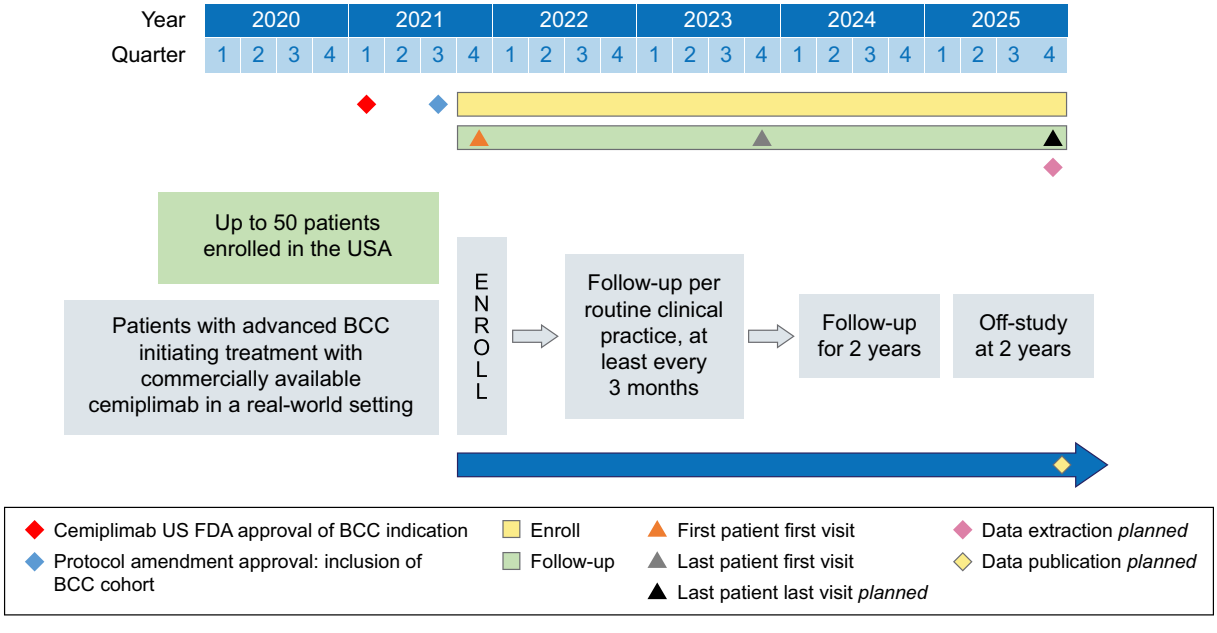

Figure 1. CASE study design.

Table 1. Inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
• Patients must be ≥18 years of age and eligible for treatment with and prescribed cemiplimab for advanced BCC in accordance with approved prescribing information • For completeness and ease of prospective data collection, it is recommended patients be enrolled before their second dose of cemiplimab • Willingness and ability to comply with standard clinical care for advanced BCC • Ability to understand and complete study-related questionnaires • Provision of signed informed consent	• Treatment with cemiplimab for an indication other than advanced BCC • Any condition that, in the opinion of the investigator, may interfere with patient's ability to participate in the study (e.g., unstable social situation such as homelessness, or psychiatric conditions such as schizophrenia, advanced depression, active substance abuse, or severe cognitive impairment or other comorbidities) or other comorbidities that would, in the opinion of the investigator, predictably limit compliance with the intended treatment plan or prevent adequate completion of quality-of-life assessments • Concurrent participation in any study, including those that involve administration of an investigational therapy (including cemiplimab) or procedure (including survival follow-up)

Patients must meet all the inclusion criteria listed in the table to be eligible for the study.
BCC, basal cell carcinoma.

who plan to initiate, treatment with commercially available cemiplimab for locally advanced or metastatic BCC according to respective label indications.

2.3. Interventions

All treatments will be prescribed at the discretion of the treating physician and other healthcare providers, with cemiplimab administered according to prescribing guidelines for BCC: 350 mg Q3W [7,8]. In addition to cemiplimab, patients may also receive other therapies as deemed necessary by their physicians for the treatment of BCC or comorbid conditions.

Only treatments prescribed by investigators will be provided to enrolled patients (no agents will be supplied by the sponsor as part of this study).

