

UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD

MERCK SHARP & DOHME LLC,
Petitioner

v.

THE JOHNS HOPKINS UNIVERSITY,
Patent Owner

Patent No. 11,591,393 B2

Inter Partes Review No. IPR2024-00240

REBUTTAL DECLARATION OF SEAN D. SHERIDAN, PH.D.

January 31, 2025

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I. INTRODUCTION

A. Qualifications

1. My name is Sean D. Sheridan, and I am a Vice President in the Intellectual Property practice at Charles River Associates (“CRA”) in its Chicago office.
2. CRA is an international business consulting firm focusing on, among other things, intellectual property matters in the context of strategy, licensing, valuation, and litigation consulting. CRA provides expert testimony on commercial success, compensatory damages, and other areas requiring accounting, financial, and economic expertise. Outside of litigation, CRA performs valuations for transactional, business decision-making, and regulatory purposes. CRA also provides strategic consulting services to help companies align their intellectual property strategy and investments with overall business strategy.
3. My consulting work has been primarily related to the valuation and strategic management of intellectual property assets. I have valued intellectual property rights in connection with litigation, licensing,

- divestitures, and acquisitions, and in a variety of other contexts. I have advised clients throughout the intellectual property commercialization process, including strategy development, financial modeling, and transaction negotiation. My work on litigation matters has involved the evaluation of commercial success, the quantification of economic damages, and assessment of domestic industry. I have taught workshops and spoken on the subject of intellectual property valuation in a variety of forums and have been selected to the IAM Patent 1000 – The World’s Leading Patent Professionals (as a recommended economic expert) every year since 2019, based on nominations from industry participants.
4. Prior to my work as a consultant, I was an assistant director at the technology transfer office at the University of Chicago. In that role, I was responsible for managing the intellectual property strategy for a broad portfolio of technologies, primarily in the life sciences field. I also personally negotiated numerous contracts including license agreements, option agreements, and collaboration agreements with companies ranging from Fortune 500 firms to small start-ups. I was also frequently required to assess the value of technology portfolios

and potential licensed products. My curriculum vitae is attached hereto as Schedule 1.

5. CRA is being compensated on a rate-times-hours basis for the work I and individuals working under my supervision perform. My billing rate for this matter is \$850 per hour, and those working at my direction have lower billing rates. CRA's compensation does not depend in any way on the outcome of this *Inter Partes* Review proceeding.

B. Assignment

6. I have been retained by counsel for Petitioner Merck Sharp & Dohme LLC ("Merck") in IPR2024-00240, which I understand concerns U.S. Patent No. 11,591,393 (the "'393 Patent").
7. I have been asked to offer my opinions, based on my knowledge, experience and analysis of information available in these proceedings, about whether the commercial performance of Keytruda[®] (pembrolizumab) when used as a treatment for microsatellite instability-high or mismatch repair deficient colorectal cancer (MSI-H/dMMR CRC) has a nexus to the methods claimed in the '393 Patent. I have also been asked to review and respond to the

Declaration of Brian J. Segers dated October 4, 2024 (Ex. 2191) which was submitted on behalf of The Johns Hopkins University (“JHU”). It is my understanding that JHU bears the evidentiary burden in establishing commercial success as a secondary consideration of nonobviousness, and for the reasons discussed below, it is my opinion that neither JHU nor Mr. Segers have met this burden.

C. Information Reviewed or Relied Upon

8. In performing my analysis and forming the opinions expressed in this report, my staff and I reviewed and/or relied upon various documents produced by Merck and publicly available information. The documents reviewed and/or relied upon by me and those under my direction are listed in Schedule 2 and referenced in the text, footnotes, and attached exhibits of this report. In addition, I had two discussions with Merck declarant Dr. Paul E. Oberstein, who is a practicing clinical oncologist.
9. I may supplement and/or amend my opinion to reflect information made available to me subsequent to the issuance of this report.

II. SUMMARY OF CONCLUSIONS

10. Based on my analysis of information gathered during the course of my work in this matter, it is my opinion that there is no evidence of a nexus between the challenged claims of the '393 Patent and the commercial performance of Keytruda's use as a treatment for MSI-H/dMMR CRC. It is also my understanding that Mr. Segers' analysis is not informed by the perspective of someone in the medical field. Additionally, Mr. Segers presents a flawed and misleading analysis which does not support any secondary consideration of nonobviousness of the '393 Patent claims.

III. BACKGROUND

A. Market Overview

1. Immune Checkpoint Inhibitors

11. I understand from Merck declarant Dr. Alfred I. Neugut, a practicing oncologist, that pembrolizumab (Keytruda) is a type of PD-1 inhibitor, and that PD-1 inhibitors are a type of immunotherapy called checkpoint inhibitors. (EX1003, ¶¶29-32.) I also understand that PD-1 inhibitors boost the immune system in a specific way, and that they

fight cancer by preventing the PD-1/PD-L1 interaction between T-cells and cancer cells from occurring. (EX1003, ¶¶ 29-32.)

According to Dr. Neugut, this interaction “uncloaks the cancer cells, making them susceptible to recognition and removal by T-cells.” (EX1003, ¶32.)

12. Current FDA-approved immune checkpoint inhibitors include the products listed in the following figure:

Figure 1: FDA-Approved Immune Checkpoint Inhibitors

Checkpoint Inhibitors	FDA Approved Products
PD-1 inhibitors	Keytruda (pembrolizumab)
	Opdivo (nivolumab)
	Libtayo (cemiplimab)
	Zynyz (retifanlimab-dlwr)
	Jemperli (dostarlimab)
	Loqtorzi (toripalimab)
PD-L1 inhibitors	Tecentriq (atezolizumab)
	Tecentriq Hybreza (atezolizumab and hyaluronidase-tqjs)
	Bavencio (avelumab)
	Imfinzi (durvalumab)
CTLA-4 inhibitors	Yervoy (ipilimumab)
	Imjudo (tremelimumab)

LAG-3 inhibitors	Opdualag ¹ (nivolumab and relatlimab-rmbw)
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(EX1152-1155; EX2203.)

2. Keytruda Overview

13. According to Merck, “Keytruda is an anti-programmed death receptor-1 (PD-1) therapy that works by increasing the ability of the body’s immune system to help detect and fight tumor cells. Keytruda is a humanized monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2, thereby activating T lymphocytes which may affect both tumor cells and healthy cells.” (EX1156.)

14. On February 27, 2014, Merck submitted Biologics License Application (“BLA”) 125514 for Keytruda (pembrolizumab) for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor. (EX1169.) Keytruda achieved Breakthrough Therapy Designation status from the FDA, and on

¹ Opdualag is a combination of a LAG-3 inhibitor and a PD-1 inhibitor.

September 4, 2014, was granted accelerated approval. (EX1169.)

Merck subsequently launched Keytruda that same month. (EX2187.)

15. Merck has invested considerable resources into Keytruda and has even moved scientists and funds from other projects to support the drug's development. (EX1158.) As a result of these investments, Keytruda has received more than 50 FDA approvals and is indicated to treat a variety of different types of cancer, as summarized in the following figure.

Figure 2: Keytruda FDA Approvals by Indication – 2014 to Present²

Tumor Type	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
Melanoma	X	X				X		X			
NSCLC		X	X	X	XX	X				XX	
HNSCC			X			XX					
cHL				X			XX				
Bladder				XX			X			XXX	
MSI-H/dMMR CRC				X			X				
MSI-H/dMMR				X							
Gastric								X		X	
Cervical					X			XX			X
PMBCL					X						
HCC					X						
MCC					X						
RCC						X		XX			
Esophageal						X		X			
Endometrial						X		X	X		X
TMB-H							X				
cSCC							X	X			
TNBC							X	XX			
Biliary										X	
MPM											X

(Schedule 9.0.)

16. Additionally, according to the NCI, off-label use of drugs (i.e., prescribing a drug for a different purpose than what the FDA approved) is very common in cancer treatment. (EX1206.)

According to an analysis conducted by researchers at the University of Chicago in which private insurance, Medicare, and Medicaid claims from January 2015 to September 2016 were reviewed, approximately

² Each 'X' represents a Keytruda FDA approval. (EX1159-1205.) When there were multiple Keytruda FDA approval letters for an indication in a given year, or multiple approved indications included in a single letter, multiple 'X' marks have been indicated. This figure excludes all approvals that were subsequently withdrawn by the FDA.

one-third of patients (292 out of 871 patients) who put in claims for Keytruda were taking the drug for an off-label use. (EX1207.)

3. MSI-H/dMMR CRC Treatments

17. I understand from Dr. Neugut that a patient's cancer is considered microsatellite instability high ("MSI-H") if the cancer cells' DNA contains small tracts of repeating DNA ("microsatellites") that are different sizes than the regularly occurring microsatellites. (EX1003, ¶¶ 26-28.) I also understand that MSI-H is caused by mismatch repair deficiency ("dMMR") where the cell's mismatch repair proteins are nonfunctional and spontaneous mutations in the DNA are therefore not repaired. (EX1003, ¶¶ 26-28.) According to Dr. Neugut, "MSI-H and dMMR are 'biologically the same.'" (EX1003, ¶ 28.)
18. According to the current National Comprehensive Cancer Network Guidelines ("NCCN Guidelines"), certain chemotherapy regimens and/or immune checkpoint inhibitors may be used to treat MSI-H/dMMR CRC. (EX1208, 20-23; EX1209, 26-29.) The immune checkpoint inhibitors recommended by the NCCN Guidelines for the treatment of MSI-H/dMMR CRC include Keytruda (pembrolizumab),

Opdivo (nivolumab), Yervoy (ipilimumab), and Jemperi (dostarlimab). (EX1208, 49, 107, 132, 140; EX1209, 26, 29, 60, 64.)

19. Keytruda, Opdivo, and Opdivo plus Yervoy have received FDA approval for the treatment of patients with MSI-H/dMMR CRC. (See Figure 1; EX1210.) Jemperi has received the FDA's Breakthrough Therapy Designation for the treatment of patients with locally advanced MSI-H/dMMR rectal cancer.³ (EX1154.)

B. The Challenged Patent

20. The '393 Patent, titled *Checkpoint blockade and microsatellite instability*, was filed on September 2, 2021, and issued on February 28, 2023. (EX1001.) I understand that the alleged priority date of the '393 Patent is July 10, 2015. (EX1212.) I understand that the '393 Patent claims methods of treating microsatellite instability high or DNA mismatch repair deficient colorectal cancer. (EX1001.) Claim 1 of the '393 Patent is shown below.

³ "The FDA's Breakthrough Therapy designation is a process designed to expedite the development and review of drugs that are intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s)." (EX1211.)

A method of treating microsatellite instability high or DNA mismatch repair deficient colorectal cancer in a human patient, the method comprising:

testing, or having tested, a biological sample obtained from a patient having colorectal cancer, thereby determining that the patient's colorectal cancer is microsatellite instability high or mismatch repair deficient; and

in response to determining that the colorectal cancer is microsatellite instability high or DNA mismatch repair deficient, treating the patient with a therapeutically effective amount of pembrolizumab.

(EX1001.)

21. I understand from Dr. Oberstein that the Keytruda antibody is not claimed by the '393 Patent. In addition, Mr. Segers appears to rely generally on the independent claims of the '393 Patent and does not tie his commercial success analysis to any dependent claims.

(EX2191 ¶¶ 36-37.) Further, Mr. Segers relies on JHU declarant Dr. Richard Goldberg for his analysis, and, as I understand from Dr. Oberstein, Dr. Goldberg did not provide any purported analysis of nexus for claims other than Claim 1. (See EX2191 ¶¶ 7, 36; EX1150, ¶ 179 (citing EX2090 ¶¶ 27-65).)

IV. COMMERCIAL SUCCESS AND NEXUS

22. I understand from counsel that the commercial success of a product can be used as an “objective indicia” in demonstrating the nonobviousness of the underlying patented invention. I also understand that in the law the concept of commercial success “presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art” and that “the law deems evidence of (1) commercial success, and (2) some causal relation or ‘nexus’ between an invention and commercial success of a product embodying that invention, probative of whether an invention was nonobvious.” *Merck & Co., Inc. v. Teva Pharms. USA*, 395 F.3d 1364, 1376 (Fed. Cir. 2005).

23. I understand that the Federal Circuit has explained the nexus requirement as follows:

To establish a proper nexus between a claimed invention and the commercial success of a product, a patent owner must offer proof that the sales were a direct result of the unique characteristics of the claimed invention—as opposed to other economic and commercial factors unrelated to the quality of the patented subject matter. If a product both embodies the claimed features and is

coextensive with the claims at issue, a nexus is presumed. In other words, a nexus exists if the commercial success of a product is limited to the features of the claimed invention. But if the commercial success is due to an unclaimed feature of the device or if the feature that creates the commercial success was known in the prior art, the success is not pertinent.⁴

Sightsound Techs., LLC v. Apple Inc., 809 F.3d 1307, 1319 (Fed. Cir. 2015) (internal citations and quotations omitted).

24. I also understand that the commercial success of a product may not support or indicate nonobviousness of a patent where market entry by others was impeded for some reason, such as the existence of a “blocking patent” (i.e., an earlier U.S. patent that is in place before the claimed invention, which prevents practice of the claimed invention).

Merck & Co., Inc. v. Teva Pharms. USA, 395 F.3d at 1376; *Acorda Therapeutics, Inc. v. Roxane Labs., Inc.*, 903 F.3d 1310, 1338 (Fed. Cir. 2018).

25. In the following sections of this report, I analyze the commercial performance of Keytruda’s use as a treatment for MSI-H/dMMR CRC and assess whether a nexus has been shown to exist between the

⁴ I understand that a presumption of nexus does not exist with respect to the '393 Patent.

methods claimed in the '393 Patent and the commercial performance of Keytruda's use as a treatment for MSI-H/dMMR CRC.

A. Lack of Nexus Between Commercial Performance of Keytruda as an MSI-H/dMMR CRC Treatment and the '393 Patent

26. I understand that JHU bears the burden of proving there is a nexus between its proffered evidence of commercial success and any alleged novel features of the '393 Patent claims, and that if it fails to do so, such evidence must be discounted when determining obviousness. *Novartis AG v. Torrent Pharms. Ltd.*, 853 F.3d 1316, 1330-31 (Fed. Cir. 2017).
27. Mr. Segers offers no independent analysis of the nexus issue, instead purporting to rely entirely on an October 1, 2024 conversation with an expert witness retained by JHU, Dr. Richard Goldberg, for the proposition that there is a nexus between the commercial success of Keytruda's use for the treatment of MSI-H or dMMR CRC and the '393 Patent claims. (EX2191, ¶¶7, 37.) Dr. Goldberg, however, testified the following about that October 1, 2024 conversation with Mr. Segers: "I don't believe that I provided him any substantive

information contained in my report. He was interested in telling me what he was opining on, *not listening to what I was opining on*, and that wasn't the purpose of the call." (EX1136, 193:13-195:17 (emphasis added).)

28. The nexus alleged in Mr. Segers' declaration is therefore entirely unsupported, and it is further undermined by Mr. Segers' failure to address several confounding factors impacting the commercial performance of Keytruda as a treatment for MSI-H/dMMR CRC, as discussed below.

**1. Merck Patents and Clinical Development Activities
Created Economic Disincentives for Others to Develop
the '393 Patent**

29. I understand that an earlier U.S. patent that is in place before a claimed invention, which prevents practice of that later claimed invention (sometimes referred to as a "blocking patent") may offer an alternative explanation for why others in the market did not develop a product or technology sooner, even if it were obvious—i.e., because others were economically disincentivized or "blocked" from doing so by potential enforcement of the blocking patent. *Acorda*

Therapeutics, Inc. v. Roxane Labs, Inc., 903 F.3d 1310, 1338 (Fed. Cir. 2018).

30. According to Merck's website, at least the following U.S. patents associated with Keytruda were filed and/or issued before the July 10, 2015 alleged priority date of the '393 Patent:

Figure 3: Merck Patents Associated with Keytruda

U.S. Patent No.	Filing Date	Date of Patent
8,354,509	June 13, 2008	January 15, 2013
8,900,587	December 19, 2012	December 2, 2014
9,220,776	September 30, 2013	December 29, 2015
9,834,605	December 19, 2014	December 5, 2017

(EX1213-1215, 1217, 1238.)

31. As of July 10, 2015, the alleged priority date of the '393 Patent, others would have been aware of Merck's rights to pembrolizumab given the fact that Merck launched Keytruda in September 2014 and at least one

of the Merck U.S. patents associated with Keytruda listed in Figure 10 had issued over a year earlier in January 2013. Others would also have been aware that Merck was pursuing related continuation or divisional applications, one of which issued in December 2014, more than seven months before the alleged priority date.

32. Furthermore, as of July 2015, others would have been aware that Merck was conducting multiple clinical trials to expand the approved indications for Keytruda. For example, on October 27, 2014 during Merck's Q3 2014 earnings call, the executive vice president of Merck Research Laboratories stated that "our development program for Keytruda has expanded to include more than two dozen studies around the world involving more than 6,000 patients and addressing more than 30 different tumor types." (EX1218, 8.) Merck's 10-Q filing for the quarterly period ended September 30, 2014 stated that "[t]he pembrolizumab clinical development program also includes studies across a broad range of cancer types including: bladder, colorectal, gastric, head and neck, melanoma, non-small cell lung, renal, triple negative breast and hematological malignancies." (EX1219, 46.)

33. Importantly, as of July 2015, others would also have been aware that Merck was a collaborator with JHU on the clinical trial related to MSI-H/dMMR CRC. On June 12, 2013, the clinical trial protocol was published on ClinicalTrials.gov, describing, among other things, using Keytruda to treat patients with MSI-H CRC, and identifying Merck as a collaborator on the trial. (EX1005.)
34. Thus, as of the alleged priority date of the '393 Patent in July 2015, an economic disincentive existed for others to develop Keytruda in accordance with the methods of the challenged claims of the '393 Patent, since others would be at risk of infringing Merck's key patents covering Keytruda and competitors would be aware that Merck was actively seeking FDA approvals for Keytruda in new indications including MSI-H/dMMR CRC.
35. Mr. Segers' failure to consider any of the above economic disincentives undermines his conclusion that "Keytruda's commercial success in treating MSI-H or dMMR colorectal cancer is due to the claimed invention." (EX2191, ¶10.)

**2. Mr. Segers Fails to Account for Other Factors that
May Have Contributed to Commercial Success**

36. The calculations and conclusions described in Mr. Segers’ declaration are flawed and unreliable for the reasons described in this declaration. However, even if these calculations were accurate—which they are not—Mr. Segers makes no attempt to consider other factors that may have led to the commercial performance of Keytruda used for the treatment of MSI-H/dMMR CRC.
37. For example, according to the previously discussed IQVIA 2023 white paper, multi-indication products such as Keytruda can benefit from “creating a ‘halo effect’ in the marketplace across indications to drive incremental brand awareness spanning different [health care provider] specialties and other stakeholders, thereby giving the asset a competitive edge.” (EX1120, 2.) This is a particularly relevant issue for Keytruda, which has obtained more than 50 approvals, and received the Prix Galien USA Award for Best Biotechnology Product in 2015, which is “considered the highest accolade for pharmaceutical research and development.” (See Figure 2; EX1221.) Mr. Segers fails to consider how Keytruda’s numerous other approvals contributed to

- its performance in the MSI-H/dMMR CRC treatment marketplace, despite Mr. Segers' testimony conceding that brand recognition could be a factor that would increase the likelihood of a physician prescribing Keytruda over another drug, such as Opdivo. (EX1137, 110:5-114:11.) Instead, Mr. Segers incorrectly assumes that Keytruda's approval for the treatment of MSI-H/dMMR CRC led to Keytruda's success in other indications (e.g., Mr. Segers incorrectly claims that there was an inflection point in Keytruda sales that occurred in May 2017). (EX2191, ¶26.)
38. Mr. Segers also fails to account for the synergies achieved by virtue of Keytruda's prior success for other indications. From launch, Keytruda's MSI-H/dMMR CRC indication benefitted from the pre-existing manufacturing infrastructure and distribution networks that Merck already had in place to support prior indications. Despite Mr. Segers' understanding that such synergies could have contributed to Merck's profit margins for the relevant years, this confounding factor went unaddressed in his declaration. (EX1137, 53:10-55:20.)
39. Mr. Segers' failure to consider any of the above factors further undermines his conclusion that "Keytruda's commercial success in

treating MSI-H or dMMR colorectal cancer is due to the claimed invention.” (EX2191, ¶10.)

**3. Mr. Segers Does Not Establish Nexus Between Any
Alleged Novel Features of the ’393 Patent Claims and
Commercial Success**

40. I understand that the validity of a patent is assessed on a claim-by-claim basis. Therefore, I understand that to potentially provide objective evidence regarding the validity of a patent claim, such evidence must correspond to any alleged novel limitations of the patent claim being evaluated. Mr. Segers fails to tie the commercial performance of Keytruda used for the treatment of MSI-H/dMMR CRC to any alleged novel limitations of the claims of the ’393 Patent.
41. First, Mr. Segers does not consider what was known in the prior art relative to any alleged novel limitations of the claims of the ’393 Patent. I understand that every limitation of every claim had been previously disclosed in the study record published on ClinicalTrials.gov on June 10, 2013 (the “MSI-H Study Record” (EX1005)), or in the MSI-H Study Record in combination with

additional prior art references. (EX1003, §§VII.A-H; EX1150, §§VII.D-K.)

42. Second, I understand that the '393 Patent has numerous dependent claims which relate to, among other things, different methods of testing a biological sample and different methods of providing treatment. The Segers declaration attributes the alleged commercial success of Keytruda for the treatment of MSI-H/dMMR CRC to the '393 patent claims, regardless of which methods were used to test the biological samples or treat patients. Thus, if the Board were to find that certain claims of the '393 Patent were not novel, the analysis presented in Mr. Segers' declaration would not be relevant because it does not tie the alleged commercial success to any of the specific claimed methods of testing a biological sample or methods of providing treatment.

B. Commercial Performance of Keytruda Used to Treat CRC

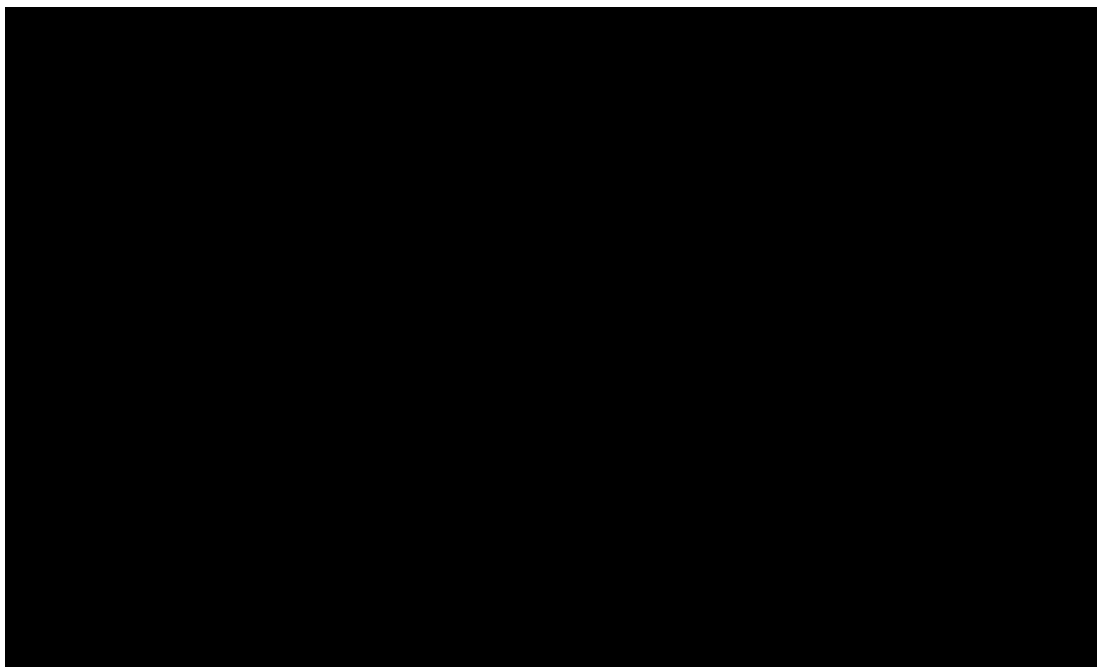
43. Even if Mr. Segers had successfully proven the requisite nexus, his underlying conclusions regarding the commercial performance of Keytruda's use as a treatment for MSI-H or dMMR colorectal cancer are based on an incomplete and flawed analysis.

44. In his declaration, Mr. Segers states that “Keytruda’s use in treating MSI-H or dMMR colorectal cancer is commercially successful because: its sales and profits have been substantial and growing since launch, its number of patients undergoing treatment has been substantial and growing since launch, [and] its share of sales within its relevant market has been growing since launch.” (EX2191, ¶9.) In the following sections, I assess each of these categories of evidence that purportedly support Mr. Segers’ conclusion.

1. Keytruda CRC Patients

45. Mr. Segers misinterprets the estimated Keytruda patient and sales data. Since Keytruda received FDA approval for the treatment of MSI-H/dMMR CRC patients in May 2017, CRC patients have accounted for [REDACTED] based on IQVIA estimates. (Schedule 3.3.) The following figure compares the monthly total number of patients receiving Keytruda to the monthly total CRC patients receiving Keytruda for the January 2017 – January 2024 period.

