UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

PLAINTIFF, on behalf of himself and all others similarly situated, Plaintiff, vs. Y-mAbs THERAPEUTICS, INC., THOMAS GAD, CLAUS JUAN MOLLER SAN PEDRO, and VIGNESH RAJAH, Defendants.	Civil Action No.: **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff, by his attorneys, alleges the following upon information and belief, except for those allegations that pertain to Plaintiff, which are based on Plaintiff's personal knowledge:

NATURE OF THE ACTION

1. Plaintiff brings this action as a class action on behalf of himself and all other persons or entities who purchased shares of Y-mAbs Therapeutics, Inc. ("Y-mAbs") common stock on the open market, or pursuant to Registration Statements filed with the U.S. Securities and Exchange Commission ("SEC"), during the period October 6, 2020 through October 28, 2022, inclusive (the "Class Period") and suffered damages caused by Defendants' violations of the federal securities laws.

JURISDICTION AND VENUE

2. This action arises under Sections 10(b) (15 U.S.C. § 78j(b)) and 20(a) (15 U.S.C. § 78t(a)) of the Securities Exchange Act of 1934, 15 U.S.C. § 78a *et seq.* (the "Exchange Act"), and Rule 10b-5 (17 C.F.R. § 240.10b-5) promulgated thereunder by the SEC.

3. Jurisdiction is conferred upon this Court by Section 27 of the Exchange Act (15

U.S.C. § 78aa), which vests exclusive jurisdiction for actions alleging violations of the Exchange Act in federal courts, and federal question jurisdiction (28 U.S.C. § 1331).

4. This Court has personal jurisdiction over the Defendants pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) because Defendants have sufficient contacts with the United States through their regular and substantial transaction of business therein and exercising jurisdiction over those Defendants is reasonable.

5. Venue is proper in this District because Y-mAbs maintained offices in this District during the Class Period and many of the acts and transactions constituting the violations of law herein complained of occurred within this District, including the preparation and dissemination of materially false and misleading financial statements and corporate documents.

6. In connection with the acts alleged herein, the Defendants directly or indirectly used the means and instrumentalities of interstate commerce, including the United States mails and facilities of a national securities exchange.

PARTIES

7. Plaintiff is a citizen of the State of New York. He resides in Rockland County. During the Class Period, Plaintiff purchased shares of Y-mAbs common stock on the open market at inflated prices.

8. Defendant Y-mAbs is a Delaware corporation, with its principal executive offices located at 230 Park Avenue, Suite 3350, New York, New York 10169. Y-mAbs stock trades on the NASDAQ Stock Exchange Global Market ("NASDAQ") under the symbol "YMAB".

9. According to its public statements, Y-mAbs is a clinical-stage biopharmaceutical company focused on developing antibody therapeutics and medicines for the treatment of cancer patients of all ages. Y-mAbs's development processes are subject to U.S. Food and Drug

Administration ("FDA") oversight and approval.

10. Defendant Thomas Gad ("Gad") is the Founder, and current Board Member, President, interim Chief Executive Officer, and Head of Business Development and Strategy, of Y-mAbs, having founded Y-mAbs in April 2015. Gad had actual knowledge and supervision over Y-mAbs's communications with the FDA and the true (undisclosed) facts concerning the FDA approval process.

11. Defendant Claus Juan Moller San Pedro ("Moller") was Y-mAbs's Chief Executive Officer from June 2015 until April 2022 and acted as the Interim Chief Commercial Officer from December 2021 until January 2022. Moller, as Y-mAbs CEO, had actual knowledge and supervision over Y-mAb's communications with the FDA.

12. Defendant Vignesh Rajah ("Rajah") has been Y-mAbs Senior Vice President, Chief Medical Officer, and Head of Late-Stage Development since June 2020. Rajah had actual knowledge and supervision over Y-mAbs's communications with the FDA.