2.4. Study outcomes

Outcome measures for the study include response to treatment, QoL, safety, treatment patterns, patient experience, and survival. Full outcome measures are shown in Supplemental Box 1.

2.5. Participant timeline

Participating sites will enroll patients who receive treatment with cemiplimab in real-world clinical settings. For BCC patients, the process will continue for approximately 24 months from the enrollment of the first patient into the study. Patients who do not initiate cemiplimab within 4 weeks of signing their informed consent form must be rescreened and must reconsent to participate in the trial. Following receipt of the informed consent signature and enrollment in the study, patients will be followed up by their primary treating physician per routine clinical practice. The interval between clinical visits may not exceed 3 months.

Enrolled patients will be encouraged to stay in the study throughout the planned treatment period, irrespective of cemiplimab treatment status (i.e., temporary or permanent discontinuation), for continued collection of data, unless consent is withdrawn. Patients who discontinue treatment and/or choose not to continue with follow-up visits and questionnaires will still be followed-up for survival at 3-month intervals, provided they do not withdraw their consent completely, for the full duration of the follow-up period (up to 24 months for each patient). Each patient will be considered to have completed the study at the time they complete 24 months of follow-up or at the time of death.

2.6. Sample size

The study will target enrollment of approximately 50 patients with advanced BCC, based on the assumptions shown in Tables 2 and 3.

2.7. Data collection methods

Data will be collected on baseline characteristics, including standard demography, BCC characteristics (e.g., date of diagnosis, staging, genetic and molecular tumor characteristics, sites of metastases), medical history, and BCC treatment history.

Data will be collected on effectiveness outcomes, which include objective response rate (ORR), duration of response

Table 2. Estimated precision (95% CIs) for various outcome event rates in the advanced BCC patient population.

		95% CIs by sample size		
Endpoint	Rate, %	n = 50	n = 75	n = 100
Objective response rate	27	15.2, 38.8	17.0, 37.2	18.3, 35.7
Disease control rate	77	66.9, 87.2	67.8, 86.1	68.8, 85.2
Overall survival at 12 months	92	85.6, 98.4	86.2, 97.8	86.7, 97.3
Overall survival at 2 years	78	68.0, 88.0	69.0, 87.0	69.9, 86.1
irAEs, Grade ≥ 3	11	3.4, 18.6	4.2, 17.8	4.9, 17.1
IRRs, Grade ≥ 2	3	−1.0, 6.9	−0.6, 6.6	−0.3, 6.3

BCC, basal cell carcinoma; CI, confidence interval; irAE, immune-related adverse event; IRR, infusion-related reaction.

Table 3. Estimated precision (95% CIs) of event rates per observed incidences of adverse events of special interest from cemiplimab clinical trials by sample size after dropout.

	Observed event incidence (%)				
Sample size (n)	0.5	0.7	1	5	7
50	−1.1, 2.3	−1.1, 2.5	−1.7, 3.8	−0.6, 10.9	0.7, 13.4
75	−1.0, 2.1	−1.0, 2.4	−1.3, 3.3	0.1, 9.9	1.4, 12.6
100	−0.9, 1.9	−0.9, 2.3	−1.0, 3.0	0.7, 9.3	2.0, 12.0

CI, confidence interval.

(DOR) and time to treatment failure (TTF), progression-free survival (PFS), and overall survival (OS).

Quality of life, including functional status and disease-related symptoms data, will be collected at baseline and follow-up visits using the European Organisation for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire Core Module 30 (EORTC QLQ-C30), EORTC QLQ for Elderly Cancer Patients (ELD14), pain numerical rating scale, and Skin Care Index (SCI).

Data will also be collected on safety outcomes, which include irAEs, IRRs, and treatment-related SARs.

Further, data will be collected on treatment patterns, which include interventions for BCC pre- and post-cemiplimab initiation, prior use of HHIs, concomitant medications, treatment of irAEs, determinants of disease sequelae, health services utilization, and discontinuation of cemiplimab.

2.8. Statistical methods

Data will be summarized descriptively for continuous variables, by frequencies and percentages for categorical and ordinal data and by Kaplan–Meier estimation and duration-adjusted statistics (for time to event). The study does not include a formal statistical hypothesis to test and there are no planned inferential comparisons.