**Figure 4: Monthly Keytruda Total Patients vs Monthly Keytruda Total
CRC Patients (January 2017 – January 2024)**



(Schedule 3.3.)

46. According to the IQVIA estimated monthly patient data, the ratio of Keytruda CRC patients to total Keytruda patients [REDACTED]

[REDACTED] (Schedule

3.3.) The average monthly growth rate of total Keytruda CRC patients per year has also [REDACTED]. (Schedule 3.1)

47. Mr. Segers also states in his declaration that “[t]he fact that [REDACTED] [REDACTED] are being treated with Keytruda each year is further evidence of its commercial success.” (EX2191, ¶32.) To the extent Mr. Segers is referring to all patients receiving Keytruda for all indications, this is

not evidence of commercial success of Keytruda in the MSI-H/dMMR CRC indication. To the extent Mr. Segers is referring specifically to MSI-H/dMMR CRC patients, this is misleading in that it fails to recognize that [REDACTED]

[REDACTED] (Schedule 3.0.) Furthermore, annual new Keytruda MSI-H/dMMR CRC patients as a percentage of all new Keytruda patients [REDACTED]. (Schedule 3.0.)

48. The analyses described above demonstrate that MSI-H/dMMR CRC patients [REDACTED] [REDACTED] and the growth rate of this [REDACTED] of Keytruda patients has [REDACTED].

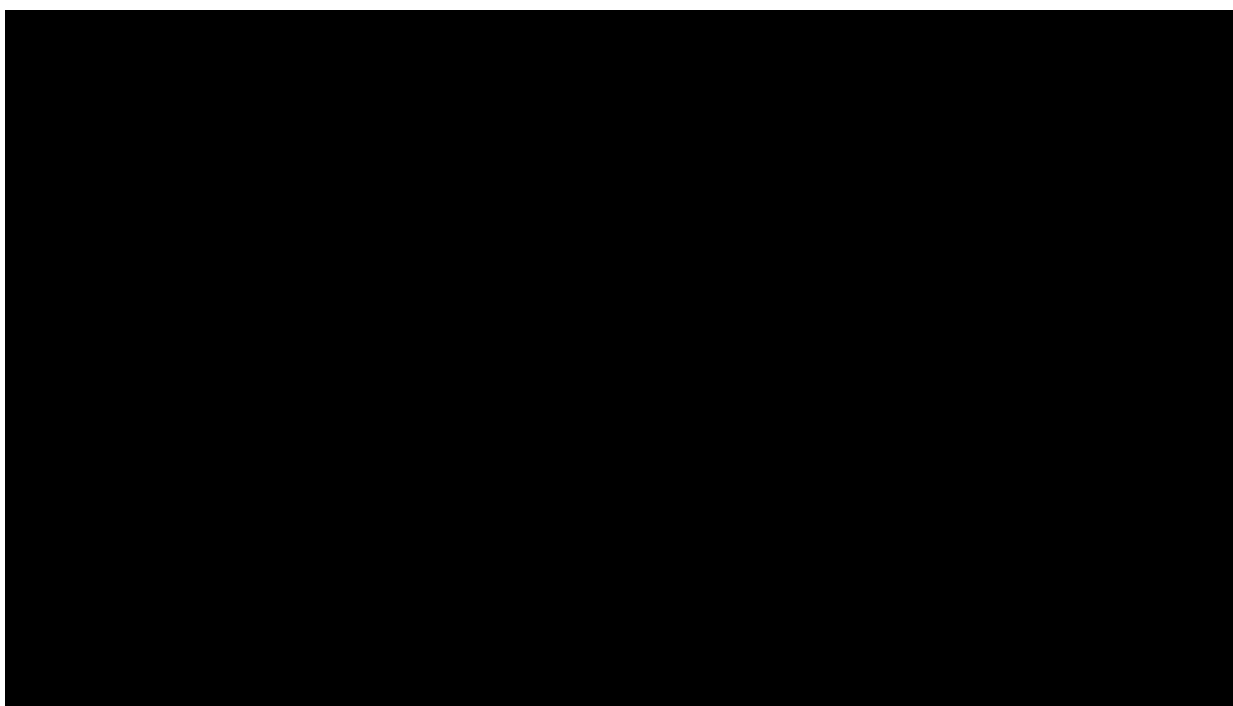
2. Keytruda CRC Sales Revenue

49. Mr. Segers “assume[s] that the percentage of total sales attributable to MSI-H or dMMR CRC is equal to the percentage of total patients that are MSI-H or dMMR CRC patients.” (EX2191, ¶27 n.35.) When asked at his deposition what percentage of Keytruda sales are associated with patients having MSI-H colorectal cancer, Mr. Segers responded “4 to 5 percent.” (EX1137, 51:6-14.) However, under the assumption that the percentage of sales attributable to MSI-H/dMMR

CRC is equal to the percentage of patients that are MSI-H/dMMR CRC, the percentage of Keytruda sales attributable to MSI-H/dMMR CRC is only approximately [REDACTED] of sales since Keytruda was approved for the treatment of MSI-H/dMMR CRC. (Schedules 4.0 and 4.1.)

50. The following figure compares total annual Keytruda revenue to the estimated annual Keytruda CRC revenue for 2015 – 2023.

Figure 5: Annual Total Keytruda Revenue vs. Estimated Annual Keytruda MSI-H/dMMR CRC Revenue (2015 – 2023)



(Schedule 4.0.)

51. Mr. Segers also asserts that “the timing of Keytruda’s FDA approval for the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or dMMR solid tumors coincides with an apparent inflection point in Keytruda’s sales trajectory.” (EX2191, ¶26.)

Setting aside the fact that this statement relates to all unresectable or metastatic MSI-H/dMMR solid tumors (as opposed to the treatment of MSI-H/dMMR CRC tumors which is the subject of the ’393 Patent claims), the May 2017 Keytruda approvals for MSI-H/dMMR CRC and MSI-H/dMMR solid tumors do not coincide with an inflection point in Keytruda’s sales trajectory.

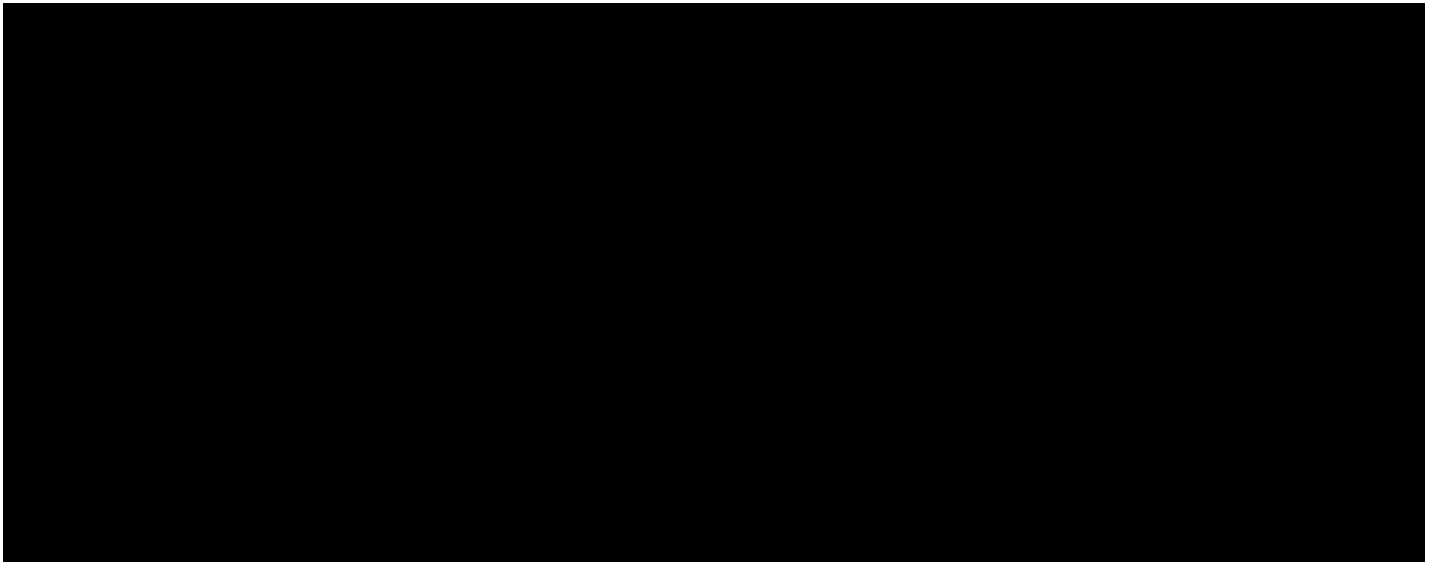
52. As purported evidence of an inflection point occurring in May 2017, Mr. Segers states:

Keytruda earned [REDACTED] in net sales in the four quarters following FDA approval for the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or dMMR solid tumors (2017 Q2 through 2018 Q1) than it had in the four quarters prior, for a growth of [REDACTED]. By comparison, Keytruda sales grew by only [REDACTED] in the four quarters prior to FDA approval for the treatment of adult and pediatric patients with unresectable or metastatic MSI-H or dMMR solid tumors (2016 Q2 through 2017 Q1), a growth rate of [REDACTED]. This increase in the rate of growth several years after launch is notable, as typically growth rates are highest in the years immediately following launch.

(EX2191, ¶26.)

53. However, the quarterly growth rate in [REDACTED]
[REDACTED]
[REDACTED] indicating that the inflection point in Keytruda sales began in
Q4 2016 rather than Q2 2017. (Schedule 5.1.) Further, as shown
below, the growth rate of the Q2 2017 – Q1 2018 period was [REDACTED]
[REDACTED] than the growth rate of the prior four quarters
while the growth rate of the Q4 2016 – Q3 2017 period was [REDACTED]
[REDACTED] than the growth rate of the prior four
quarters.

Figure 6: Q4 2016 vs. Q2 2017 – Inflection Point Comparison⁵



(Schedule 5.0.)

⁵ Dollar values are in millions.

54. These data demonstrate that the inflection point in Keytruda's sales trajectory began Q4 2016, prior to the Q2 2017 Keytruda approvals for MSI-H/dMMR CRC and MSI-H/dMMR solid tumors.
55. The Q4 2016 inflection point in Keytruda's sales trajectory coincides with Keytruda's October 24, 2016 approval which provided "an expansion of the metastatic NSCLC indication to include first-line treatment of patients whose tumors have high PD-L1 expression (TPS $\geq$ 50%) as determined by an FDA approved test, with no EGFR or ALK genomic tumor aberrations." (EX1199.) Prior to this approval, Keytruda's use in the NSCLC indication was limited to "the treatment of patients with metastatic, PD-L1 positive, non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy." (EX1171.)
56. The expansion of the metastatic NSCLC indication has been recognized as being key to Keytruda's success. An IQVIA 2023 white paper titled "Success Multiplied: Launch Excellence for Multi-Indication Assets" describes the significance of this approval to Keytruda's launch strategy which focused first on narrow indications

before obtaining subsequent approvals in broader indications (referred to as a “narrow first” launch strategy). (EX1220, 4.)

Keytruda is a case in point for a tremendously successful ‘narrow first’ strategy, in which the PD-L1 biomarker played a crucial role. When launching Keytruda, Merck chose a highly targeted approach, focusing on second-line NSCLC patients with high PD-L1 expression who should see the greatest benefit. Conversely, Opdivo launched with a broad strategy, targeting all second-line NSCLC patients regardless of PD-L1 expression.

By demonstrating superior outcomes in its narrow initial population, Keytruda secured subsequent approval for first-line NSCLC patients with tumours expressing high levels of PD-L1, opening up the larger first-line market opportunity. At the same time, the FDA expanded use of Keytruda to all second-line NSCLC patients regardless of level of PD-L1 expression. Thus ‘narrow-first’, followed by strategic indication expansion, provided the path towards broad use of Keytruda and, ultimately, its dominant market position [].

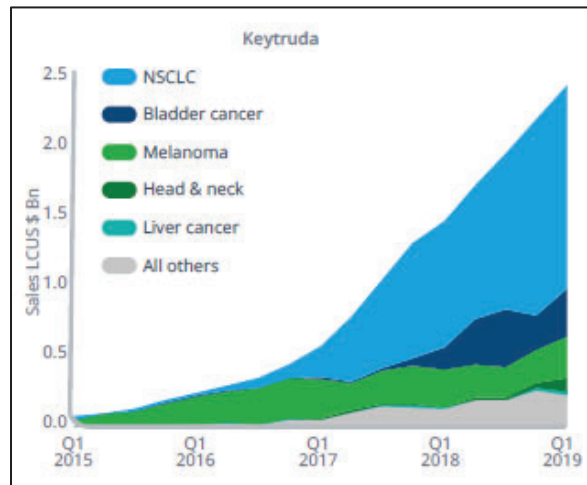
Today, most multi-indication oncology products pursue a narrow-first indication sequencing strategy, a reflection of the growing number of approvals based on less mature data, an increasingly crowded and competitive oncology landscape which payers use to their advantage, and the reality of significant differences in products’ relative value in different indications.

(EX1220, 4.)

57. By the time Keytruda received approval for the treatment of MSI-H/dMMR CRC and MSI-H/dMMR solid tumors in Q2 2017, lung cancer accounted for approximately 50% of all US sales of Keytruda.

(EX2231, 6.) The IQVIA whitepaper also included the following graph illustrating the significance of the NSCLC indication to Keytruda’s global sales.

Figure 7: Keytruda Sales by Indication (Q1 2015 – Q1 2019)



(EX1220, 3-4.)

58. I also note that numerous public sources indicate that Keytruda has the leading share of the NSCLC market. (EX1222, 4; EX1223-1225.)
59. Mr. Segers states that the “increase in the rate of growth several years after launch is notable, as typically growth rates are highest in the years immediately following launch.” (EX2191, ¶26.) This statement fails to recognize that an increasing growth rate several years after launch is the expected outcome of a multi-indication product pursuing

a “narrow first” strategy because the product’s initial approved indications are intended to be smaller in size than later approved indications.

60. Mr. Segers also asserts that “Keytruda’s sales for MSI-H or dMMR CRC have been strong compared to competitor products in the market.” (EX2191, ¶28.) This assertion, however, is based on an incomplete analysis of the MSI-H/dMMR CRC marketplace and based on arbitrary assumptions about competing product sales. The only competing products that Mr. Segers considers are BMS’s Opdivo and Yervoy. (EX2191, ¶28.) Yet, Mr. Segers testified that he agreed that [REDACTED] of new MSI-H/dMMR CRC patients were not receiving Keytruda or one of the BMS drugs, that he did not have data indicating what [REDACTED] of MSI-H CRC patients were being treated with, and that some patients “may be on other treatments and not on immunotherapies at all.” (EX1137, pp. 63:3-68:8.) In other words, Mr. Segers excludes [REDACTED] of MSI-H/dMMR CRC patient treatments in his comparison of competitor products. Additional treatments that Mr. Segers ignores include at least standard chemotherapies and Jemperli, which, as previously stated, is recommended by the NCCN guidelines for the treatment of MSI-

H/dMMR CRC and has received the FDA’s Breakthrough Therapy Designation for the treatment of patients with locally advanced MSI-H/dMMR rectal cancer.⁶

61. Moreover, Mr. Segers’ estimates of Opdivo and Yervoy sales for the treatment MSI-H/dMMR CRC are wholly unsupported. Mr. Segers incorrectly claims that “[a]ccording to Bristol-Myers Squibb, MSI-H or dMMR CRC indications accounted for no more than—and likely less than—5 percent of OPDIVO and YERVOY U.S. sales in 2018 and 2019.” (EX2191, ¶28.) He then assumes without support that MSI-H/dMMR CRC accounted for no more than 5% of Opdivo and Yervoy U.S. sales for the entire 2018-2023 time period. (EX2191, app. 6.) To support the claim that 5% or less of Opdivo and Yervoy sales in 2018 and 2019 were attributable to the MSI-H/dMMR CRC indication, Mr. Segers cites to BMS earnings call transcripts which provide the following breakdown of U.S. sales of Opdivo and Yervoy by indication.

⁶ Opdivo as a single agent and the combination of Opdivo and Yervoy are approved for the treatment of MSI-H/dMMR CRC that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan. (EX1226; EX2236.)

Figure 8: Sales of Opdivo and Yervoy by Indication in the U.S.
According to BMS Earnings Call Transcripts (Q2-Q3 2018 & Q1 2019)⁷

Indication	Q2 2018	Q3 2018	Q1 2019
Lung	35%	35%	25%
Melanoma	35%	30%	30%
Renal	20%	20%	20%
Head and Neck	5%	N/A	N/A
Other Indications	5%	15%	20%
Total	100%	100%	95%

(EX2213, 10; EX2214, 12; EX2215, 10.)

62. Mr. Segers testified that according to the statement made in the Q2 2018 Earnings Call, “35 percent of their mix is melanoma, the lung cancers in line with that 20 percent for renal, 5 percent for head and neck, little bit of all the others, which would presumably include this

⁷ The estimates provided in Bristol-Myers Squibb Company, Q1 2019 Earnings Call, dated April 25, 2019 (EX2215) sum to only 95% of total U.S. sales.

CRC indication. So that's why I've used the upper bound of 5 percent, because in his public statement, he quit listing the indications at 5 percent." (EX1137, 151:8-152:13.) In other words, Mr. Segers' assumption that MSI-H/dMMR CRC accounted for no more than 5% of Opdivo and Yervoy U.S. sales in 2018 and 2019 is based solely on the 5% attributed to other indications in the Q2 2018 Earnings Call transcript. Mr. Segers provides no support for his assumption that this percentage remained the same over the subsequent five-year period of 2019-2023. Furthermore, although Mr. Segers cites the Q3 2018 and Q1 2019 Earnings Calls as "mentioning similar percentages for lung, melanoma, and renal and not mentioning MSI-H or colorectal cancer," he provides no explanation for why he ignores the substantial increase in sales attributed to other indications that occurred between Q2 2018 and Q1 2019, as shown in the figure above. (EX2191, ¶28 n.37.) If Mr. Segers' analysis had accounted for the percentages provided in the Q3 2018 and Q1 2019 Earnings Calls, the estimated sales of Opdivo and Yervoy for the treatment of MSI-H/dMMR CRC

would have quadrupled by Q1 2019 (from 5% Q3 2018 to 20% in Q1 2019).⁸

63. Mr. Segers also includes an estimate of the profits that Merck allegedly earned on sales of Keytruda for the treatment of MSI-H/dMMR CRC. (EX2191, ¶30.) These estimates are based on the assumption that Merck's profit margin percentage on these sales are equal to the operating profit percentage for the company as a whole. (EX2191, ¶30.) Mr. Segers fails to provide any support, and I am unaware of any support, for this assumption.
64. The above analyses demonstrate that Keytruda sales attributable to the treatment of MSI-H/dMMR CRC do not, and have never, accounted for a substantial portion of Keytruda revenue and that the approvals of Keytruda for the treatment of MSI-H/dMMR CRC and MSI-H/dMMR solid tumors did not cause an inflection point in Keytruda's sales trajectory as suggested by Mr. Segers. Additionally, there is no basis for Mr. Segers' claim that Keytruda's sales for MSI-H/dMMR CRC

⁸ The Segers Declaration assumes the other indications category in the BMS Earnings Call transcripts reflects the upper bound of MSI-H/dMMR CRC sales as a percentage of total sales (EX1137, 151:8-152:13). The other indications category grew four-fold, from 5% in Q2 2018 to 20% in Q1 2019 (*See* Figure 8). Thus, had Mr. Segers accounted for the percentages from the Q1 2019 Earnings Call, the estimated MSI-H/dMMR CRC sales would be calculated by multiplying total Opdivo and Yervoy U.S. sales for the 2019-2023 period by 20%, resulting in a four-fold increase in the estimated sales of Opdivo and Yervoy over that period.

have been strong compared to competitor products in the market given that: 1) he excluded [REDACTED] of MSI-H/dMMR CRC patient treatments in his analysis, and 2) his estimates of Opdivo and Yervoy MSI-H/dMMR CRC sales are wholly unsupported.

3. Keytruda CRC Market Share

65. Mr. Segers asserts that Keytruda's share of the MSI-H/dMMR CRC market grew from [REDACTED] in 2017 to [REDACTED] in 2023 and that "Keytruda's success relative to its competitors within the MSI-H or dMMR CRC indication is another clear indication that the '393 Patent has created economic value and that if the invention were obvious others would have had an incentive to undertake the same research as the Patent Owner." (EX2191, ¶¶34-35, app. 9.) As described below, Mr. Segers' market share calculation reflects an incomplete and unreliable analysis and, therefore, any conclusions based on that calculation are equally unreliable.
66. First, Mr. Segers incorrectly assumes that "the total market for drugs specifically targeted to treat MSI-H or dMMR colorectal cancer is defined by the sales of Keytruda, Opdivo, and Yervoy for the indication of MSI-H or dMMR colorectal cancer" because, according

to Mr. Segers, “there are only two other drugs approved to treat MSI-H or dMMR colorectal cancer, Opdivo and Yervoy.” (EX2191, ¶34.) This is a flawed assumption given Mr. Segers’ testimony that [REDACTED] [REDACTED] of MSI-H/dMMR CRC patients receive treatments other than Keytruda, Opdivo and Yervoy. (EX1137, 63:10-67:19.) Furthermore, since Opdivo and Yervoy are approved as second line treatments for patients that have previously tried first line chemotherapy, Mr. Segers should have, but did not, include chemotherapies in his market share analysis.⁹ Additionally, Mr. Segers ignores other products which may be used to treat MSI-H/dMMR CRC such as Jemperli, which is recommended by the NCCN guidelines for the treatment of MSI-H/dMMR CRC and has received the FDA’s Breakthrough Therapy Designation for the treatment of patients with locally advanced MSI-H/dMMR rectal cancer. (EX1208, 49, 107, 132, 140; EX1209, 26, 29, 60, 64; EX1154.) Given these deficiencies, the market share analysis presented in Mr. Segers’ declaration is incomplete and therefore

⁹ See *supra* text accompanying note 6. (EX1226; EX2236.)

overstates Keytruda's share of the MSI-H/dMMR CRC treatment market.

67. Second, even if the marketplace for MSI-H/dMMR CRC treatments was comprised only of Keytruda, Opdivo and Yervoy—which it is not—Mr. Segers' estimates of Opdivo and Yervoy sales are based on arbitrary assumptions. As previously explained, Mr. Segers assumes that MSI-H/dMMR CRC accounted for no more than 5% of Opdivo and Yervoy U.S. sales from 2018 through 2023 based solely on the 5% of sales attributed to “other” indications in BMS's Q2 2018 Earnings Call transcript. This assumption is inconsistent with Mr. Segers' own testimony that he has not seen anything to suggest that the percentage of Opdivo and Yervoy sales attributable to CRC has stayed the same since 2019. (EX1137, 159:16-160:16.) Additionally, despite citing to the BMS Q3 2018 and Q1 2019 Earnings Call transcripts, Mr. Segers ignores the fact that those documents state that the percentage of Opdivo and Yervoy sales attributed to other indications increased to 15% in Q3 2018 and to 20% in Q1 2019.¹⁰ (EX2213, 10; EX2214, 12; EX2215, 10.) Mr. Segers also testified

¹⁰ See *supra* text accompanying note 7. (EX2215.)

that he agreed that if CRC patients accounted for 15% of Opdivo and Yervoy sales in 2023, then Opdivo alone would have a larger market share than Keytruda. (EX1137, 159:3-8.) Since Mr. Segers' estimate of Opdivo and Yervoy MSI-H/dMMR CRC sales and market share are based on unsupported and arbitrary assumptions, his calculation of Keytruda's market share is also unsupported and arbitrary.

68. Given the absence of revenue data for Keytruda's competitors in the MSI-H/dMMR CRC marketplace, a more reliable market share metric is Keytruda's share of MSI-H/dMMR CRC patients. To calculate Keytruda's share of MSI-H/dMMR CRC patients, I began with the total number of CRC patients in the U.S. for the years 2017 through 2021 (the latest year for which this data was available) which was obtained from the NCI website. (EX1227-1231.) To estimate the total number of MSI-H/dMMR CRC patients in the U.S., I multiplied total U.S. CRC patients by 15%, which according to Mr. Segers is the portion of all CRC cancers that are MSI-H/dMMR. (EX2191, app. 10.) I then obtained the total U.S. Keytruda MSI-H/dMMR CRC monthly patients from the IQVIA data produced in this case. (EX1157.) In addition, the portion of MSI-H/dMMR CRC patients that received Keytruda in the U.S. was calculated by dividing

Keytruda CRC total U.S. patients by the total number of MSI-H/dMMR CRC patients in the U.S. The results of this analysis indicate that Keytruda's monthly share of total U.S. MSI-H/dMMR CRC patients ranged from [REDACTED] over the 2017 to 2021 period. (Schedule 7.0.)