13. Defendants Gad, Moller, and Rajah are sometimes referred to herein as the "Individual Defendants."

14. The Individual Defendants made, disseminated, or oversaw the publication of, the public statements alleged to be materially false and misleading herein.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

15. Plaintiff brings this action as a class action pursuant to Rules 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of all persons or entities who purchased shares of Y-mAbs common stock on the open market, or pursuant to Registration Statements filed with the SEC, during the Class Period October 6, 2020 through October 28, 2022, inclusive, and suffered damages caused by Defendants' violations of the federal securities laws (the "Class").

Excluded from the Class are the Defendants herein, officers and directors of Y-mAbs ("Excluded D&Os"), members of the Defendants' and the Excluded D&A's immediate families, affiliates of Y-mAbs, and any entity in which a Defendant or an Excluded D&O has a controlling interest. .

16. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes there are hundreds or thousands of members of the Class. Y-mAbs's common stock was actively traded on the NASDAQ throughout the Class Period.

17. Plaintiff will fairly and adequately protect the interests of the members of the Class. Plaintiff has retained competent counsel experienced in class action litigation under the federal securities laws to further ensure such protection; he is a member of the Class; his claims are typical of the claims of all Class members; and he does not have interests antagonistic to, or in conflict with, those of the Class.

18. A class action is superior to other available methods for the fair and efficient adjudication of this controversy since a multiplicity of actions could result in an unwarranted burden on the Court system and could create the possibility of inconsistent judgments. Moreover, a class action will allow redress for many persons whose claims would otherwise be too small to litigate individually. There will be no difficulty in the management of this action as a class action.

19. There are numerous questions of law or fact that are common to the Class and that predominate over any questions affecting individual members of the Class, including:

(i) whether Defendants violated the federal securities laws as alleged herein;

(ii) whether the Defendants made materially false and misleading statements, or

failed to disclose material information necessary to make the statements made not misleading, concerning the FDA approval process for ^{131}I-omburtamab; and

(iii) whether members of the Class were damaged by virtue of their investments in Y-mAbs common stock during the Class Period, and if so, the appropriate measure of damages.

SUBSTANTIVE ALLEGATIONS

A. Background

20. According to Y-mAbs's Form 10-K for fiscal 2021 (at 4), filed with the SEC on March 1, 2022, Y-mAbs is "a biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer."

21. According to Y-mAbs's public statements, "Omburtamab, our lead product candidate, is a murine monoclonal antibody that targets B7-H3, an immune checkpoint molecule that is widely expressed in tumor cells of several cancer types. ^{131}I-omburtamab, which is omburtamab radiolabeled with Iodine-131, is currently being studied in several clinical trials including pivotal stage development Study 101 and Study 03-133 for the treatment of pediatric patients who have CNS/LM from NB." 2021 Form 10-K at 7.[1]

22. Study 03-133 included pediatric patients with neuroblastoma (NB) that relapsed in the central nervous system (CNS) or leptomeninges (CNS/LM).

23. Leptomeningeal metastases occurs when cancer cells have spread to thin layers of tissue that cover the brain and spinal cord.

24. According to Y-mAbs's 2021 Form 10-K (at 27), there are approximately 700 children diagnosed with neuroblastoma (NB) in the United States each year. Of those,

[1] ^{131}I-Omburtamab is referred to herein (except where quoted) as "omburtamab."

approximately 50-60% are high-risk, and of those at high-risk who relapse, Y-mAbs believes approximately 20% will suffer from leptomeningeal (central nervous system) metastases from neuroblastoma.

25. One treatment cycle of omburtamab takes 4 weeks and includes a treatment dose during week one followed by a 3-week observation period including a repeated MRI, CSF cytology, and safety monitoring.

26. Y-mAbs sought FDA approval of omburtamab through a Biologics License Application first in 2020 and again in 2022, based on a comparison between Study 03-133 performed at Memorial Sloan Kettering Cancer Center ("MSKCC") and an external cohort comprising data from the Central German Childhood Cancer Registry, or CGCCR, database.