Baseline characteristics and treatment effectiveness will be described with summary statistics, such as mean, standard deviation, minimum, 25th percentile, 75th percentile, median, maximum, minimum for continuous variables, and category counts and frequencies (percentages) for categorical variables; descriptive statistics were calculated for cemiplimab treatment duration and number of treatment cycles.

For the primary analyses, data will be summarized for the full analysis set (all enrolled patients who have received ≥ 1 dose of cemiplimab), which includes: ORR, complete response (CR), partial response (PR), stable disease (SD), disease control rate (DCR), and disease-specific death rate, which will be reported in terms of number and percentage of patients along with 95% confidence interval; DOR and TTF, which will be summarized by median and range and displayed by the Kaplan–Meier approach; PFS and OS, which will be summarized by median, if observed, and displayed by the Kaplan–Meier approach. Progression-free survival and OS rates will be reported at milestone timepoints (3 months, 6 months, 9 months, 12 months, and every 6 months thereafter until 36 months). Quality of life measurements, including EORTC QOL QLC-C30 and ELD14, SCI, and pain numerical rating scale will be summarized in terms of baseline, change from baseline, and observed value at each assessment visit. In addition, longitudinal and cross-sectional analyses at each treatment cycle will be performed. Treatment patterns will be summarized descriptively.

Safety includes irAEs (overall and grade ≥ 3), IRRs (overall and grade ≥ 2), and SARs, in which frequencies and percentages will be presented and incidence per 100 person-years will be calculated. Two types of duration-adjusted incident rates will be considered, specifically, number of patients (with ≥1 treatment-related irAE, IRR, or SAR) per 100-patient-year and number of events per 100-patient-year.

For ORR, PFS, DOR, and OS outcomes, subgroup analyses will be performed in immunosuppressed/immunocompromised patients and non-immunosuppressed patients with advanced BCC, regardless of etiology and in patients with prior exposure to radiation therapy.

2.9. Monitoring

The study monitor and/or designee (e.g., contract research organization monitor) may visit each site prior to enrollment of the first patient, and periodically during the study.

Data obtained during the study will be recorded on electronic case report forms by trained site personnel. Investigators will maintain accurate patient records, and all source documents will be kept on file with the case report forms. The investigator will monitor the safety of study patients at their site(s) in line with routine clinical practice. The sponsor will also monitor safety data from across all study sites.

Safety monitoring will be performed on an ongoing basis (e.g., individual review of SARs, irAEs, and IRRs) and on a periodic cumulative aggregate basis.

3. Ethics and dissemination

This study is being conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practice and applicable regulatory requirements. An appropriately constituted institutional review board/ethics committee at each site has reviewed and approved the protocol, informed consent form, and all other materials provided to the patients (NCT03836105).

Written informed consent has been obtained from each patient prior to participation in the study and after the aims, methods, objectives, and potential hazards of the study have been explained to the patient in language that they can understand.

Patients are identified solely by a patient identification number on electronic case report forms or other documents submitted to the sponsor. The patient's and investigator's

personal data are being treated in compliance with all applicable laws and regulations. All appropriate measures are being taken to ensure data confidentiality.

4. Conclusions

Prior to the approval of cemiplimab, patients with advanced BCC had limited treatment options, particularly if unsuitable for treatment with an HHI. As the first PD-1 inhibitor approved for this patient population, cemiplimab offers a new treatment option for patients with advanced BCC and disease progression or intolerance to HHIs. However, there is limited knowledge of survivorship and epidemiology among patients with advanced BCC in real-world clinical practice.

The ongoing phase IV prospective, non-interventional CASE study is evaluating the treatment effectiveness, safety, disease evolution, survivorship, and QoL in patients with advanced BCC receiving cemiplimab in the real-world setting. The CASE study will help better understand outcomes of BCC patients treated with cemiplimab in a real-world setting. These results may help to optimize patient management and guide future research initiatives.

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Author contribution

SJ Park, G Rabinowits, and NI Khushatani were investigators and conceptualized and designed the study. DM Ellison, R Weight, J Homsi, ES Ruiz, J Strasswimmer, J Simmons, and T Panella were investigators. RGW Quek supervised and acquired funding. J-F Pouliot supervised, acquired funding, and curated data. All authors reviewed and edited the manuscript and gave final approval of the version to be published. Each author agrees to be accountable for all aspects of the work.