69. Third, Mr. Segers asserts that "Keytruda has [REDACTED]
[REDACTED]
[REDACTED]" (EX2191, ¶35, app. 10.)

As purported support for this claim, Mr. Segers compares trendline estimates of Keytruda's share of total new patients for MSI-H/dMMR CRC, NSCLC, melanoma, and bladder cancer for the 2017 to 2023 time period. (EX2191, app. 10.) However, these estimates are flawed and unreliable for at least the following reasons:

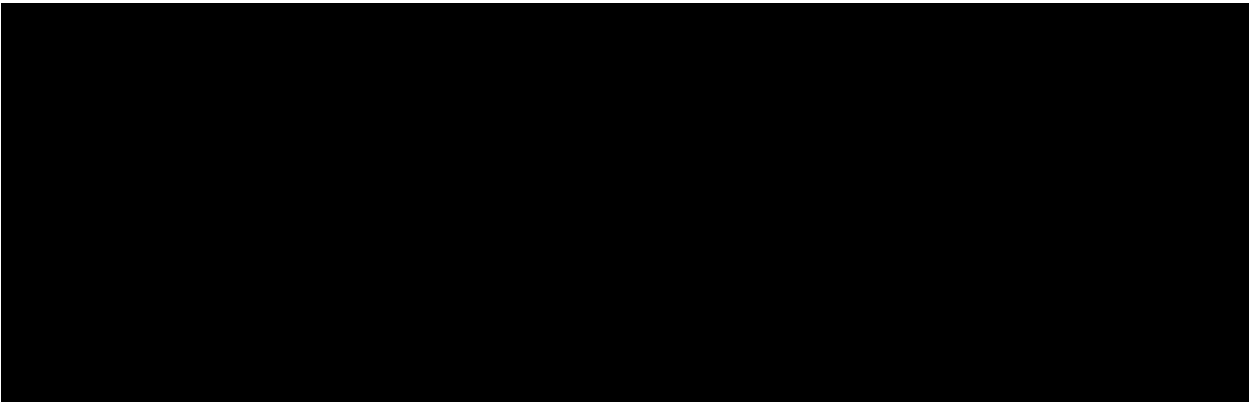
- (a) Mr. Segers' new patient comparison relies on estimates of new CRC, NSCLC, melanoma and bladder cancer patients from publications that state "[t]hese are model-based estimates that should be interpreted with caution and not compared with those for previous years." (EX2223, 27; EX2224, 2; EX2225, 4; EX2226, 3; EX2227, 4; EX2228, 4; EX2229, 5.) Despite this

caution, Mr. Segers makes year-over-year comparisons using these estimates to support his claim that Keytruda allegedly increased its penetration in MSI-H/dMMR CRC faster than it did in NSCLC, melanoma, and bladder cancer over the 2017-2023 time period.

- (b) Mr. Segers' new patient comparison fails to account for the fact that Keytruda was approved for NSCLC and melanoma years prior to its approval for MSI-H/dMMR CRC. As shown in Figure 2, Keytruda received its first approval for melanoma in 2014 and its first approval for NSCLC in 2015. To support a conclusion about the penetration rates over time, Mr. Segers should have, but did not, compare the share obtained beginning from the approval date of each indication.
- (c) Mr. Segers' new patient comparison also fails to account for Keytruda's share of total patients in each indication. I calculated Keytruda's share of total U.S. NSCLC patients over the 2017 to 2021 timeframe using a similar methodology to the one previously described for calculating Keytruda's share of total U.S. MSI-H/dMMR CRC patients. The results of this

analysis indicate that Keytruda's monthly share of total U.S. NSCLC patients ranged from [REDACTED] over the 2017 to 2021 period. (Schedule 8.0.) The following table compares Keytruda's share of total U.S. NSCLC patients to its share of total U.S. MSI-H/dMMR CRC patients.

Figure 9: Keytruda Average Monthly Shares of Estimated Total U.S. MSI-H/dMMR CRC and NSCLC Patients (2017 – 2023)



(Schedule 6.0.)

70. The analysis shown above demonstrates that Keytruda's share of total U.S. NSCLC patients has [REDACTED] its share of total U.S. MSI-H/dMMR CRC patients.
71. For the reasons described above, Mr. Segers' market share analysis is incomplete and unreliable and, as such, his conclusions regarding Keytruda's market share are also unreliable.

V. CONCLUSION

72. Based on the analyses described throughout this declaration, it is my opinion that there is no evidence of a nexus between the challenged claims of the '393 Patent and the commercial performance of Keytruda's use as a treatment for MSI-H/dMMR CRC. Additionally, as explained above, Mr. Segers' declaration presents a flawed and misleading analysis which does not establish any secondary considerations of the '393 Patent claims.
73. I declare that all statements made herein to my knowledge are true, and that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.

Respectfully submitted:



Sean Sheridan, Ph.D.
Vice President
Charles River Associates
January 31, 2025

Tab 1

Sean D. Sheridan
Vice PresidentPhD, Genetics
The University of ChicagoMBA, Finance and Economics
The University of Chicago
Booth School of BusinessBS, Biology
Appalachian State University

Dr. Sheridan has served as an expert witness in cases brought before federal and state courts, the Patent Trial and Appeal Board, the International Trade Commission (ITC), and domestic and international arbitration tribunals. He has developed numerous damages analyses related to patent infringement, breach of contract, and trade secret misappropriation, including analyses quantifying lost profits, reasonable royalties, and unjust enrichment. He has also analyzed the issues of commercial success, irreparable harm, and the economic prong of the domestic industry requirement in ITC Section 337 proceedings. Outside of litigation, Dr. Sheridan has provided financial consulting services for purposes such as transaction due diligence, license negotiations, and strategic decision-making. The engagements he has worked on span a wide range of industries and products, including pharmaceuticals, biologics, medical devices, diagnostics, research tools, electronic health records, telecommunications, mobile devices, oil and gas, automotive technologies, computer software and hardware, insurance, and financial products, among others.

Previously, Dr. Sheridan was as an assistant director at the technology transfer office at the University of Chicago where he was responsible for managing the intellectual property strategy for a broad range of technologies and was frequently required to assess the value of new discoveries and potential products. In that role he personally negotiated a variety of contracts including licenses, option agreements, and collaboration agreements with companies ranging from Fortune 500 firms to small start-ups.

Dr. Sheridan is a frequent speaker and instructor on intellectual property valuation and publishes on related topics. He was named to the *IAM Patent 1000: The World's Leading Patent Professionals* (economic experts) every year since 2019.

Selected experience

Intellectual property consulting

- Performed an analysis of the terms of a pharmaceutical collaboration agreement to determine whether the agreement provided economic evidence of a sale of certain compounds; deliverables included a rebuttal report.
- Performed a domestic industry analysis in the context of a Section 337 investigation conducted by the U.S. International Trade Commission; deliverables included a report, deposition, and trial testimony regarding certain liquid coolers.

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- Developed economic analyses to determine whether there was evidence of commercial success for a Parkinson's disease psychosis treatment; deliverables included an initial report, reply report and deposition testimony on commercial success.
 - Performed a domestic industry analysis in the context of a Section 337 investigation conducted by the U.S. International Trade Commission; deliverables included a report, deposition testimony and trial testimony regarding certain ice making machines.
 - Performed an assessment of the economic harm to a biologics manufacturer assuming biosimilar manufacturers launch at risk; deliverables included a declaration on irreparable harm and deposition testimony.
 - Performed an assessment of a pharmaceutical company's commercial launch plan and its sales and marketing efforts with respect to its "commercially reasonable efforts" obligations under a license agreement; deliverables included an expert report, deposition testimony and trial testimony.
 - Performed a domestic industry analysis and an analysis of the alleged threat of injury to a domestic industry in the context of a Section 337 investigation conducted by the U.S. International Trade Commission; deliverables included an expert report, deposition testimony, and trial testimony regarding domestic investments in, and the alleged threat of injury to, certain botulinum toxin products.
 - Developed economic analyses to determine damages in a trade secret misappropriation case related to antibody discovery technology; deliverables included a report on counterclaim damages calculating lost profits, a rebuttal report calculating unjust enrichment and deposition testimony.
 - Provided opinions on technology transfer licensing practices; deliverables included an initial report and deposition testimony.
 - Provided opinions on various agreements involving technology transfer offices and typical technology transfer practices; deliverables included an initial report and deposition testimony.
 - Performed a domestic industry analysis in the context of a Section 337 investigation conducted by the U.S. International Trade Commission; deliverables included two declarations, a report, deposition testimony, and trial testimony regarding domestic investments in integrated circuit chips.
 - Developed economic analyses to determine whether there was evidence of commercial success for a Parkinson's disease psychosis treatment; deliverables included an initial report, reply report and deposition testimony on commercial success.
 - Developed economic analyses to determine whether there was evidence of commercial success for certain pre-operative skin sterilization products; deliverables included two reports on commercial success and deposition testimony.
 - Developed economic analyses to determine damages in a patent infringement case involving adjunctive stent technology; deliverables included an initial report on economic damages calculating reasonable royalties and deposition testimony.

- Developed economic analyses to determine whether there was evidence of commercial success for a pharmaceutical product used for the treatment of psoriasis; deliverables included an initial report on commercial success and deposition testimony.
- Provided opinions on practices and procedures of technology transfer offices; deliverables included an initial report, deposition testimony and trial testimony.
- Developed economic analyses relating to the interpretation of certain licensing provisions and the quantification of damages in a breach of contract case; deliverables included an initial report, deposition testimony and hearing testimony.
- Developed economic analyses as a neutral advisor to the Tribunal in an international arbitration involving a licensing dispute relating to a novel rice herbicide candidate; deliverables included a flexible valuation model and report providing recommendations for license agreement terms and hearing testimony.
- Developed economic analyses to determine damages in a breach of contract case related to the development of a vaccine product; deliverables included a report calculating actual loss damages, deposition testimony and hearing testimony.
- Performed a domestic industry analysis in the context of a Section 337 investigation conducted by the U.S. International Trade Commission; deliverables included an initial report, deposition testimony and hearing testimony regarding domestic investments in electrical connectors and cages.
- Performed a domestic industry analysis in the context of a Section 337 investigation conducted by the U.S. International Trade Commission; deliverables included an initial report, deposition testimony and hearing testimony regarding domestic investments in polycrystalline diamond compacts.
- Developed economic analyses to determine damages in a patent infringement case involving crafting tools; deliverables included an initial report on economic damages calculating lost profits and reasonable royalties.
- Developed economic analyses to determine an appropriate intercompany royalty rate to be paid for certain technological contributions to a comprehensive genomic profiling kit.
- Developed economic analyses to determine damages in a breach of contract case related to therapeutic antibody products; deliverables included a report on economic damages calculating actual loss damages and unjust enrichment.
- Developed economic analyses to determine whether there was evidence of commercial success for a pharmaceutical product used for the treatment of diabetes; deliverables included an initial report on commercial success.
- Developed economic analyses to determine damages in a breach of contract and trade secret misappropriation case related to a propane dehydrogenation technology; deliverables included a report on economic damages calculating unjust enrichment.

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- Performed a domestic industry analysis in the context of a Section 337 investigation conducted by the U.S. International Trade Commission; deliverables included an initial declaration regarding domestic investments in liquid crystal display devices.
 - Performed a valuation analysis related to sustainable packaging technologies for consumer goods; deliverables included a flexible valuation model and a presentation for executive management.
 - Developed economic analyses to determine damages in a breach of contract case related to proprietary securities pricing data; deliverables included an initial report and reply report on economic damages calculating actual loss.
 - Developed economic analyses to determine damages in a breach of contract case related to the development of a cystic fibrosis therapy; deliverables included a report on economic damages calculating expectation damages.
 - Performed a valuation analysis related to a turbocharger patent portfolio; deliverables included a flexible valuation model and presentation.
 - Developed economic analyses to determine whether there was evidence of commercial success for certain medical procedure kits; deliverables included four reports on commercial success.
 - Developed economic analyses to determine whether there was evidence of commercial success for an antiparasitic medication; deliverables included an initial report on commercial success.
 - Developed economic analyses to determine damages in a patent infringement case involving catheter-related technology; deliverables included an initial report on economic damages calculating lost profits and reasonable royalties.
 - Developed economic analyses to determine whether there was evidence of commercial success for a pharmaceutical product used for the treatment of post-operative ileus; deliverables included an initial report on commercial success.
 - Developed economic analyses to determine damages in a trade secret misappropriation case related to reporting and accounting software used for portfolio management; deliverables included a report on economic damages calculating unjust enrichment.
 - Developed economic analyses to assist a biosimilar manufacturer in settlement negotiations with a competitor; deliverables included a flexible valuation model and decision tree analysis to address issues related to litigation risk, acceptable date of entry for the biosimilar product.
 - Developed economic analyses to determine damages in a trade secret misappropriation and breach of contract case related to cloud storage technology; deliverables included a report on economic damages calculating actual loss and unjust enrichment and deposition testimony.
 - Performed an assessment of the economic harm to a biologics manufacturer that could arise if a competitor was permitted to continue developing certain biosimilar products in the context of a trade secret case; deliverables included a report on irreparable harm.

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- Developed economic analyses to assist a pharmaceutical company in settlement negotiations with a potential generic competitor; deliverables included a flexible valuation model and decision tree analysis to address issues related to litigation risk, acceptable date of generic entry and the impact of an authorized generic.
 - Performed a valuation analysis to assist a research hospital in determining the expected future licensing value of certain patents and the risk-adjusted settlement value related to an inventorship dispute involving a cancer immunotherapy technology.
 - Performed a domestic industry analysis in the context of a Section 337 investigation conducted by the U.S. International Trade Commission; deliverables included an initial report regarding domestic investments in certain batteries and electrochemical device components and deposition and trial testimony.
 - Provided consulting expertise to assist a university with renegotiating a license agreement related to a gene-editing technology; deliverables included a flexible valuation model and a presentation for use in ongoing negotiations.
 - Developed economic analyses to determine whether there was evidence of commercial success for a pharmaceutical product used for the treatment of acne; deliverables included an initial report on commercial success.
 - Developed economic analyses to determine damages in a patent infringement case involving search engine technology; deliverables included an initial report on economic damages calculating reasonable royalties.
 - Developed economic analyses to determine damages in a breach of contract case related to microarray technology; deliverables included a preliminary damages report for settlement purposes, an initial report on economic damages and deposition testimony.
 - Developed economic analyses to determine damages in a patent infringement case involving transcatheter heart valve technology; deliverables included an initial report on economic damages calculating reasonable royalties.
 - Performed a valuation analysis related to packaging technology for consumer goods; deliverables included a flexible valuation model and a presentation for use in ongoing license negotiations.
 - Developed economic analyses to determine whether there was evidence of commercial success for a pharmaceutical product used for the treatment of pulmonary arterial hypertension; deliverables included an initial report on commercial success.
 - Developed economic analyses to assist a large telecommunications company in determining a reasonable licensing payment to settle ongoing litigation; deliverables included multiple decision tree analyses.
 - Developed economic analyses to determine damages in a patent infringement case involving smart home technology; deliverables included an initial report on economic damages calculating lost profits and reasonable royalties.

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- Performed a domestic industry analysis in the context of a Section 337 investigation conducted by the U.S. International Trade Commission; deliverables included an initial report regarding domestic investments in certain hybrid electric vehicle components.
 - Developed economic analyses to determine damages in a patent infringement case involving automotive multimedia systems; deliverables included an initial report on economic damages calculating reasonable royalties.
 - Developed economic analyses to determine damages in a patent infringement case involving a pharmaceutical product used for the treatment of congestive heart failure and skinny labeling by a generic competitor; deliverables included an initial report on economic damages calculating lost profits and reasonable royalties.
 - Developed economic analyses to determine damages in a breach of contract and patent infringement case involving orthopedic implants; deliverables included an initial report on economic damages calculating breach of contract damages and reasonable royalties. Prepared counsel for the deposition of the opposing expert on various topics.
 - Developed economic analyses to determine damages in a patent infringement case involving flash memory technology; deliverables included an initial report on economic damages calculating reasonable royalties. Prepared counsel for the deposition of the opposing expert on various topics.
 - Performed a valuation analysis related to orthopedic implant technology; deliverables included a flexible valuation model and a presentation for use in ongoing license negotiations.
 - Developed economic analyses to determine damages in a patent infringement case involving automotive safety technologies; deliverables included an initial report on economic damages calculating reasonable royalties.
 - Provided consulting expertise to assist a large insurance company with analyzing its IP management and licensing practices; deliverables included a comparison of the client's processes to industry best practices, specific recommendations to help align the client's IP and business strategies and, a detailed roadmap for achieving long-term IP goals.
 - Developed economic analyses to determine damages in a patent infringement case involving multiple telecommunication technologies; deliverables included an initial report on economic damages. Prepared counsel for the deposition of the opposing expert on various topics including reasonable royalties.
 - Performed a domestic industry analysis in the context of a Section 337 investigation conducted by the U.S. International Trade Commission; deliverables included an initial report and trial demonstratives regarding domestic investments in certain patented dental implant products.
 - Provided consulting expertise to assist an oil and gas company with strategic decision-making related to a subsidiary; deliverables included a patent landscape analysis and related market research.

- Developed economic analyses used in a bankruptcy litigation case involving asset sale proceeds in excess of \$7.5B; deliverables included an initial report, rebuttal report, and trial demonstratives regarding the valuation of over 9,000 telecommunications patents and related license rights, as well as the inventive and financial contributions made by multiple debtor groups.
- Performed a valuation analysis in a patent malpractice dispute involving missed foreign patent application deadlines and other alleged patent prosecution errors. Provided pre-litigation analysis related to the risk adjusted present value of certain pending patent applications in Japan.
- Performed a valuation analysis in a patent infringement dispute involving electronic health records. Provided analysis related to the expected future value of multiple patent families in support of ongoing settlement negotiations.

Intellectual property transactions

- Negotiated and drafted a successfully executed exclusive patent license agreement with a multinational pharmaceutical company on behalf of a research university. The licensed patents related to a therapeutic protein scaffold technology.
- Negotiated and drafted a successfully executed exclusive patent license agreement with a large privately held biotechnology company on behalf of a research university. The licensed patents related to a protein immobilization technology with research and medical diagnostic applications.
- Negotiated and drafted a successfully executed exclusive patent license agreement with a start-up company on behalf of a research university. The licensed patents related to a biofuel production technology.
- Negotiated and drafted a successfully executed R&D collaboration agreement and a license option agreement with a start-up company on behalf of a research university. The subject of the R&D collaboration and the option agreement related to a peptide synthesis technology with therapeutic applications. The negotiated financial terms of the R&D collaboration included an equity stake in the start-up and funding for the research program.
- Negotiated and drafted a successfully executed exclusive patent license agreement with a start-up company on behalf of a research university. The licensed patents related to a medical diagnostic technology.
- Assisted a children's hospital in the negotiation and drafting of a successfully executed intellectual property management agreement with a research university. The negotiated financial terms included various cost-sharing and revenue-sharing structures.
- Assisted a coatings and paints manufacturer with its efforts to license or sell a patented 3D printing technology. Evaluated potential market applications, valued the technology in selected market applications, and created a flexible valuation model. Assisted in monetization strategy and term sheet negotiations with potential licensees.

Expert witness experience

- Abbvie Inc., Abbvie Ltd, and Neurocrine Biosciences, Inc. v. Alkem Laboratories Limited, et al.
Civil Action No. 1:22-cv-01423 (JLH)
United States District Court for the District of Delaware
Expert report.
- Certain Liquid Coolers for Electronic Components in Computers, Components Thereof, Devices for Controlling Same, and Products Containing Same
Cooler Master Co. Ltd. et al. v. SilverStone Technology Co., Ltd. et al.
U.S. International Trade Commission
Investigation No. 337-TA-1394.
Expert report, deposition testimony and hearing testimony.
- Acadia Pharmaceuticals Inc. v. Aurobindo Pharma Limited, et al.
Civil Action No. 1:22-cv-01387-GBW
United States District Court for the District of Delaware
Expert report, reply report, and deposition testimony.
- Certain Icemaking Machines and Components Thereof
Hoshizaki America Inc. v. Bluenix Co. Ltd., Blue Air FSE LLC.
U.S. International Trade Commission
Investigation No. 337-TA-1369
Expert report, deposition testimony and hearing testimony.
- Regeneron Pharmaceuticals, Inc. v. Amgen, Inc., Celltrion, Inc., Samsung Bioepis, Co., LTD., Formycon AG, and Mylan Pharmaceuticals, Inc.
Case Nos. 1:24-cv-00039-TSK, 1:23-cv-00089-TSK, 1:23-cv-00094-TSK, 1:23-cv-00097-TSK, 1:22-cv-00061-TSK
United States District Court for the Northern District of West Virginia
Declaration and deposition testimony.
- Consolidated Arbitration re: AltaThera Pharmaceuticals LLC, Hyloris Pharmaceuticals SA, Academic Pharmaceuticals Inc., and Dr. John Somberg
Case No. 01-22-0004-8710
American Arbitration Association
Expert report, deposition testimony and hearing testimony.
- Certain Botulinum Toxin Products and Processes for Manufacturing or Relating to Same
Medytox Inc. v. Hugel, Inc., et al.
U.S. International Trade Commission
Investigation No. 337-TA-1313
Expert report, deposition testimony and hearing testimony.

- Adimab, LLC v. LinkedUp Bioscience, Inc., et al.
Civil Action No. 2084CV00843 BLS2
Commonwealth of Massachusetts, Suffolk County Superior Court, Business Litigation Session
Initial expert report, rebuttal report and deposition testimony.
- Northwestern University v. Universal Robots A/S and Universal Robots USA, Inc.
Case No. 1:21-cv-00149-MN
United States District Court for the District of Delaware
Expert report and deposition testimony.
- University of Tennessee Research Foundation v. Caelum Biosciences, Inc., et al.
Case No. 3:19-cv-00508-CEA-HBG
United States District Court for the Eastern District of Tennessee at Knoxville
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- Certain Integrated Circuits, and Products Containing the Same Realtek Semiconductor Corporation v. Advanced Micro Devices, Inc.
U.S. International Trade Commission
Investigation No. 337-TA-1350
Two declarations, expert report, deposition testimony and hearing testimony.
- Acadia Pharmaceuticals Inc. v. Aurobindo Pharma Limited, et al.
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United States District Court for the District of Delaware
Initial expert report, reply report and deposition testimony.
- Becton Dickinson and Company v. Sage Products, LLC
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Two expert reports and deposition testimony.
- W.H. Wall Family Holdings, LLLP v. Stryker Corporation
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Expert report and deposition testimony.
- The United States of America v. Gilead Sciences, Inc., et al.
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Expert report.

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- Bausch Health Ireland Ltd., et al. v. Padagis Israel Pharmaceuticals Ltd., et al.
Civil Action No. 2-20-cv-05426 (SRC) (CLW)
United States District Court for the District of New Jersey
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 - Gilead Sciences, Inc. v. The United States of America
Case No. 1:20-cv-00499-CFL
United States Court of Federal Claims
Initial expert report, rebuttal report, deposition testimony and trial testimony.
 - Baxter International, Inc. and Baxter Healthcare Corp. v. CyDex Pharmaceuticals, Inc.
Case No. 01-21-0002-6106
American Arbitration Association
Initial expert report, rebuttal report, deposition testimony and hearing testimony.
 - Syngenta Crop Protection AG v. FMC Corp.
Case Nos. 01-19-0002-4208 and 01-19-0002-4192
American Arbitration Association, International Centre for Dispute Resolution
Expert report, flexible valuation model and hearing testimony.
 - Soligenix, Inc. v. Emergent BioSolutions, Inc., et al.
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American Arbitration Association
Expert report, deposition testimony and hearing testimony.
 - Certain Electrical Connectors and Cages, Components Thereof, and Products Containing the Same
Amphenol Corporation v. Luxshare Precision Industry Co., Ltd., et al.
U.S. International Trade Commission
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 - Certain Polycrystalline Diamond Compacts and Products Containing Same
US Synthetic Corporation v. CR Gems Superabrasives Co., Ltd., et al.
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 - My Sweet Petunia, Inc. v. Stampin' Up! Inc.
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Expert report for mediation.
 - UOP, LLC and Nikki-Universal Co. Ltd. v. Hyosung Corporation
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- Certain Liquid Crystal Display Devices, Components Thereof, and Products Containing Same Sharp Corporation and Sharp Electronics Corporation v. VIZIO, Inc. et al.
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- CR Bard, Inc. et al v. Medline Industries, Inc.
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- Arbor Pharmaceuticals, LLC v. Taro Pharmaceuticals USA, Inc., and Taro Pharmaceutical Industries, Ltd.
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- Falcon Group, LLC v. The Estate of Dennis Maetzold by and through its personal representative, David Logelin, and OCNA, L.L.C.
Civil Case No. 27-CV-17-15503
State of Minnesota – District Court, Hennepin County, Fourth Judicial District
Expert report and deposition testimony.
- Batteries and Electrochemical Devices Containing Composite Separators, Components Thereof, and Products Containing Same LG Chem, Ltd., et al. v. Amperex Technology Limited, et al.
U.S. International Trade Commission
Investigation No. 337-TA-1087
Expert report, deposition testimony and hearing testimony.
- Rutgers, The State University v. BioArray Solutions, Ltd., Immucor, Inc. and Michael Seul
Civil Action No. L-4747-14
Superior Court of New Jersey, Law Division, Middlesex County
Expert report and deposition testimony.

Publications and presentations

“Valuation as a Tool for Early-Stage Tech Transfer Agreements” Department of Energy, Technology Transfer Working Group, Webcast, 2024.

“Negotiating Successful Biopharma Partnerships” LES Annual Meeting, Chicago, IL, 2023, Moderator.

“Hot Topic: Pharmaceuticals and Biotechnology Patent Litigation,” *Corporate Disputes Magazine*, Jan-Mar 2023 Issue, Co-author.

“Determining Royalty Rates for University IP: A Webinar Workshop for Tech Transfer and IP Professionals” Technology Transfer Tactics, Webcast, 2022.

“LES Life Sciences Global Royalty Rate Survey Report” Webcast, 2022, Co-presenter.

“LES@BIO 2022, Royalty Rates & Deal Terms Survey” BIO International Convention, San Diego, CA, 2022, Co-presenter.

“Biologically similar but competitively not so? Economic considerations of IP litigation settlements involving biosimilars” Podcast, *Our Curious Amalgam*, 2022, Guest.

“What’s New for Hatch-Waxman Litigation: Exploring Trends, Updates, and Critical Issues” Webcast, The Knowledge Group, 2022, Co-presenter.

“IP Valuation and Licensing” Guest Lecture, University of Chicago Booth School of Business, Chicago, IL, 2022.

“FDA Biosimilar Approval Foreshadows IP Litigation Issues” With Archan Ruparel. *Law360*, 2021.

“Balancing Financial Risk in IP Licensing” Webcast, Washington State Bar Association, 2021.

“Intellectual Property Valuation” Guest Lecture, University of Chicago Booth School of Business, Chicago, IL, 2021.

“IP Valuation Basics” LES Course, Webcast, 2020, Co-instructor.

“Early Stage Intellectual Property Valuation” LES Course, Webcast, 2020, Co-instructor.

“Mini-Roundtable: Patent Disputes,” *Corporate Disputes Magazine*, April-June 2020 Issue, Co-author.

“BPCIA Patent Dance: Navigating the Biosimilar Litigation Landscape in 2020” Webcast, The Knowledge Group, 2020, Co-presenter.

“Global Life Sciences Royalty Rate and Deal Terms Survey 2018” LES Annual Meeting, Phoenix, AZ, 2019, Co-presenter.

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“Apportionment and the Entire Fair Market Value Rule (EMVR) in Patent Damages: Trends, Methods and Best Practices in 2019” Webcast, The Knowledge Group, 2019, Co-presenter.

“Deal Terms - Do You Really Know What's Happening in Your Therapeutic Areas?” LES Webinar, 2019, Co-presenter.

“IP Valuation” LES University Course, Vancouver, BC, 2019, Co-instructor.

“Managing Risks and Uncertainty in Licensing Early-Stage Therapies” *Bloomberg Law*, 2018, Co-author.

“Navigating Implications for Reasonable Royalty Damages in Light of Exmark v. Briggs & Stratton and Other Recent Court Rulings” Webcast, The Knowledge Group, 2018, Co-presenter.

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“Business Development for Life Sciences” LES University Course, Chicago, IL, 2017, Co-presenter.

“Global Life Sciences Royalty Rates and Deal Terms Survey, Implications and Applications” Webinar, 2017, Co-presenter.

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“Valuing IP” Guest Lecture, University of Notre Dame, Notre Dame, IN, 2016.

“Portfolio Analysis and Due Diligence for Monetization” IP Enforcement Summit, Chicago, IL, 2016, Co-presenter.

“How Mayo, Myriad and Alice May Impact Patent Valuations” *Law360*, 2015.

“Intellectual Property Valuation” Guest Lecture, University of Notre Dame, Notre Dame, IN, 2015.

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“Red Hed regulation: recombinase Rad51, though capable of playing the leading role, may be relegated to supporting Dmc1 in budding yeast meiosis.” With Douglas K. Bishop. *Genes & Development*, 2006.

Professional history

2023–Present	<i>Vice President</i> , Charles River Associates, Chicago, IL
2016–2023	<i>Principal</i> , Charles River Associates, Chicago, IL
2014–2016	<i>Associate Principal</i> , Charles River Associates, Chicago, IL
2014	<i>Director</i> , Ocean Tomo, Chicago, IL
2013–2014	<i>Associate</i> , Ocean Tomo, Chicago, IL
2012–2013	<i>Assistant Director</i> , UChicagoTech, Chicago, IL

2009–2012 *Project Manager*, UChicagoTech, Chicago, IL
2008–2009 *Associate Project Manager*, UChicagoTech, Chicago, IL
2001–2008 *Graduate Researcher*, The University of Chicago, Chicago, IL

Professional Affiliations

Licensing Executives Society, Member
American Intellectual Property Law Association, Member
Association of University Technology Managers, Member

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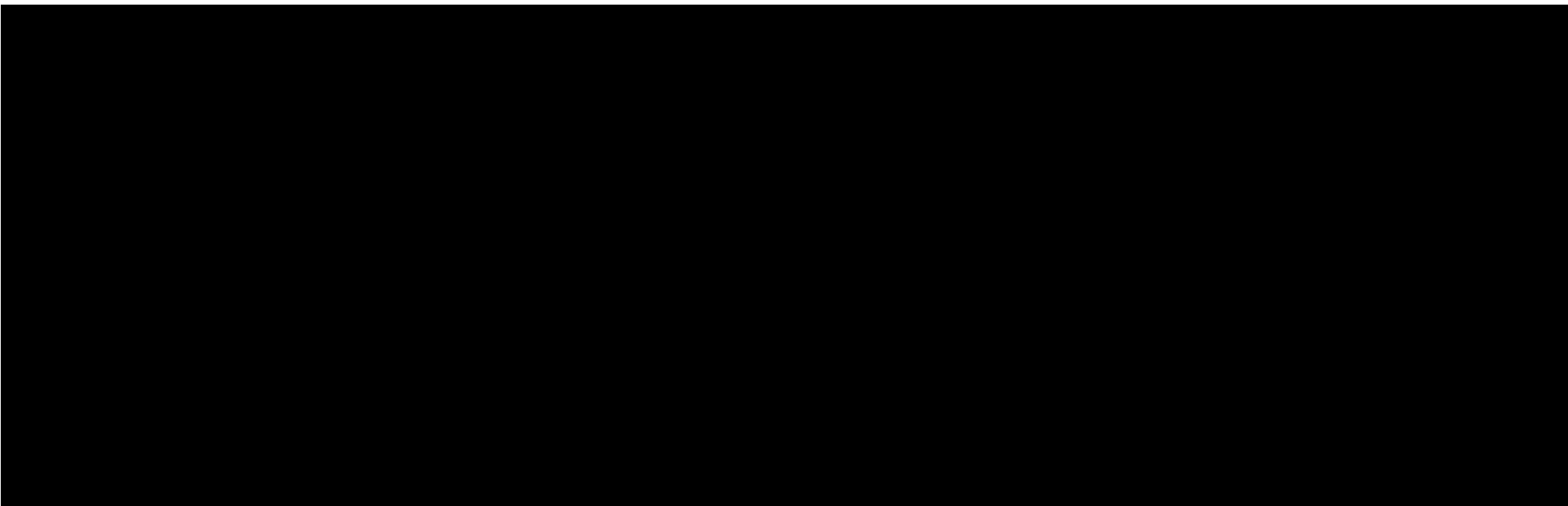
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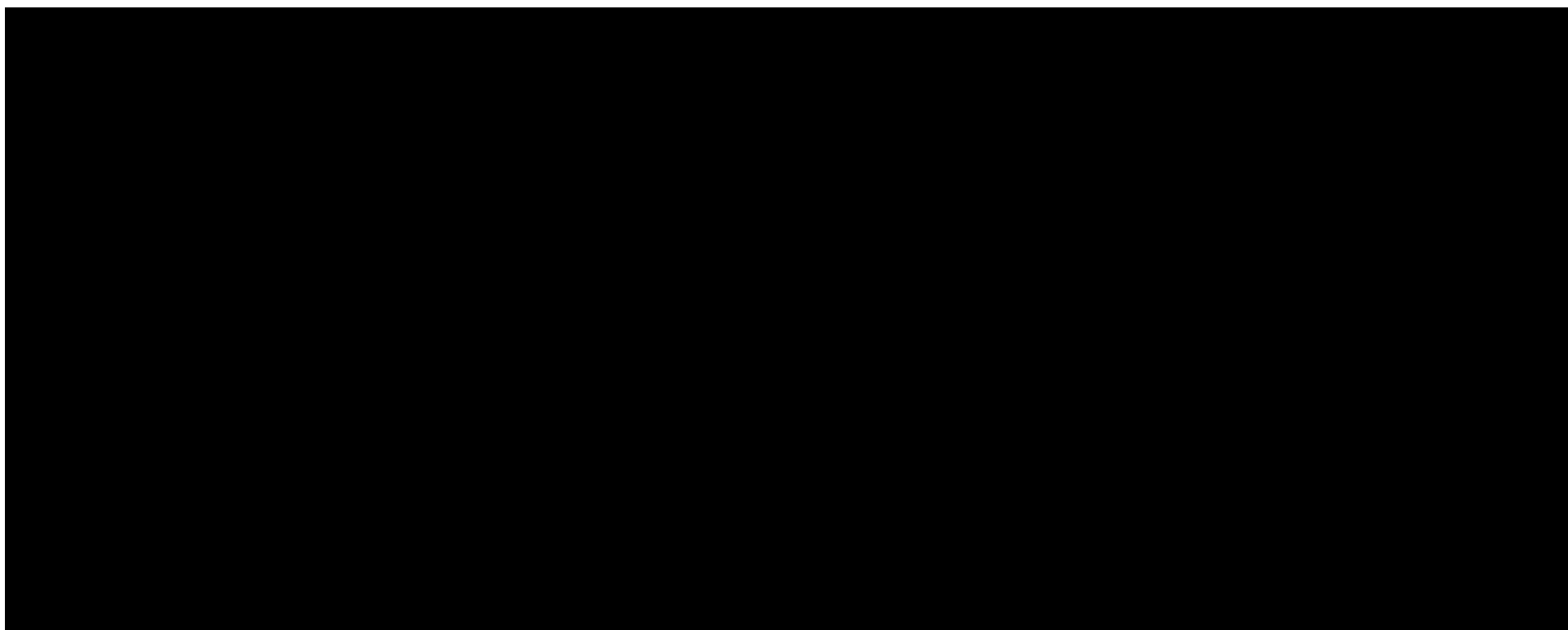
Total New U.S. Keytruda CRC Patients Share of Total New U.S. Keytruda Patients (Jan. 2017 - Dec. 2023) ⁽¹⁾



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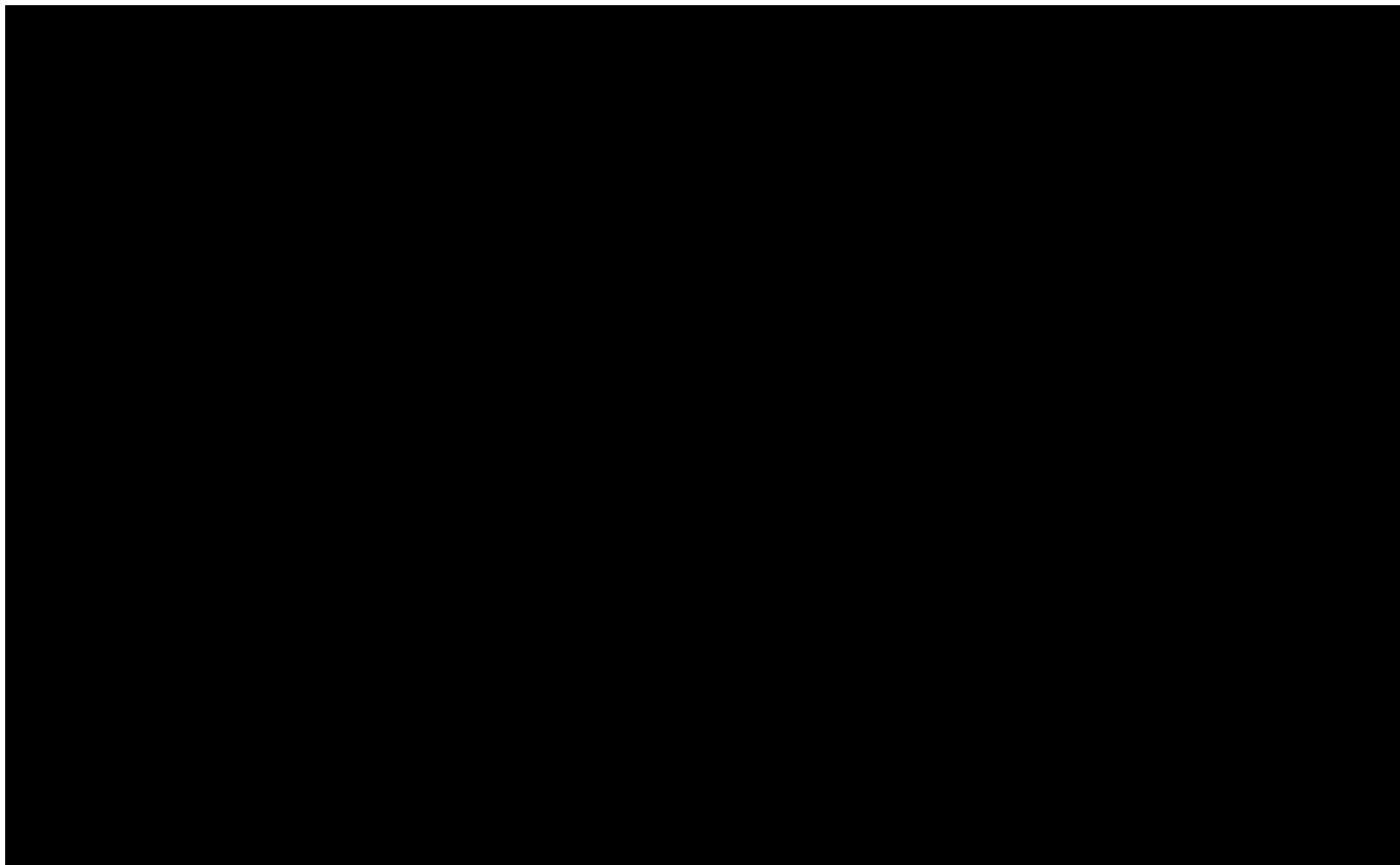
Average Monthly Growth Rate of New and Total U.S. Keytruda CRC Patients (Jan. 2017 - Dec. 2023) ⁽¹⁾