Disclosure statement

Soo J Park reports consulting/advisory roles for Regeneron Pharmaceuticals, Inc. and funding to the institution from Regeneron Pharmaceuticals, Inc. David M Ellison reports stock and other ownership interests in Bristol-Myers Squibb, Illumina, Merck, Pfizer, and Janssen. Ryan Weight reports serving on a speaker's bureau for Immunocore and Castle Biosciences; consulting/advisory roles for Regeneron Pharmaceuticals, Inc., Pfizer, Castle Biosciences, Immunocore, Novartis, Merck, and the Association of Community Cancer Centers; and steering committee roles for the Association of Community Cancer Centers: ECHO Program. Jade Homsi reports no conflict of interest. Guilherme Rabinowits reports consulting/advisory roles for Replimune, Sanofi, Merck, Exelixis, and Biomedical insights. Emily S Ruiz reports advisory board and consulting fees from Genentech, Feldan Therapeutics, Regeneron Pharmaceuticals, Inc., and Sanofi; and serves on the board of directors for Checkpoint Therapeutics. John Strasswimmer reports consulting/advisory roles for Regeneron Pharmaceuticals, Inc.; serving on a speaker's bureau for Regeneron Pharmaceuticals, Inc., Sanofi, and Genentech; research funding from Biofrontera, Regeneron Pharmaceuticals, Inc., and Phio Pharmaceuticals, Inc.; and travel, accommodation, or expenses from Regeneron Pharmaceuticals, Inc., and Sanofi. Josh Simmons reports no conflict of interest. Timothy Panella reports no conflict of interest. Ruben GW Quek, and Jean-Francois Pouliot are employees and shareholders of Regeneron Pharmaceuticals, Inc. Nikhil I Khushalani reports grants and advisory board fees from Regeneron Pharmaceuticals, Inc., Bristol-Myers Squibb, Merck, Replimune, and Novartis; advisory board fees from Iovance, Instil Bio, Castle Biosciences, Nektar, Incyte (data safety monitoring committee), AstraZeneca (data safety monitoring committee), and Jounce Therapeutics; grants from GlaxoSmithKline, HUYA, and Celgene; honoraria from Genzyme, an NCCN ORP investigator panel (paid by Pfizer), Nektar (study steering committee), Regeneron Pharmaceuticals, Inc. (study steering committee), BMS (study steering committee), and Replimune (study steering committee); a grant from Modulation Therapeutics; travel support from Regeneron Pharmaceuticals, Inc. and Castle Biosciences; and common stock ownership of Bellicum Pharmaceuticals, Amarin, and Asensus Surgical (formerly Transenetrix). The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval and/or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

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Data availability statement

Qualified researchers may request access to study documents (including the clinical study report, study protocol with any amendments, blank case report form, statistical analysis plan) that support the methods and findings reported in this manuscript. Individual anonymized participant data will be considered for sharing once the product and indication has been approved by major health authorities (e.g., FDA, EMA, PMDA, etc.), if there is legal authority to share the data and there is not a reasonable likelihood of participant re-identification. Submit requests to https://vivli.org/.

References

Papers of special note have been highlighted as either of interest (•) or of considerable interest (••) to readers.

1. Skin Cancer Foundation. Our new approach to a challenging skin cancer statistic. 2021 [cited 2023 Oct 10]. Available from: https://www.skincancer.org/blog/our-new-approach-to-a-challenging-skin-cancer-statistic/