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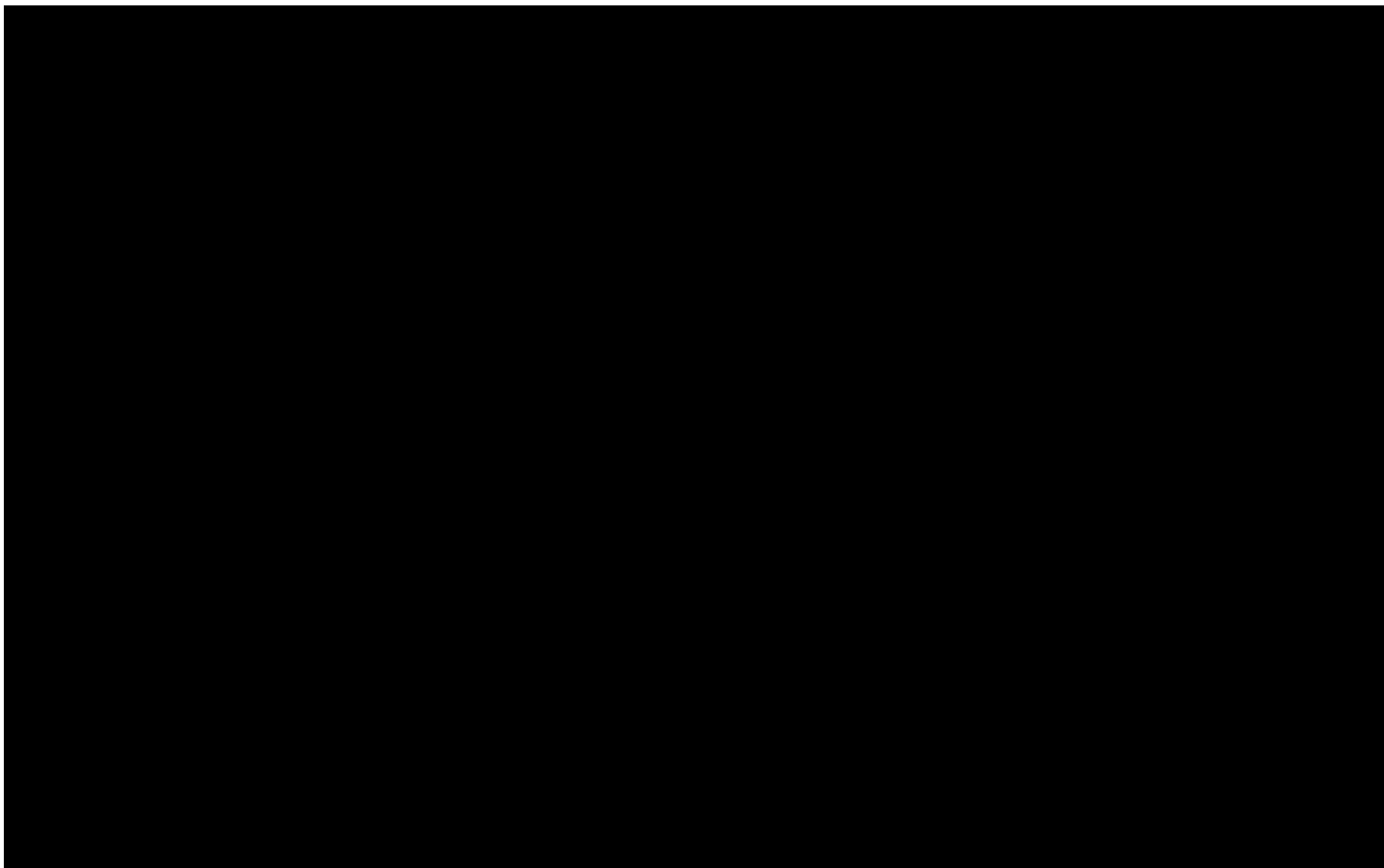
Monthly Growth Rate of U.S. Keytruda CRC Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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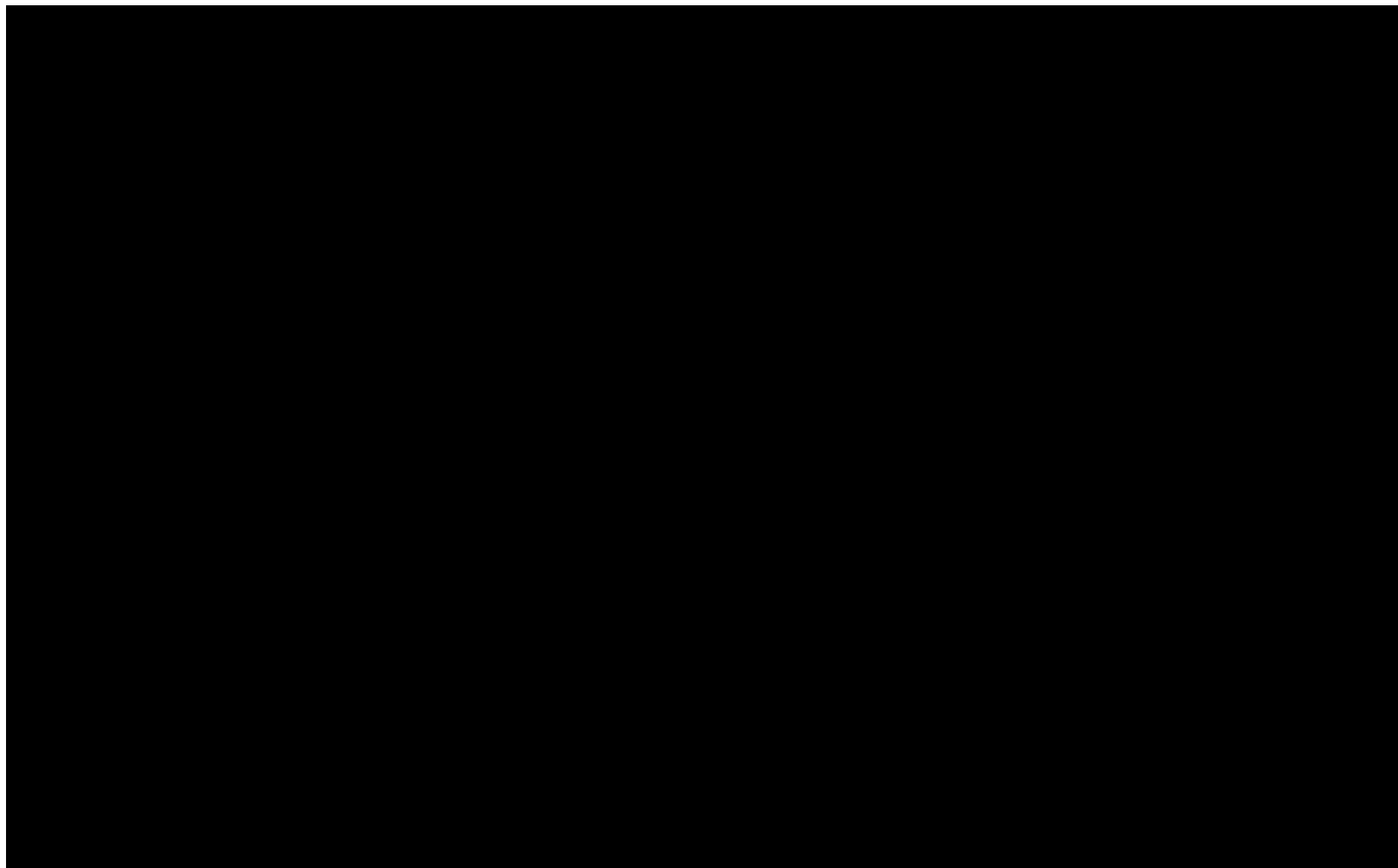
Monthly Growth Rate of U.S. Keytruda CRC Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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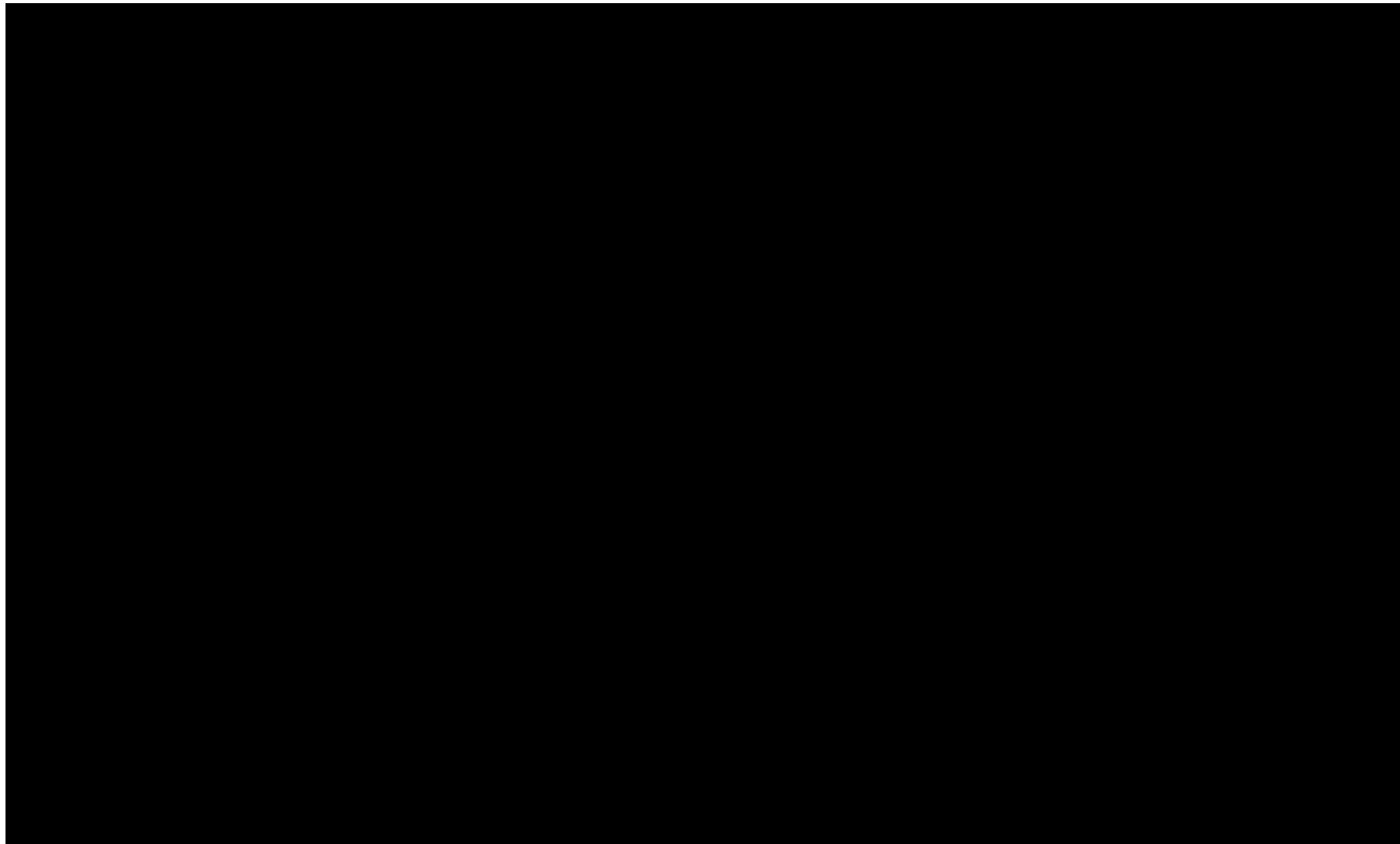
Monthly Growth Rate of U.S. Keytruda CRC Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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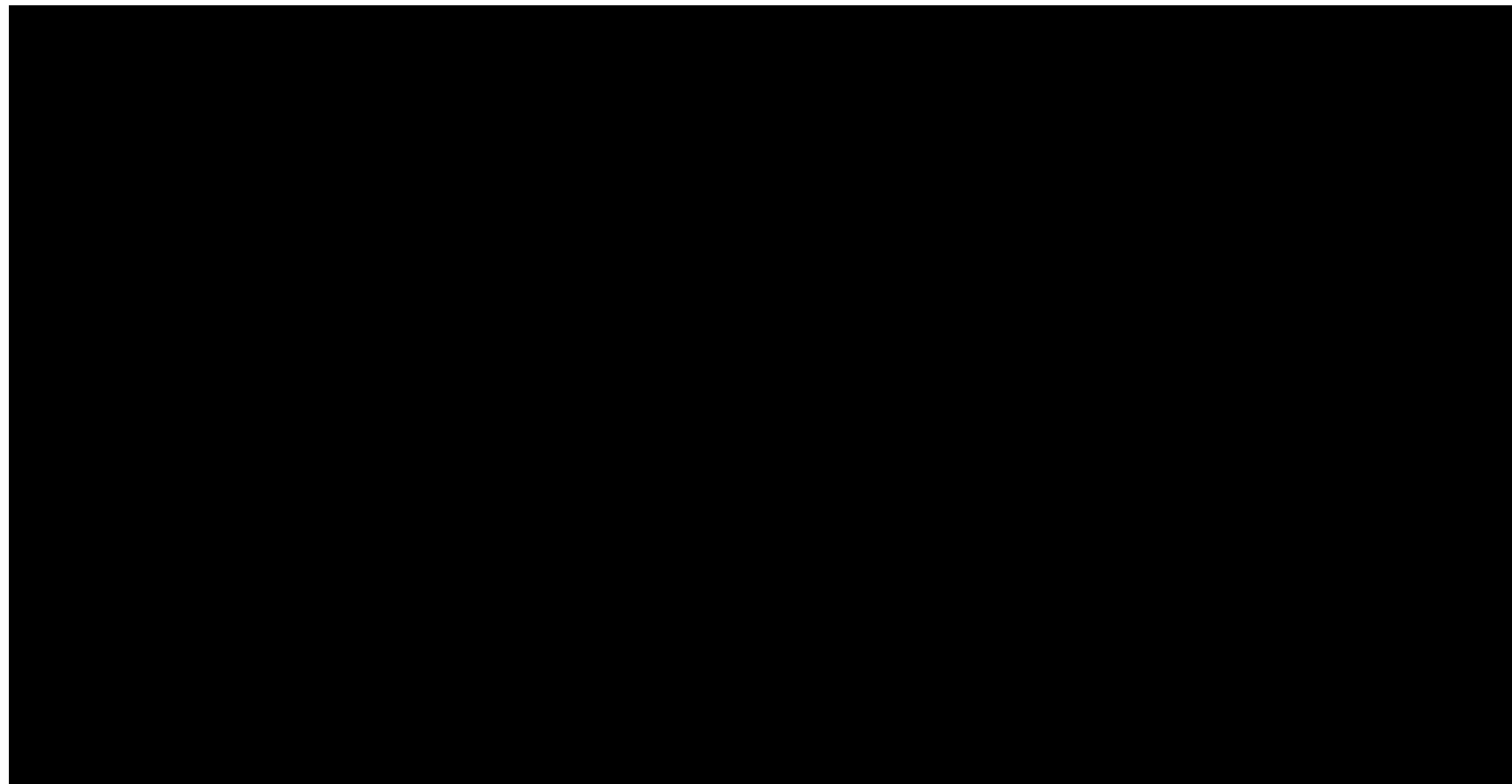
Monthly Growth Rate of U.S. Keytruda CRC Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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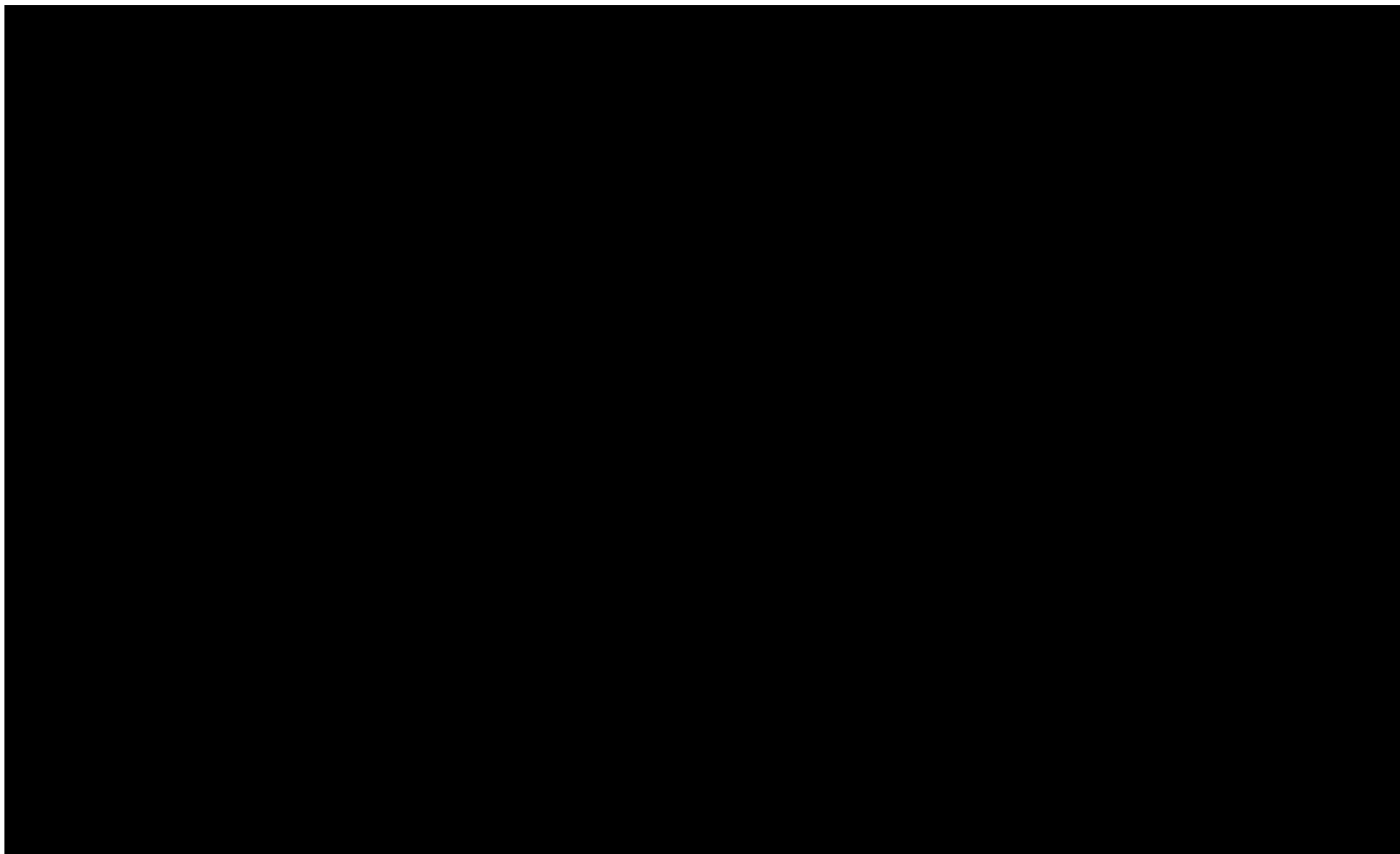
Monthly Growth Rate of U.S. Keytruda CRC Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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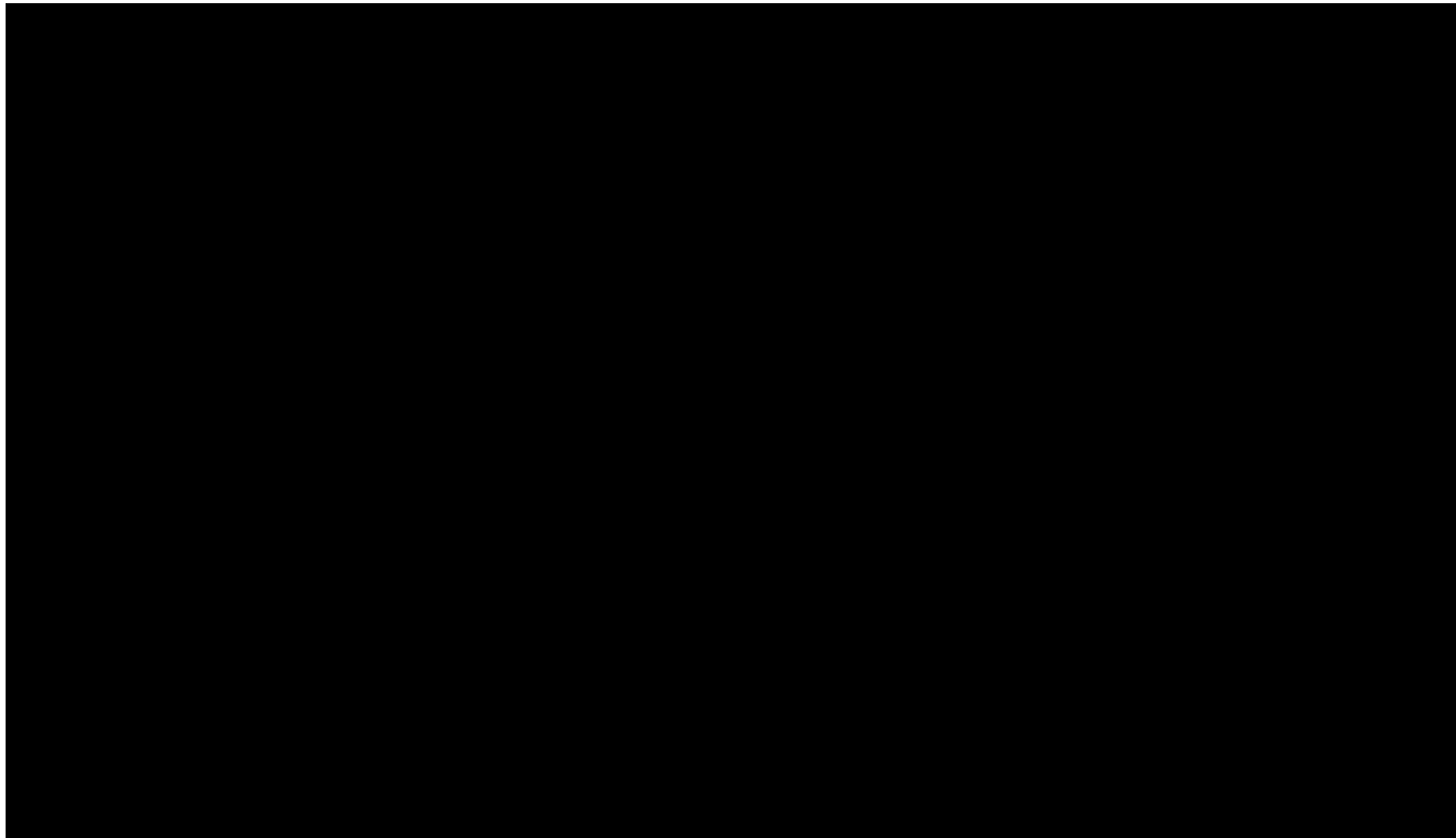
CRC Share of U.S. Keytruda Total Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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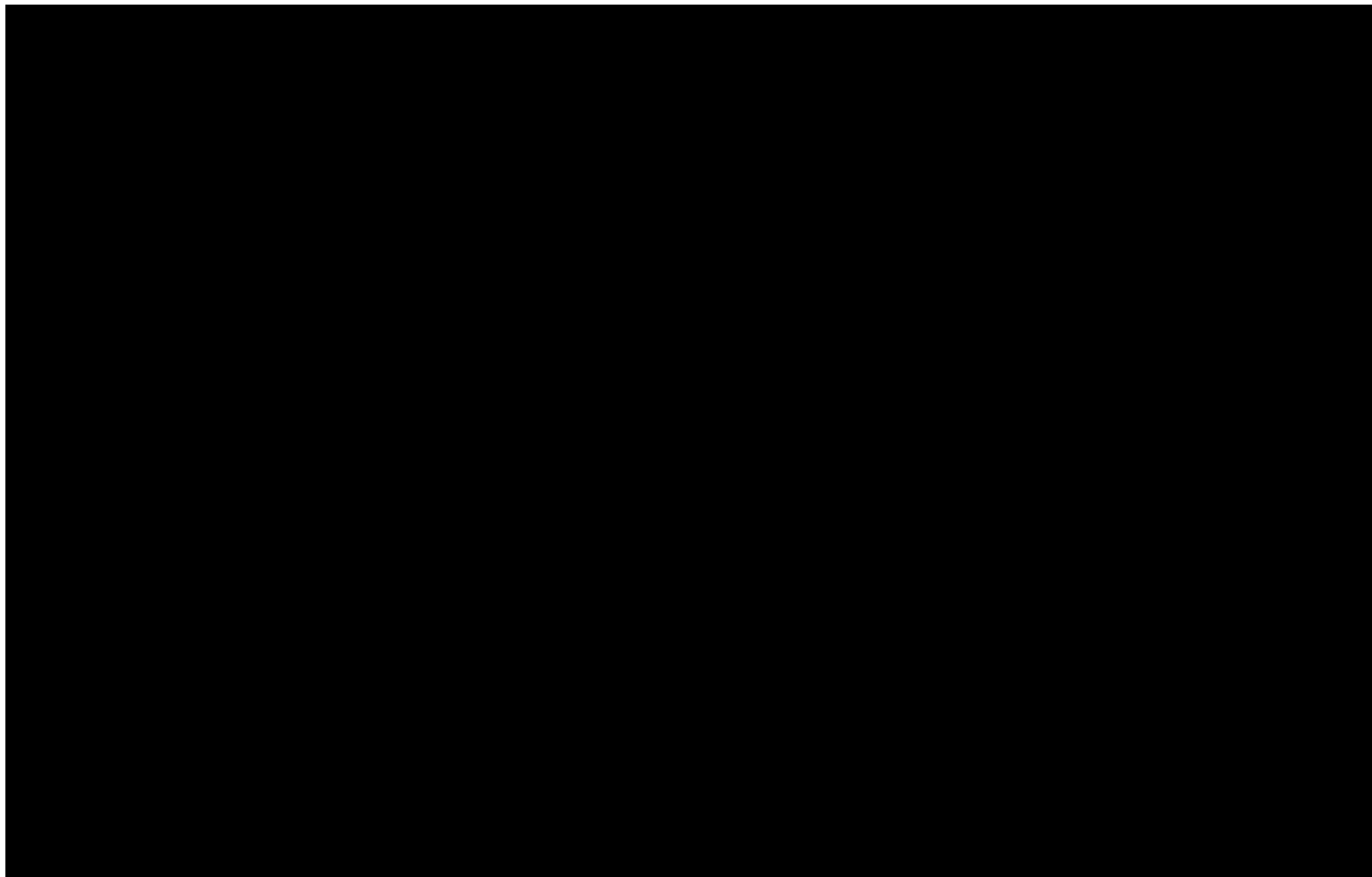
CRC Share of U.S. Keytruda Total Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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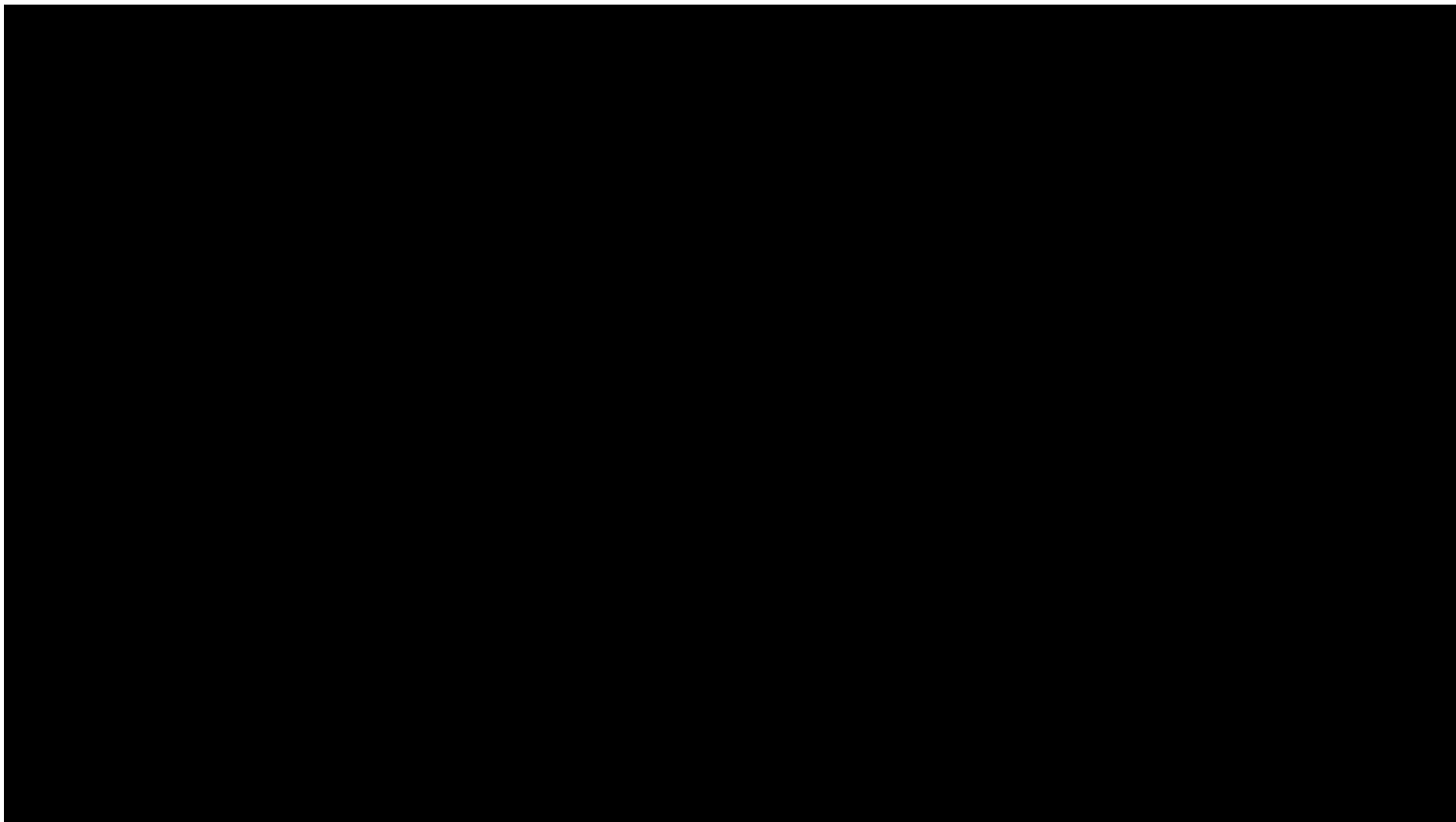
CRC Share of U.S. Keytruda Total Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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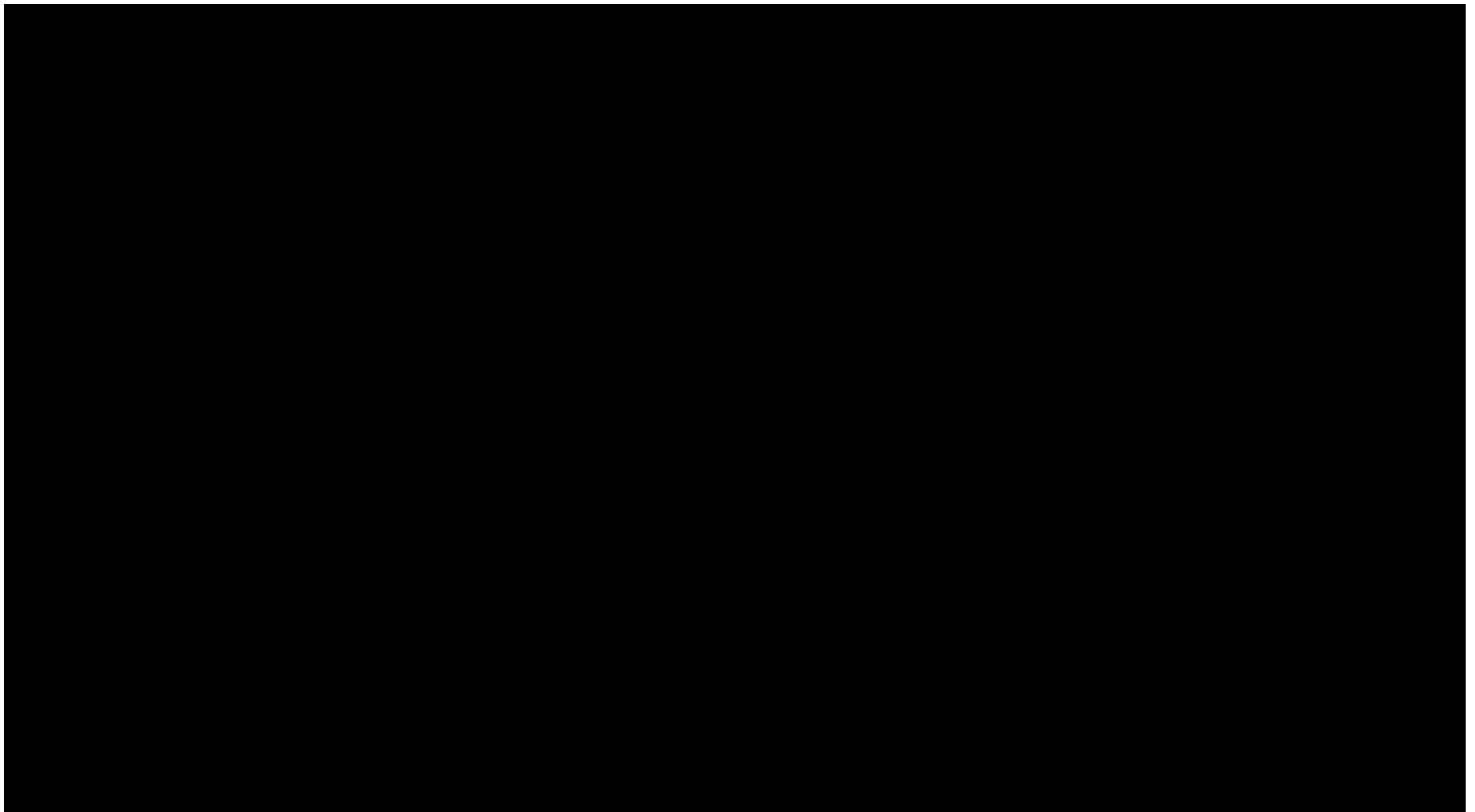
CRC Share of U.S. Keytruda Total Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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CRC Share of U.S. Keytruda Total Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾

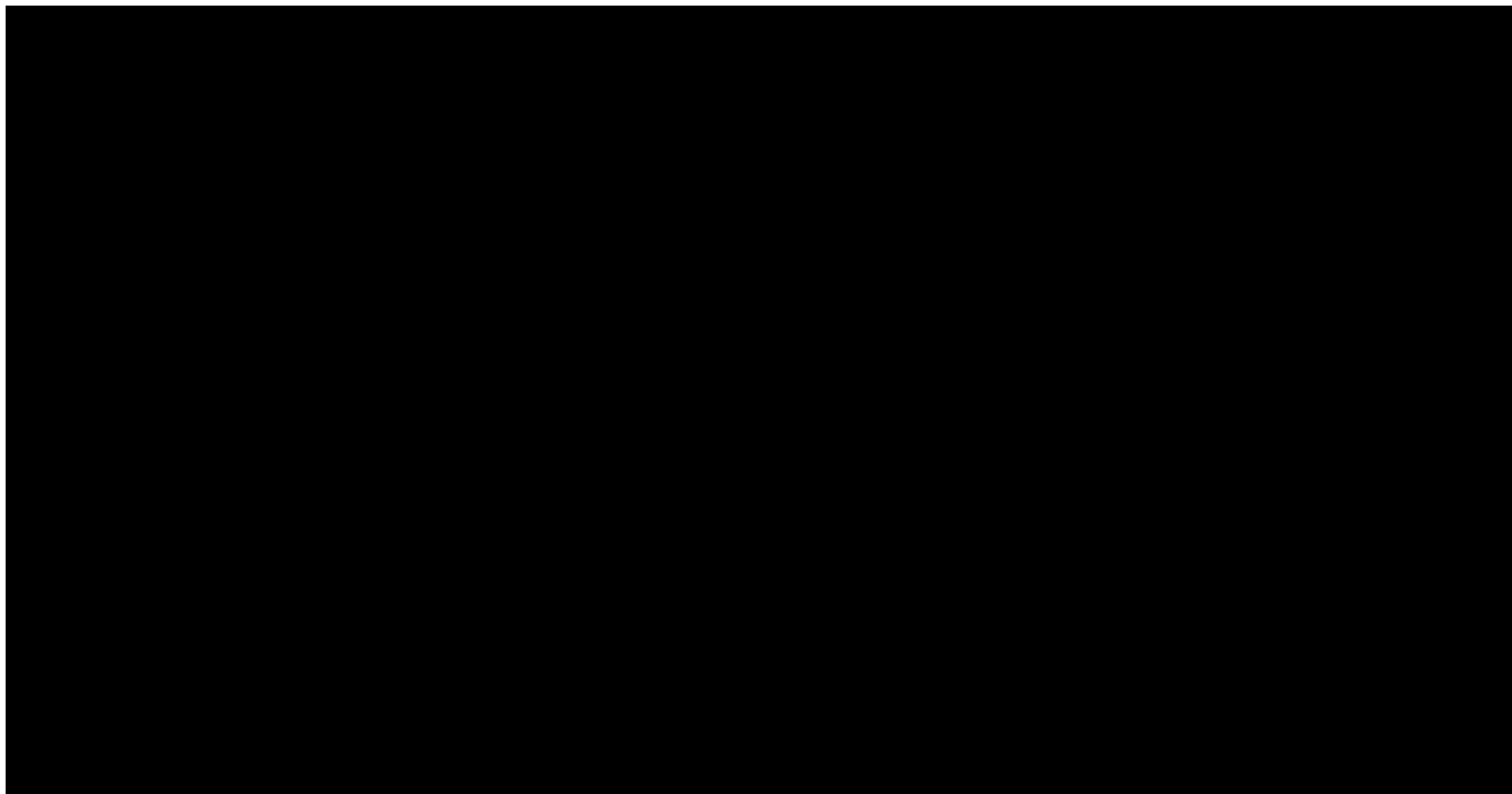


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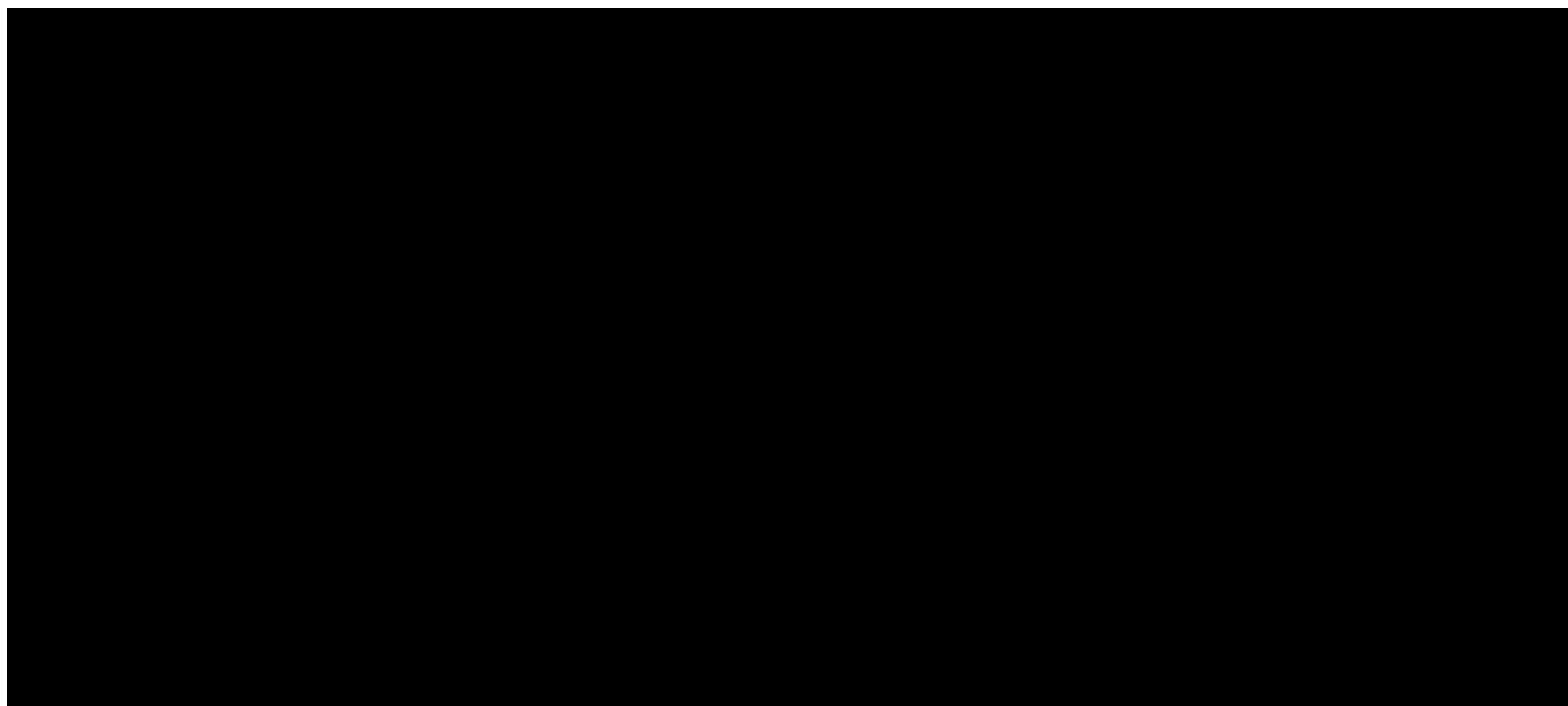
Estimated Total U.S. Keytruda CRC Net Sales v. Total Keytruda U.S. Net Sales (Sep. 2014 - Jan. 2024)



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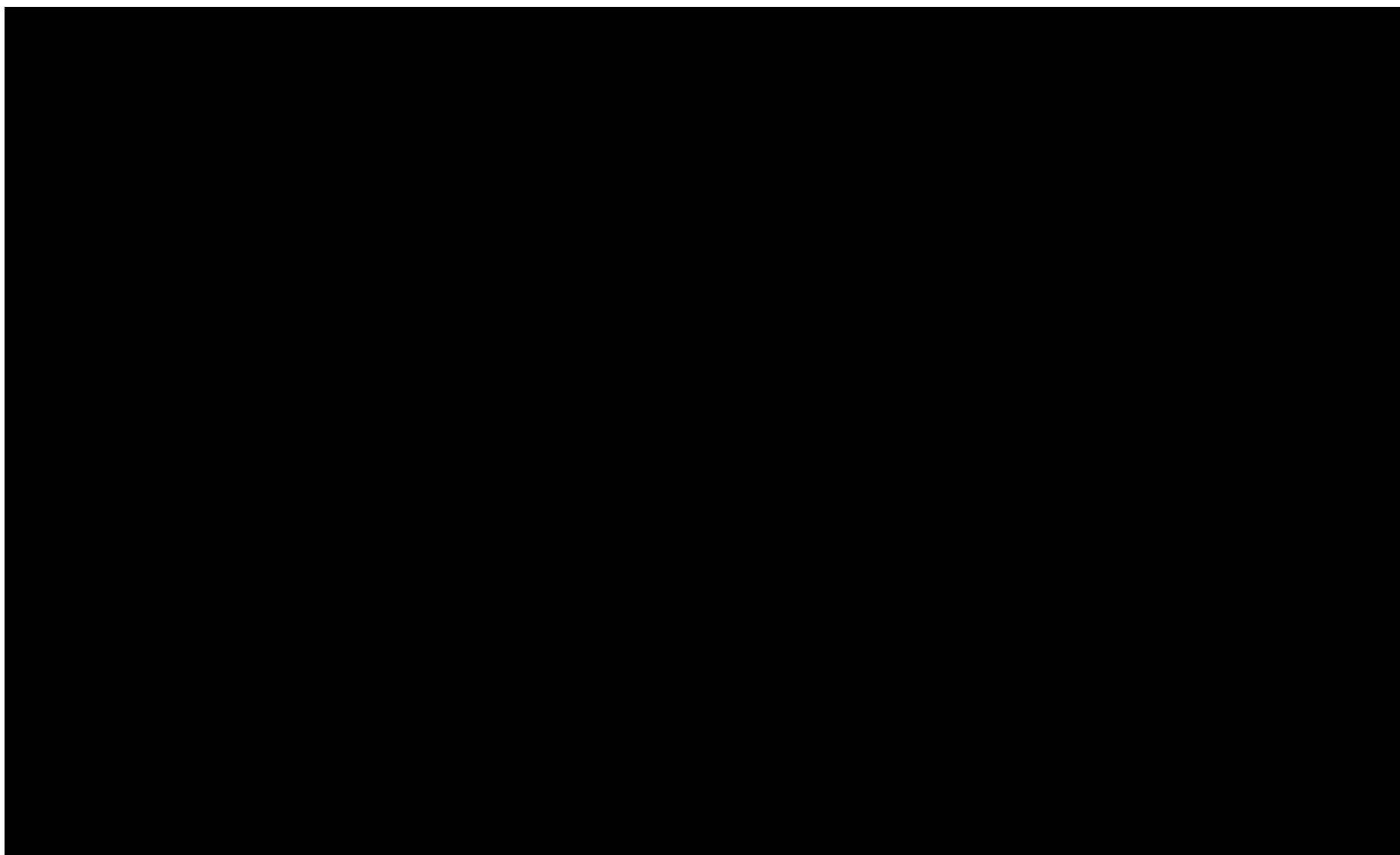
Estimated Total U.S. Keytruda CRC Net Sales v. Total Keytruda U.S. Net Sales (Sep. 2014 - Jan. 2024)



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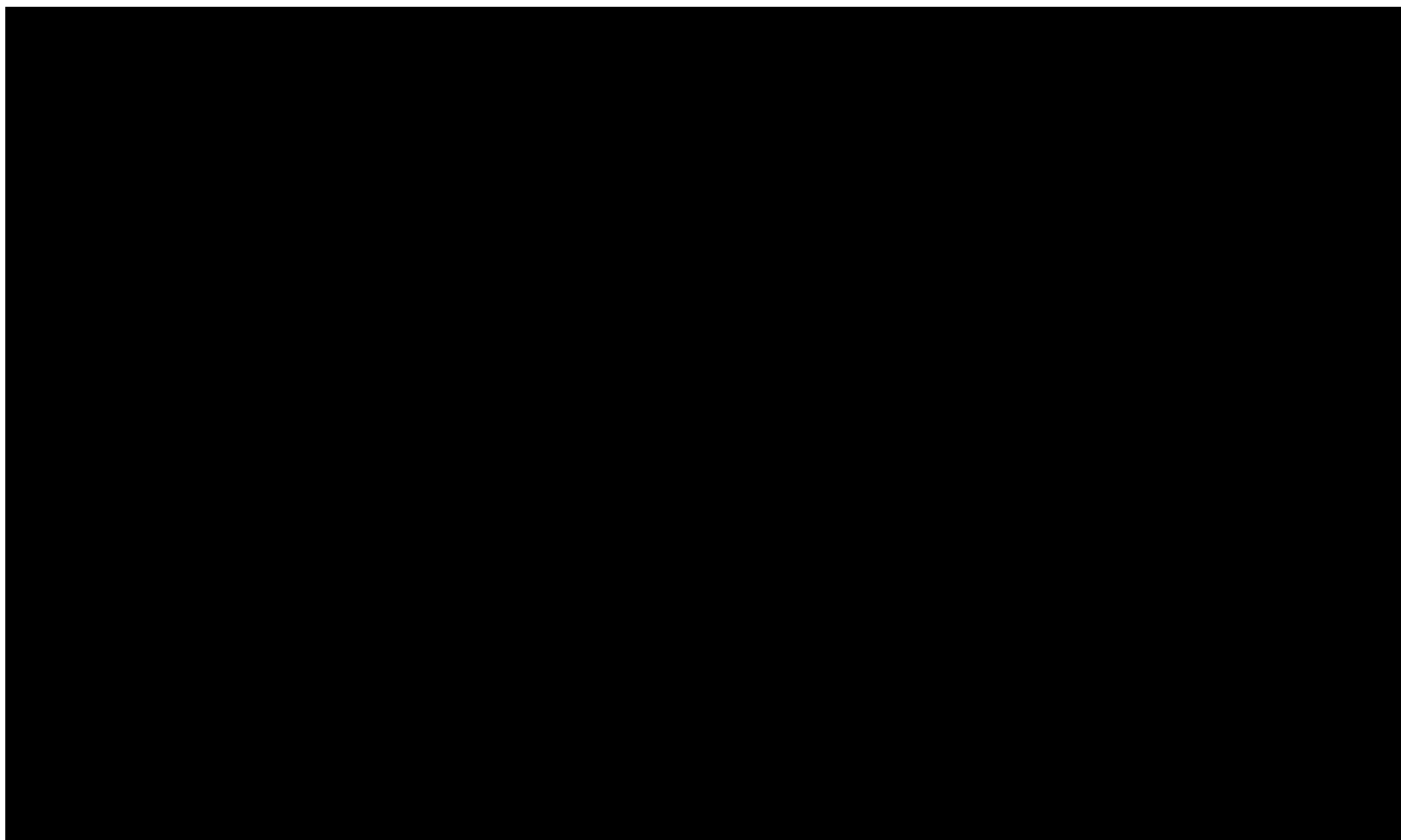
Estimated Total U.S. Keytruda CRC Net Sales (Jan. 2017 - Jan. 2024)



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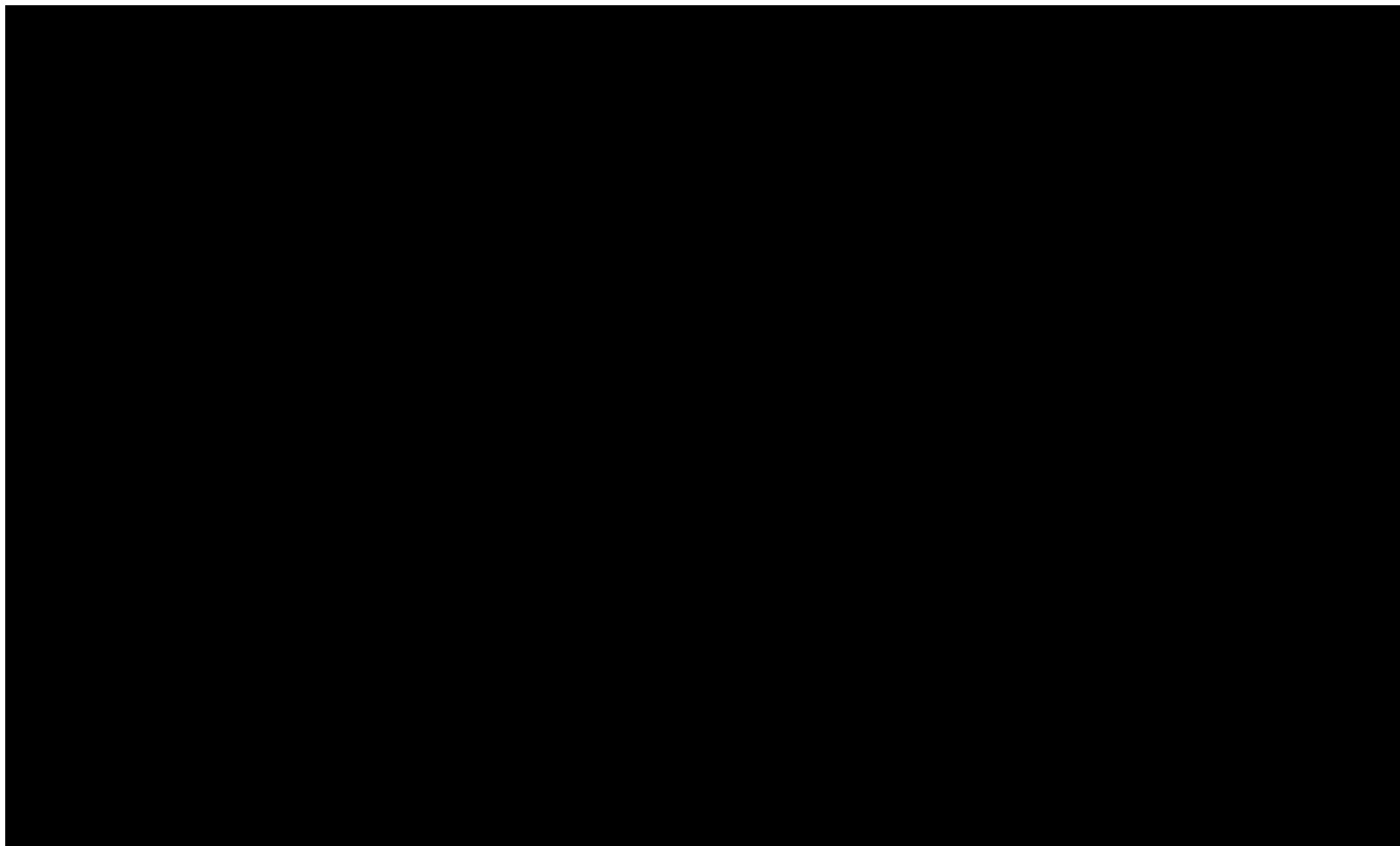
Estimated Total U.S. Keytruda CRC Net Sales (Jan. 2017 - Jan. 2024)



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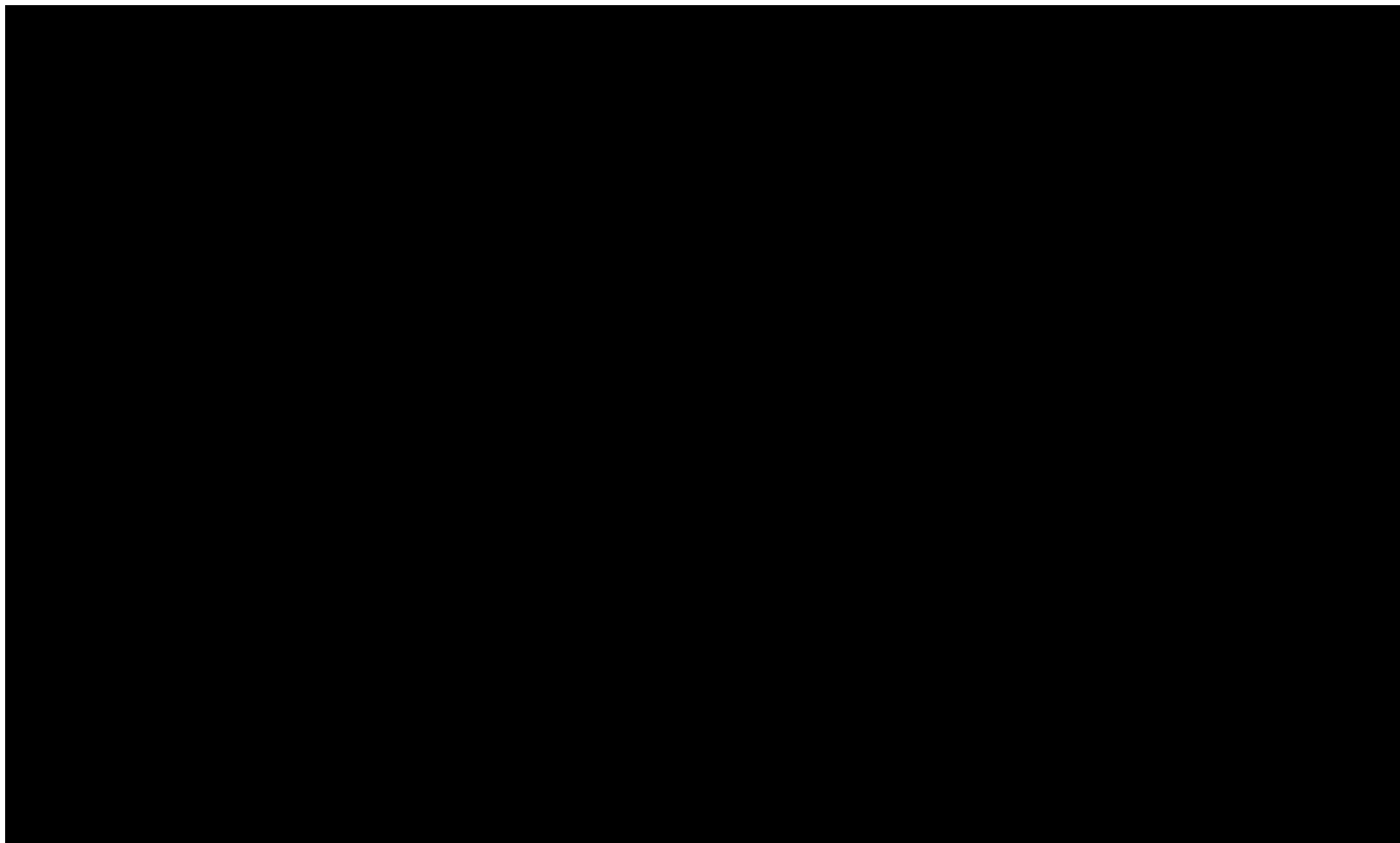
Estimated Total U.S. Keytruda CRC Net Sales (Jan. 2017 - Jan. 2024)

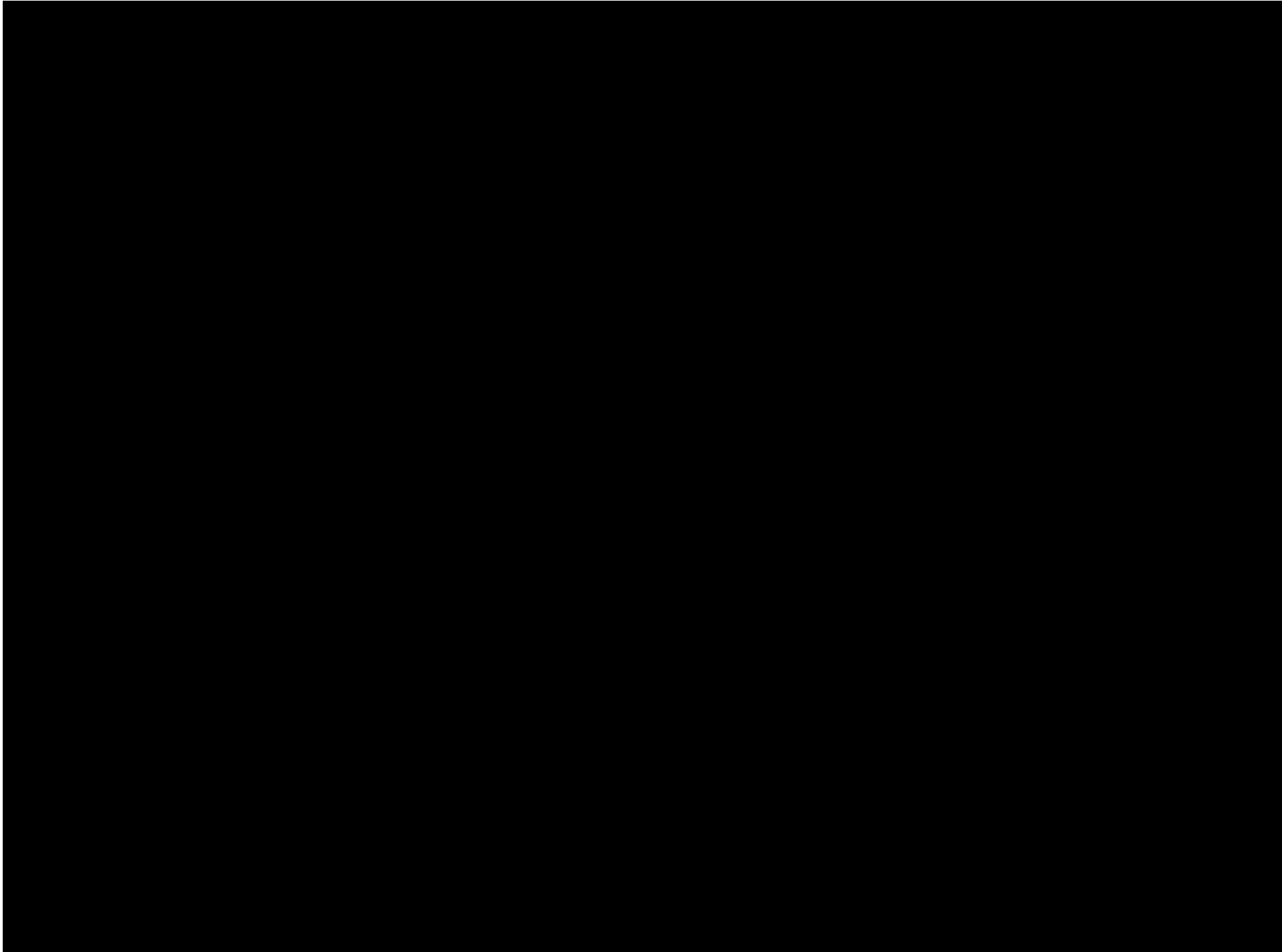


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Estimated Total U.S. Keytruda CRC Net Sales (Jan. 2017 - Jan. 2024)