2. National Cancer Institute. Skin cancer treatment (PDQ®)–health professional version. 2023 [cited 2023 Sep 17]. Available from: https://www.cancer.gov/types/skin/hp/skin-treatment-pdq
3. Bichakjian C, Armstrong A, Baum C, et al. Guidelines of care for the management of basal cell carcinoma. J Am Acad Dermatol. 2018;78(3):540–559.
4. von Domarus H, Stevens PJ. Metastatic basal cell carcinoma. Report of five cases and review of 170 cases in the literature. J Am Acad Dermatol. 1984;10(6):1043–1060.
5. Bossi P, Ascierto PA, Basset-Seguin N, et al. Long-term strategies for management of advanced basal cell carcinoma with hedgehog inhibitors. Crit Rev Oncol Hematol. 2023;189:104066.
6. Referenced with permission from the NCCN clinical practice guidelines in oncology (NCCN Guidelines®) for basal cell skin cancer V.3.2024. © National Comprehensive Cancer Network, Inc; 2024. All rights reserved. cited 2024 Dec 7. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.
7. European Medicines Agency. LIBTAYO EPAR. 2023 [cited 2023 Aug 22]. Available from: https://www.ema.europa.eu/en/documents/product-information/libtayo-epar-product-information_en.pdf
8. Regeneron Pharmaceuticals Inc. LIBTAYO United States prescribing information (USPI). 2023 [cited 2023 Sep 18]. Available from: https://www.regeneron.com/downloads/libtayo_fpi.pdf
9. U.S. Food & Drug Administration. FDA approves cemiplimab-rwlc for locally advanced and metastatic basal cell carcinoma. 2021. [cited 2023 Oct 16]. Available from: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-cemiplimab-rwlc-locally-advanced-and-metastatic-basal-cell-carcinoma
10. Sanofi. Sanofi: Libtayo® (cemiplimab) approved by the European Commission as the first immunotherapy indicated for patients with advanced basal cell carcinoma. 2021. [cited 2023 Sep 18]. Available from: https://www.sanofi.com/en/media-room/press-releases/2021/2021-06-25-05-15-26-2252997
11. US Food and Drug Administration. LIBTAYO (cemiplimab) prescribing information. 2021. [cited 2024 Mar 21]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/761097s007lbl.pdf
12. US Food and Drug Administration. FDA approves cemiplimab-rwlc for 410 locally advanced and metastatic basal cell carcinoma. [cited 2021 Mar 25]. Available from: https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approvescemiplimab-rwlc-locally-advanced-and-metastatic-basal-cell-415carcinoma.
13. Migden M, Rischin D, Schmults C, et al. PD-1 blockade with cemiplimab in advanced cutaneous squamous-cell carcinoma. N Engl J Med. 2018;379(4):341–351.
14. Migden MR, Khushalani NI, Chang ALS, et al. Cemiplimab in locally advanced cutaneous squamous cell carcinoma: results from an open-label, phase 2, single-arm trial. Lancet Oncol. 2020;21(2):294–305.
15. Rischin D, Migden MR, Lim AM, et al. Phase 2 study of cemiplimab in patients with metastatic cutaneous squamous cell carcinoma: primary analysis of fixed-dosing, long-term outcome of weight-based dosing. J Immunother Cancer. 2020;8(1):e000775.
16. Sezer A, Kilickap S, Gümüş M, et al. Cemiplimab monotherapy for first-line treatment of advanced NSCLC with PD-L1 ≥50%: a randomised controlled trial. Lancet. 2021;397(10274):592–604.
17. Chalmers ZR, Connelly CF, Fabrizio D, et al. Analysis of 100,000 human cancer genomes reveals the landscape of tumor mutational burden. Genome Med. 2017;9(1):34.
18. Buttner R, Longshore JW, Lopez-Rios F, et al. Implementing TMB measurement in clinical practice: considerations on assay requirements. ESMO Open. 2019;4(1):e000442.
19. Stratigos AJ, Sekulic A, Peris K, et al. Cemiplimab in locally advanced basal cell carcinoma after hedgehog inhibitor therapy: results from an open-label, phase 2, single-arm trial. Lancet Oncol. 2021;22(6):848–857.
• **This article highlights the clinically meaningful antitumour activity and an acceptable safety profile with cemiplimab in patients with locally advanced BCC after HHI therapy. This article is of interest as it shows there is precedence for the use of cemiplimab in this population.**
20. Lewis KD, Peris K, Sekulic A, et al. Final analysis of phase II results with cemiplimab in metastatic basal cell carcinoma after hedgehog pathway inhibitors. Ann Oncol. 2024;35(2):221–228.
• **This article highlights the clinically meaningful antitumour activity and an acceptable safety profile with cemiplimab in patients with locally advanced BCC who had progression or intolerance to HHI therapy.**
21. Migden MR, Chandra S, Rabinowits G, et al. CASE (CemiplimAb-rwlc Survivorship and Epidemiology) study in advanced cutaneous squamous cell carcinoma. Future Oncol. 2020;16(4):11–19.
•• **This article highlights the CASE study which is a Phase IV study evaluating outcomes data from patients with advanced CSCC receiving cemiplimab in a real-world setting. As limited information exists on cemiplimab outside of clinical trials this article is of considerable interest.**