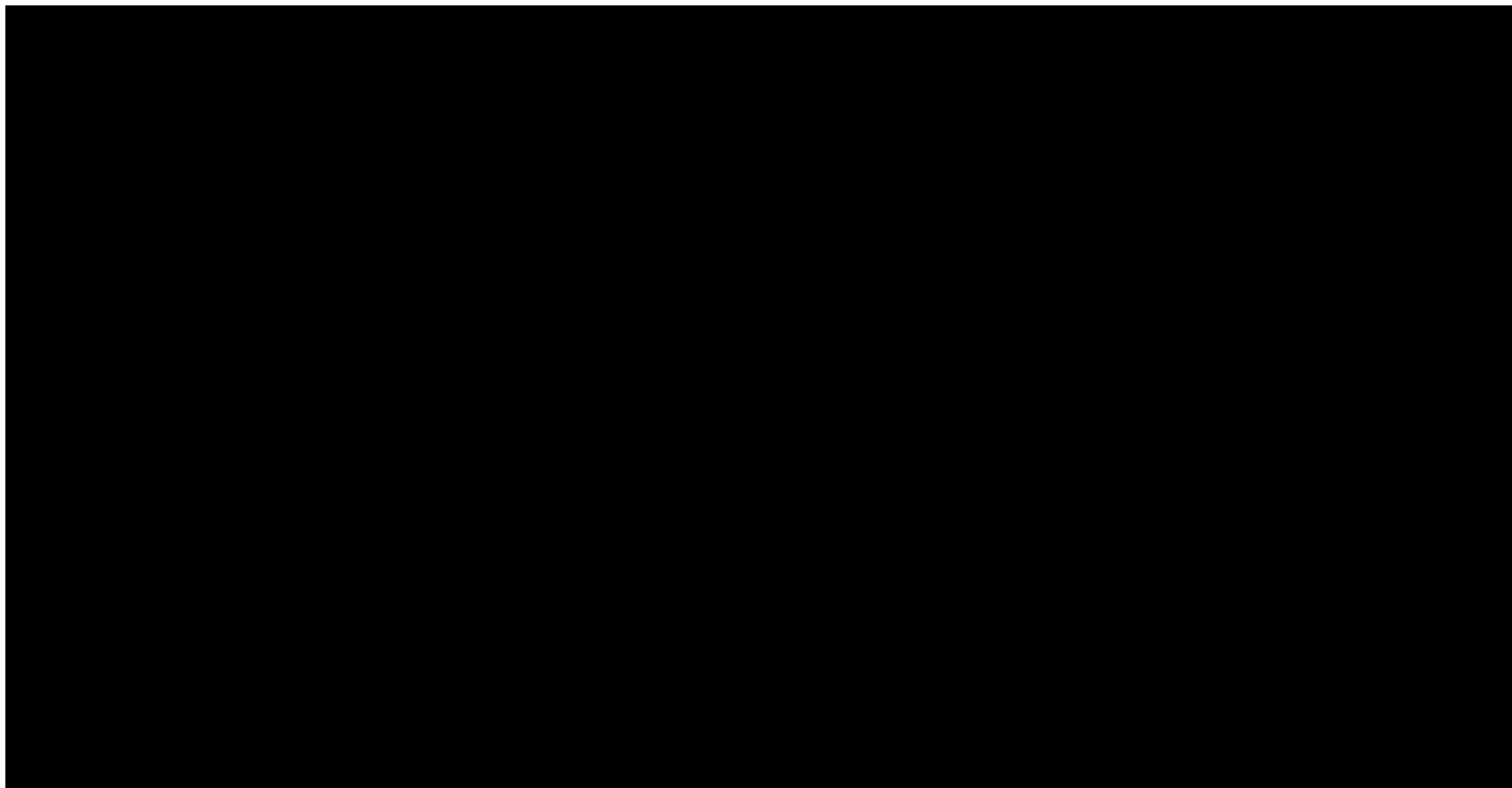


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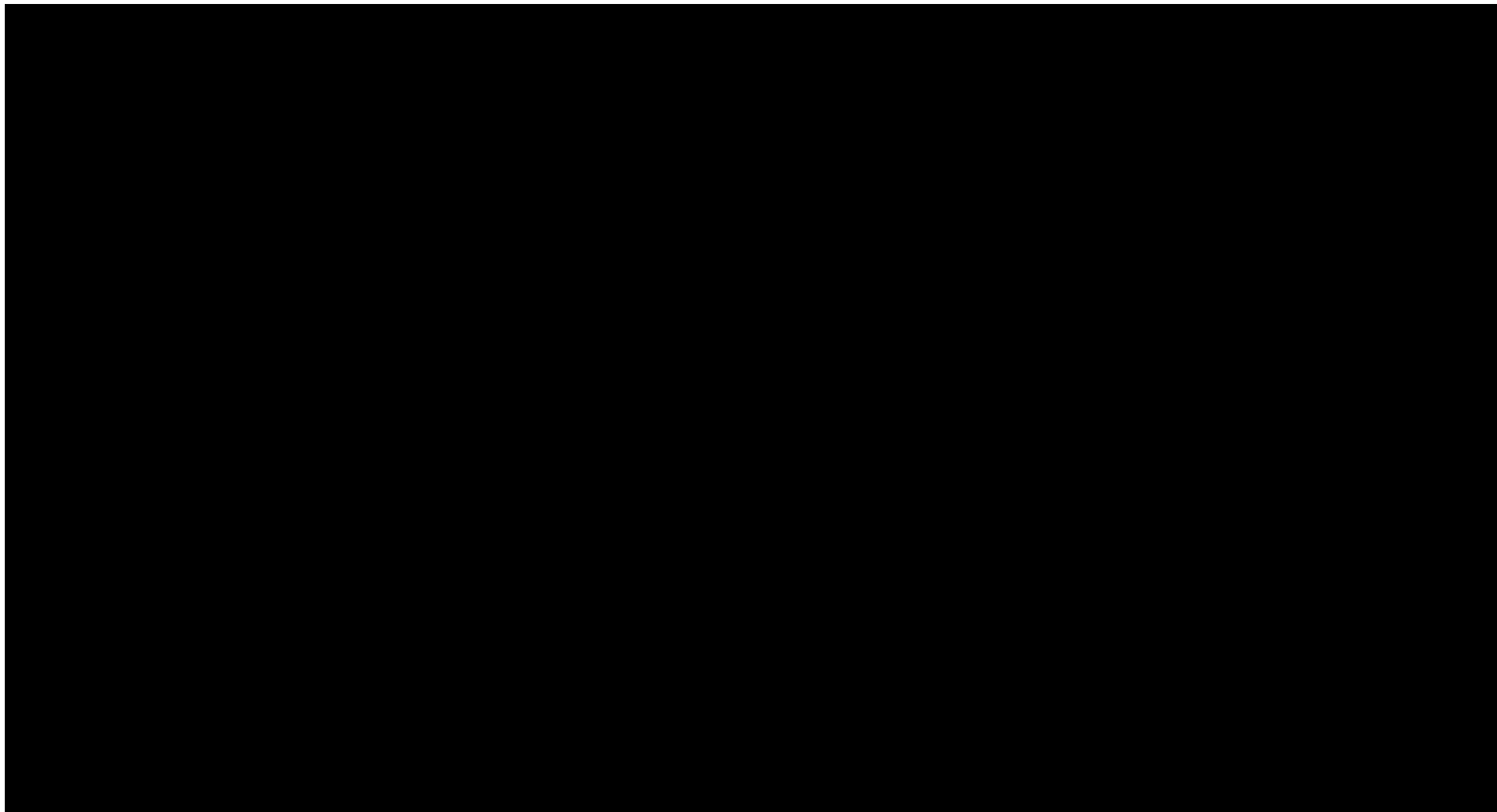
Total U.S. Keytruda Net Sales Growth Rate Delta (Q4 2016 v. Q2 2017 Inflection Point)



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Total U.S. Keytruda Net Sales and Quarterly Growth Rates (2014 - 2018) ⁽¹⁾



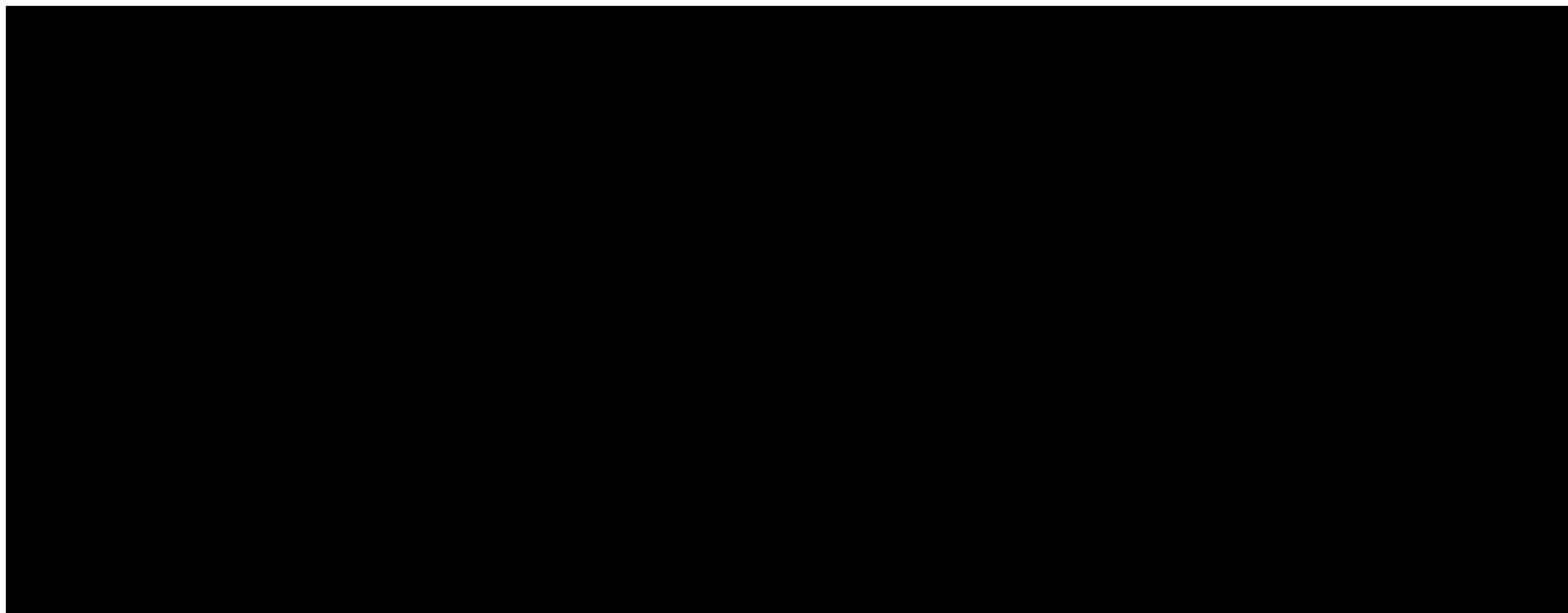
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Keytruda Average Monthly Share of

Estimated Total U.S. MSI-H/dMMR CRC and NSCLC Patients (2017 - 2021) ⁽¹⁾

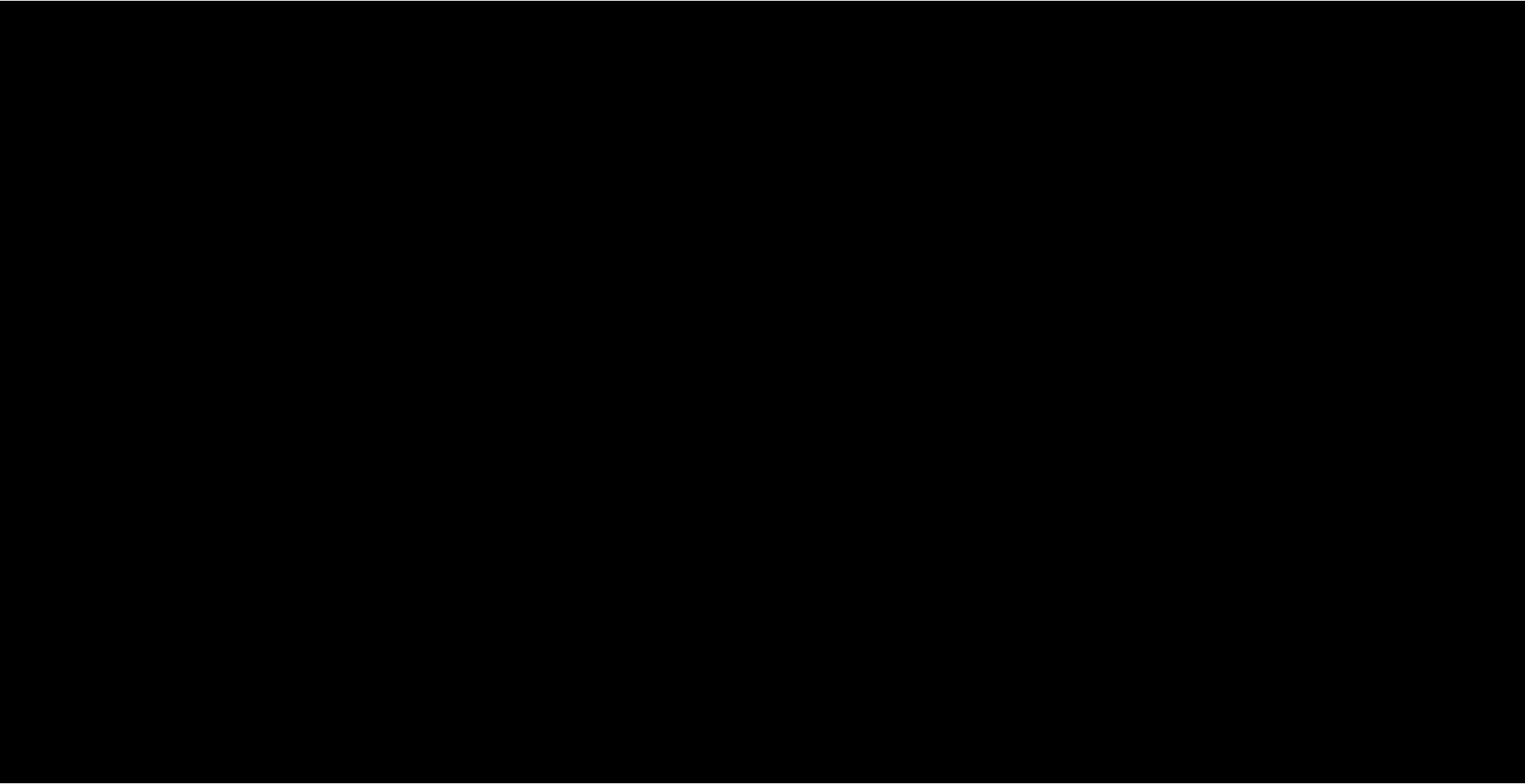


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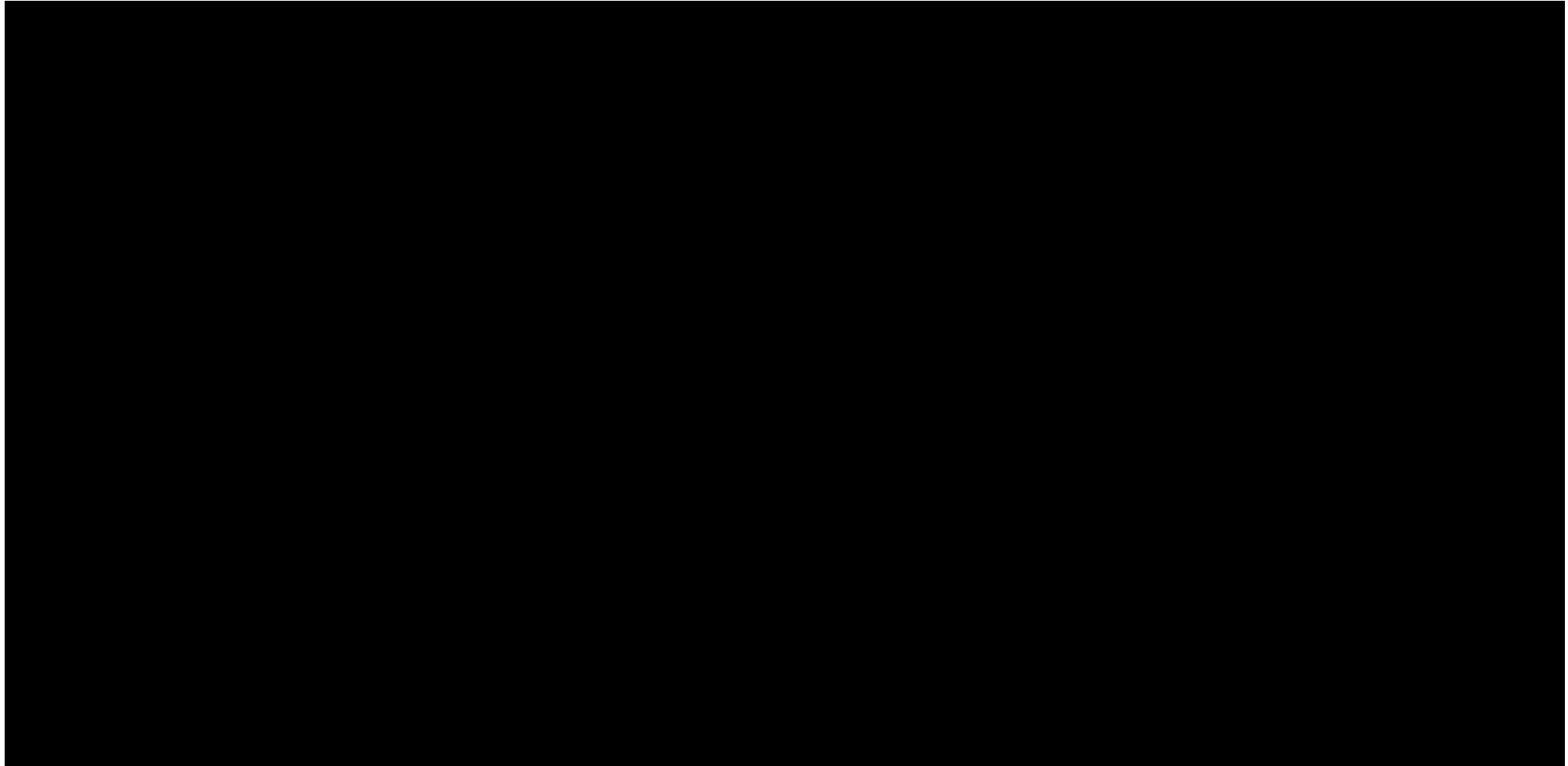
Keytruda Share of Estimated Total U.S. MSI-H/dMMR CRC Patients (2017 - 2021) ⁽¹⁾



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Keytruda Share of Estimated Total U.S. MSI-H/dMMR CRC Patients (2017 - 2021) ⁽¹⁾



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Schedule 7.1

Estimated Total U.S. MSI-H/dMMR CRC Patients (2017 - 2021) ⁽¹⁾

	2017	2018	2019	2020	2021
Total U.S. CRC Patients ⁽¹⁾	1,348,087	1,365,135	1,369,005	1,388,422	1,392,445
Percent of CRC Patients that are MSI-H/dMMR ⁽²⁾	15%	15%	15%	15%	15%
Estimated Total U.S. MSI-H/dMMR CRC Patients	202,213	204,770	205,351	208,263	208,867

Note(s):

(1) Total U.S. CRC Patient figures for a given year are sourced from the National Cancer Institute. Available year-by-year sources are from EX1227-EX1231.

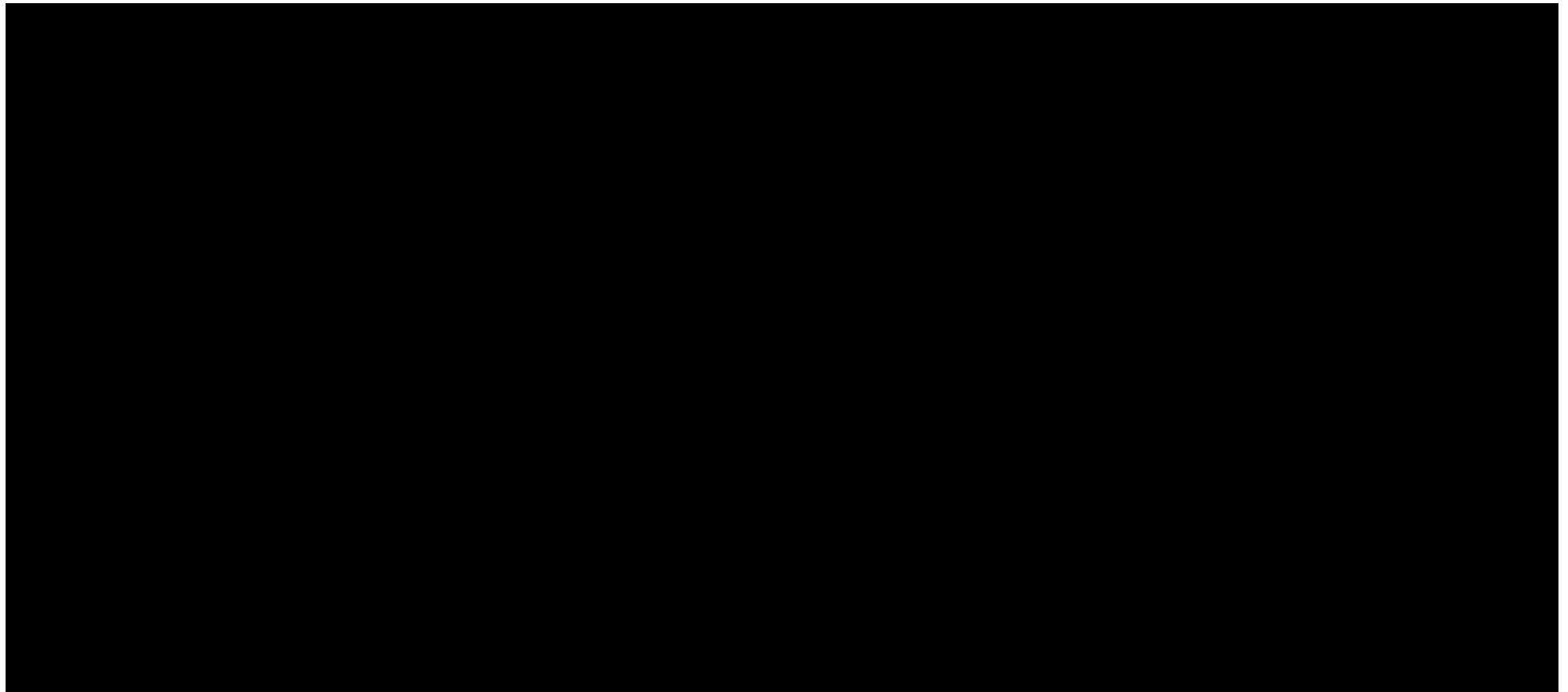
(2) “Microsatellite instability high biomarker (MSI-H) and colorectal cancer,” Colorectal Cancer Alliance, 1/18/2024 (EX2230) ("Approximately 15% of colorectal tumors are MSI-H and dMMR."); Segers Declaration, Appendix 10 (Notes) (EX2191).

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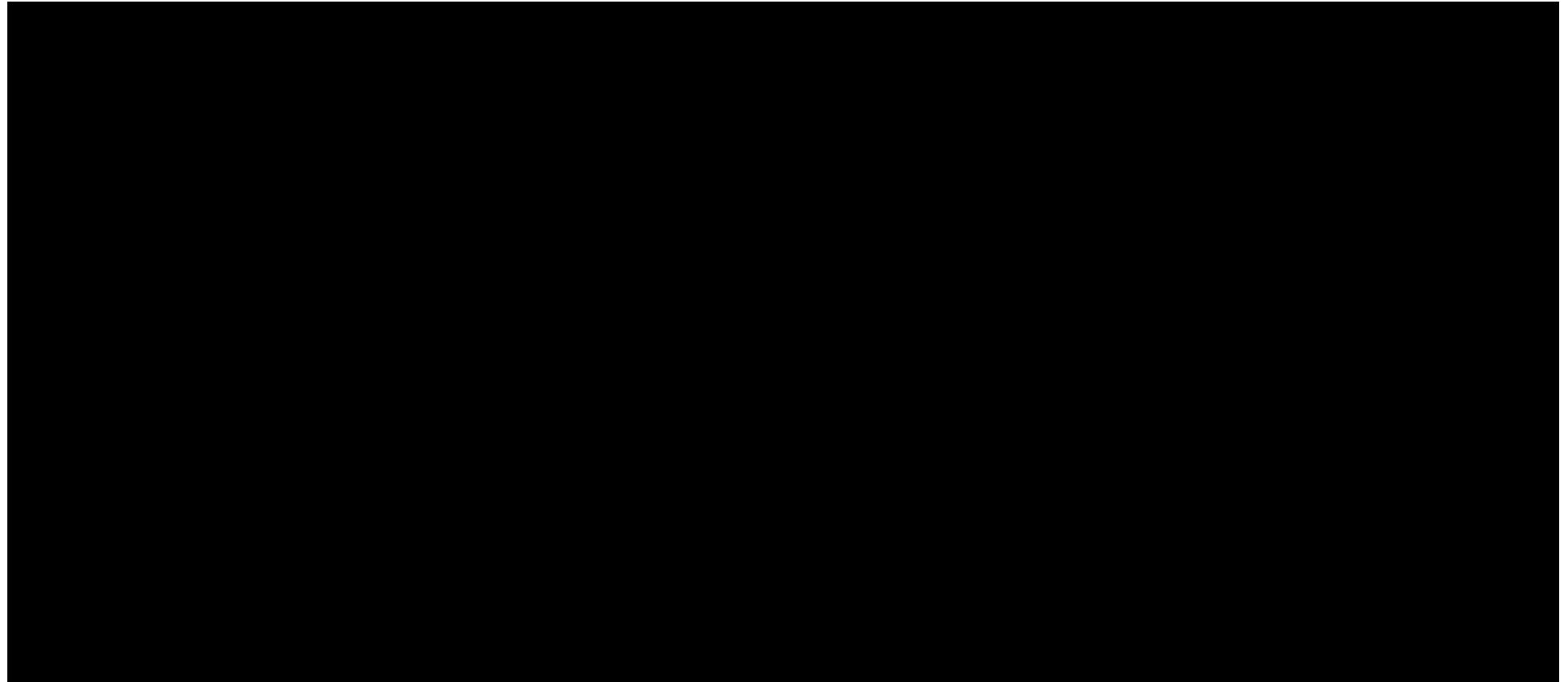
Keytruda Share of Estimated Total U.S. NSCLC Patients (2017 - 2021) ⁽¹⁾



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Keytruda Share of Estimated Total U.S. NSCLC Patients (2017 - 2021) ⁽¹⁾



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Estimated Total U.S. NSCLC Patients (2017 - 2021) ⁽¹⁾

	2017	2018	2019	2020	2021
Total U.S. Lung and Bronchus Cancer Patients ⁽¹⁾	558,250	582,631	576,924	603,989	610,816
Percent of Lung and Bronchus Cancer Patients that are NSCLC ⁽²⁾	85%	85%	85%	85%	85%
Estimated Total U.S. NSCLC Patients	474,513	495,236	490,385	513,391	519,194

Note(s):

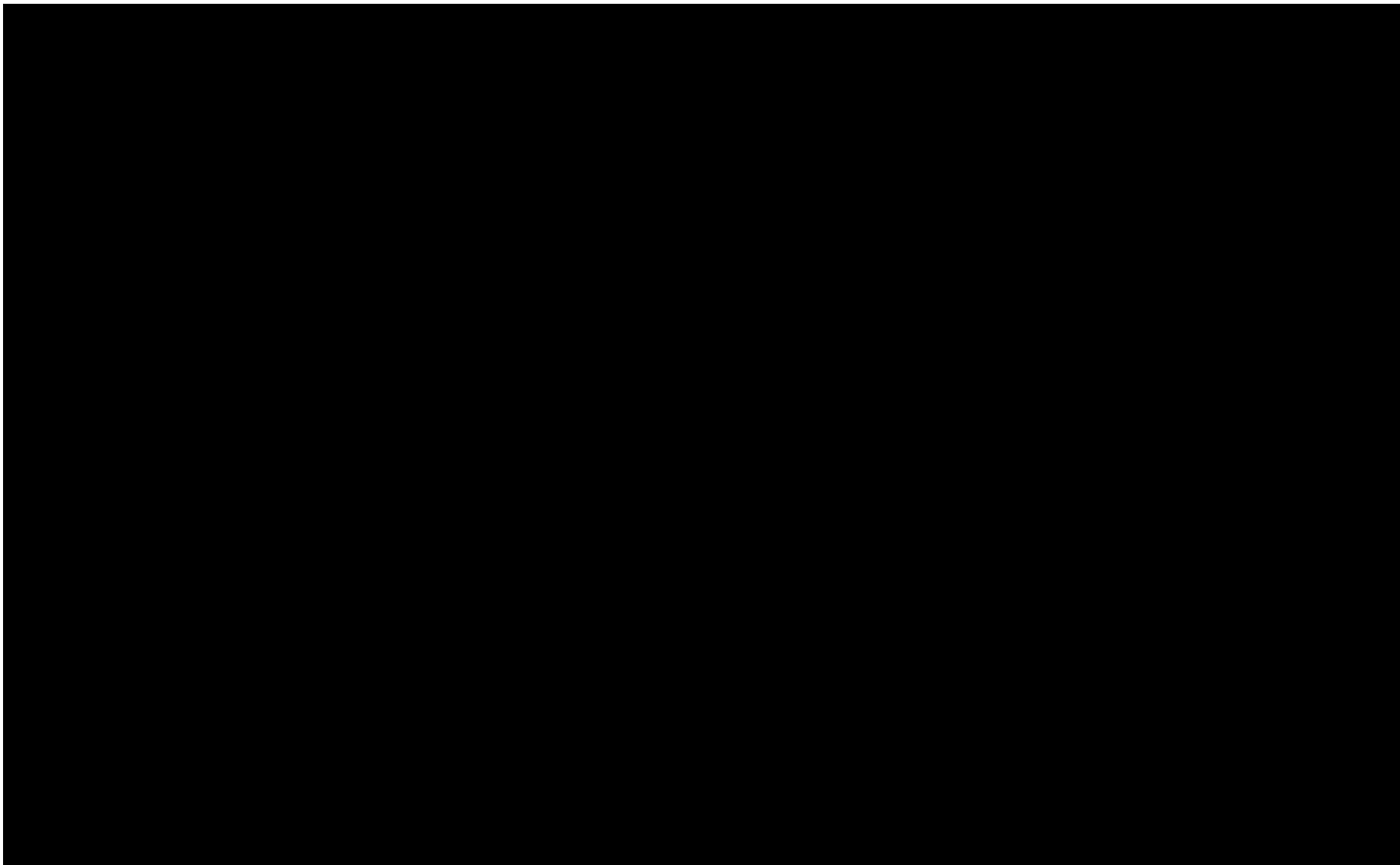
(1) Total U.S. Lung and Bronchus Patient figures for a given year are sourced from the National Cancer Institute. Available year-by-year sources are from EX1232-EX1236.

(2) “The vast majority (85 percent) of lung cancers fall into the category called non-small cell lung cancer” (“Non-Small Cell Lung Cancer,” Yale Medicine (<https://www.yalemedicine.org/conditions/non-small-cell-lung-cancer>) (EX1237); Segers Declaration, Appendix 10 (Notes) (EX2191).

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Schedule 8.2

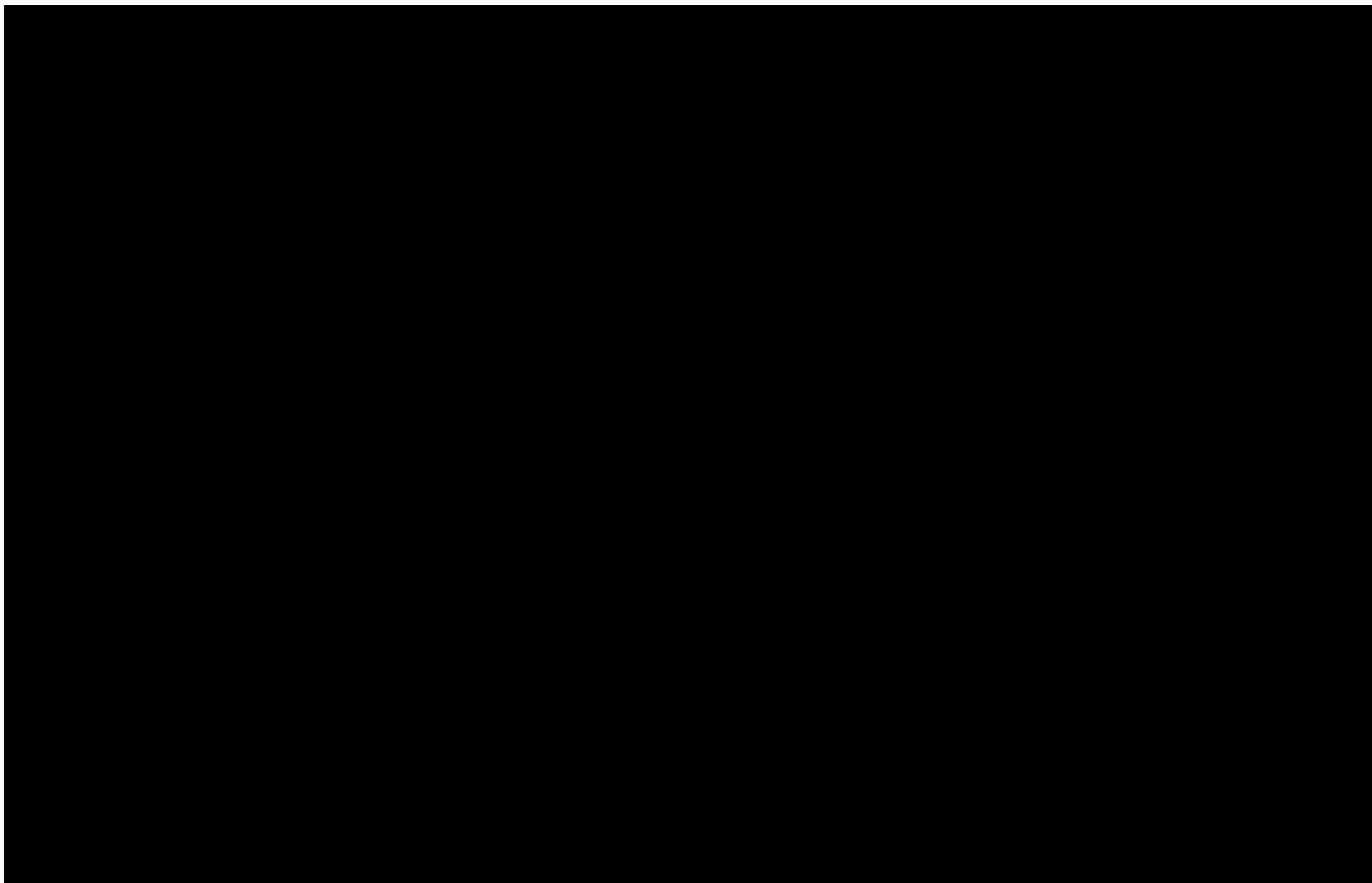
Keytruda U.S. NSCLC Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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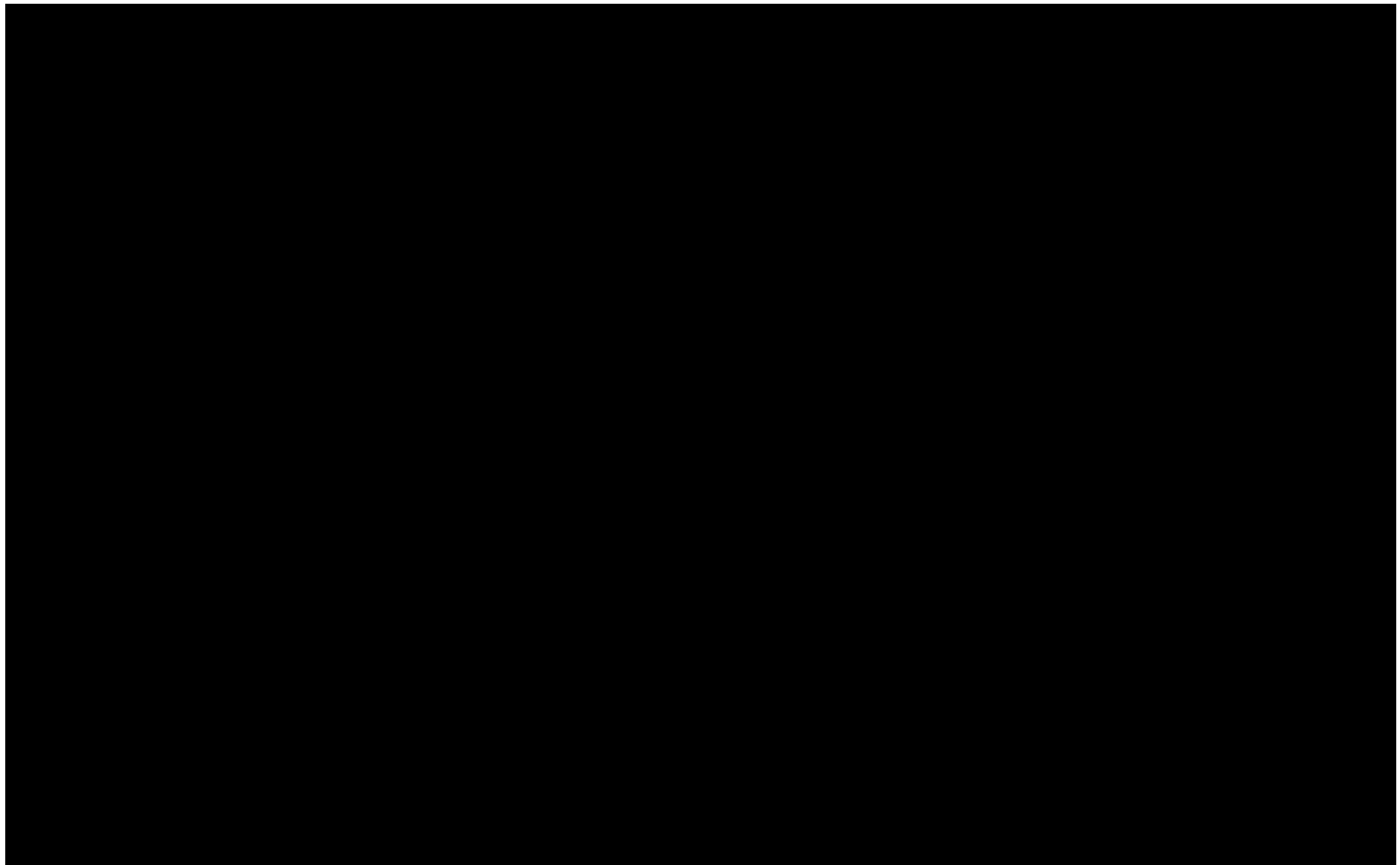
Keytruda U.S. NSCLC Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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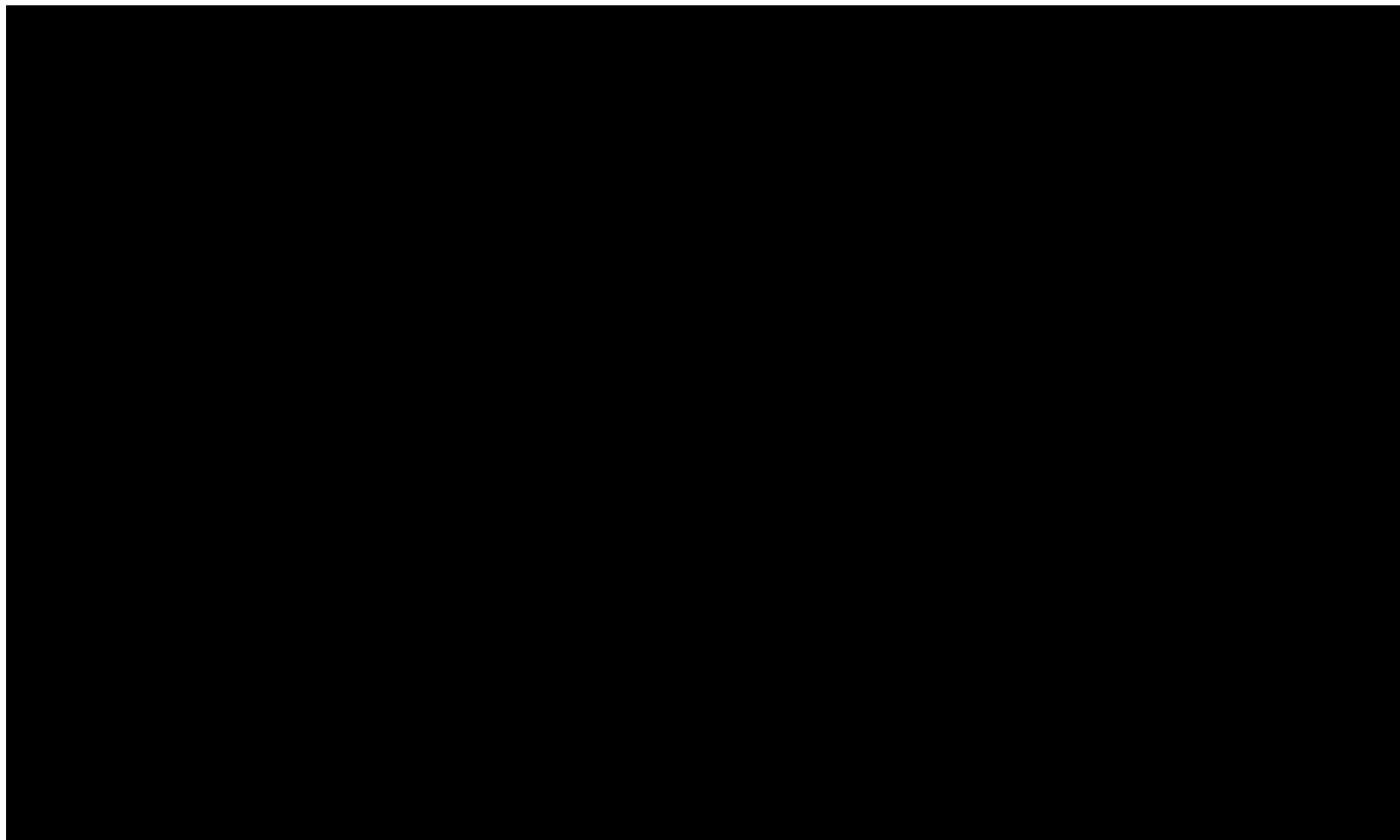
Keytruda U.S. NSCLC Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



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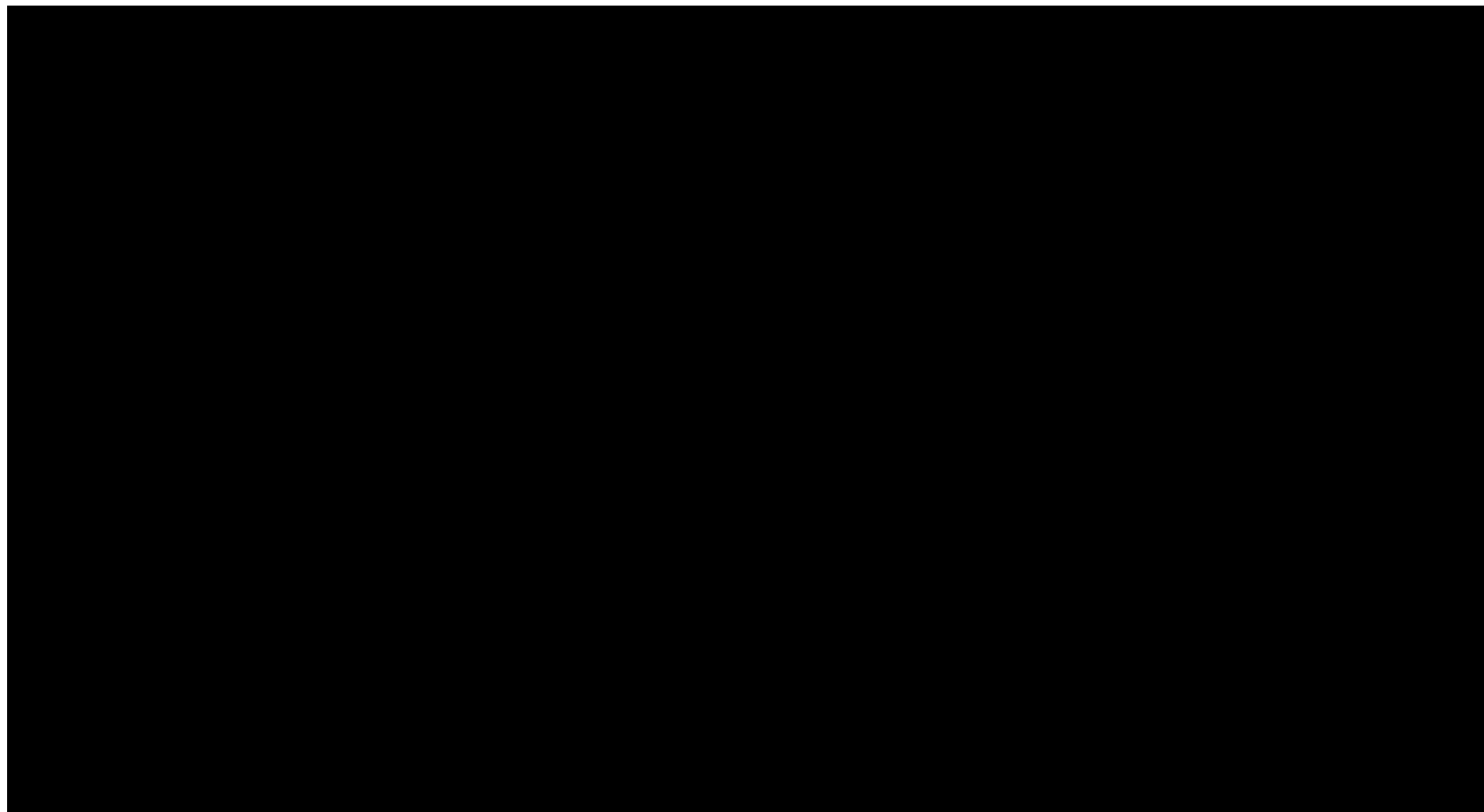
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Keytruda U.S. NSCLC Patients by Patient Type (Jan. 2017 - Jan. 2024) ⁽¹⁾



Tab 9

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Keytruda FDA Approvals by Indication (Sep. 2014 - Dec. 2024) ⁽¹⁾

Tumor Type	Total No. of Approvals	Approval Dates ⁽¹⁾	Source
Melanoma	4	9/4/2014	EX1169
		12/18/2015	EX1205
		2/15/2019	EX1178
		12/3/2021	EX1203
Non-small cell lung cancer (NSCLC)	8	10/2/2015	EX1171
		10/24/2016	EX1199
		5/10/2017	EX1162
		8/20/2018	EX1193
		10/30/2018	EX1200
		4/11/2019	EX1181
		1/26/2023	EX1177
		10/16/2023	EX1197
Head and neck squamous cell carcinoma (HNSCC)	3	8/5/2016	EX1168
		6/10/2019 (2)	EX1183
Classical hodgkin lymphoma (cHL)	3	3/14/2017	EX1159
		10/14/2020 (2)	EX1196

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Keytruda FDA Approvals by Indication (Sep. 2014 - Dec. 2024) ⁽¹⁾

Tumor Type	Total No. of Approvals	Approval Dates ⁽¹⁾	Source
Bladder Cancer	6	5/18/2017	EX1163
		5/18/2017	EX1164
		1/8/2020	EX1175
		4/3/2023	EX1160
		12/15/2023 (2)	EX1204
MSI-H/dMMR Colorectal cancer (MSI-H/dMMR CRC)	2	5/23/2017	EX1165
		6/29/2020	EX1187
MSI-H/dMMR solid tumors (MSI-H/dMMR)	1	5/23/2017	EX1165
Gastric cancer	2	5/5/2021	EX1161
		11/16/2023	EX1201
Cervical cancer	4	6/12/2018	EX1184
		10/13/2021 (2)	EX1195
		1/12/2024	EX1176
Primary mediastinal large B cell lymphoma (PMBCL)	1	6/13/2018	EX1166
Hepatocellular carcinoma (HCC)	1	11/9/2018	EX1172
Merkel cell carcinoma (MCC)	1	12/19/2018	EX1174
Renal cell carcinoma (RCC)	3	4/19/2019	EX1182
		8/10/2021	EX1192
		11/17/2021	EX1202

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Keytruda FDA Approvals by Indication (Sep. 2014 - Dec. 2024) ⁽¹⁾

Tumor Type	Total No. of Approvals	Approval Dates ⁽¹⁾	Source
Esophageal cancer	2	7/30/2019	EX1191
		3/22/2021	EX1180
Endometrial cancer	4	9/17/2019	EX1170
		7/21/2021	EX1189
		3/21/2022	EX1179
		6/17/2024	EX1185
Tumor mutational burden-high (TMB-H) solid tumors	1	6/16/2020	EX1167
Cutaneous squamous cell carcinoma (cSCC)	2	6/24/2020	EX1186
		7/1/2021	EX1188
Triple negative breast cancer (TNBC)	3	11/13/2020	EX1173
		07/26/2021 (2)	EX1190
Biliary cancer	1	10/31/2023	EX1198
Malignant pleural mesothelioma (MPM)	1	9/17/2024	EX1194

Note(s):

(1) Includes FDA Approval Letter dates for Keytruda Approvals/Expansions by indication. Excludes all approvals that were subsequently withdrawn by the FDA. If there were two or more indication approvals/expansions granted by a letter, the number of indications has been indicated in parentheses beside the letter date.