27. The efficacy population in Study 03-133 consisted of a subset of 94 patients ages 0.9 to 13 years. The first patient was enrolled in 2004, and the last patient enrolled in 2018.

28. Study 03-133 was a single-arm study without a control group.

29. The primary endpoint was overall survival (OS) at 3 years.

30. Tumor responses were not systematically analyzed in this study.

31. After CNS/LM relapse and prior to receiving omburtamab, all patients received at least one type of CNS-directed therapy (surgery, chemotherapy, and/or radiotherapy) and the majority of patients (76%) received all three treatment modalities.

32. The 3-year OS rate after CNS/LM relapse in the efficacy population of 94 patients was 54%.

33. The external control group (CGCCR), against which Study 03-133 was compared, included clinical data from patients with Stage 4 neuroblastoma included in the German national neuroblastoma clinical trials NB90, NB97 and NB2004 from 1990 to 2015.

34. Y-mAbs identified 79 patients in the source population who received at least one type of post-CNS relapse treatment (radiotherapy, chemotherapy, or surgery).

35. According to the 2021 Form 10-K "Data from 85 patients sourced from The Central German Childhood Cancer Registry, or CGCCR, showed a median OS of 4.7 months." 2021 Form 10-K at 28.

36. Y-mAbs has represented in Form 10-K filings with the SEC that "An analysis of 107 patients with pediatric CNS/LM from NB who were treated with ^{131}I-Omburtamab in Study 03-133 demonstrated a median overall survival, or OS, of 50.8 months, as compared to historical median OS of approximately six to nine months." 2021 Form 10-K at 7.

37. Study 101 is an ongoing international multi-center single-arm trial, to investigate the safety and efficacy of omburtamab in pediatric patients with neuroblastoma with relapse in the CNS including parenchymal or LM metastases.

38. The primary endpoint of the trial is 3-year OS rate, with a key secondary endpoint of overall tumor response rate (ORR).

39. Y-mAbs sought to utilize "interim efficacy, safety and pharmacokinetic data from Study 101 [to] support the BLA resubmission." 2021 Form 10-K at 81.

40. As of October 2022, Study 101 was fully enrolled, but survival data remained immature.

41. 21 CFR 314.126 contains the elements required to be satisfied in order to receive FDA approval for omburtamab. A drug or biologic product must demonstrate substantial evidence of effectiveness through adequate and well-controlled studies. To establish effectiveness, it is essential to distinguish the effect of the drug "from influences, such as spontaneous change in course of disease, placebo effect, or biased observation" (21 CFR

314.126(a)).

42. The FDA declined marketing approval of omburtamab in a Refusal to File (RTF) letter dated October 2, 2020, informing Y-mAbs that additional data, including evidence of durable response were necessary to provide the level of evidence needed to support an approval.

43. Y-mAbs disclosed the existence of the RTF letter in a press release dated October 5, 2020 and in an investor conference call the morning of October 6, 2020, but misrepresented the FDA's willingness to approve omburtamab for marketing based on the existing clinical trials.

44. In fact, throughout the Class Period, beginning on October 6, 2020, Y-mAbs misrepresented to investors that, pursuant to a series of meetings and other communications between Y-mAbs and the FDA, that progress was being made that would align with the FDA's requirement to demonstrate substantial evidence of effectiveness, sufficient for approval of omburtamab, through adequate and well-controlled studies.

45. Specifically, the FDA had repeatedly advised the Defendants that the FDA was unlikely to grant approval for the marketing of omburtamab based on a comparison between Study 03-133 and CGCCR because of substantial differences in the patient populations, and the absence of tumor response data, and that Study 101 was neither sufficiently advanced nor indicative of efficacy to justify approval.

46. The statements alleged to be false and misleading were not forward-looking statements because they misrepresented existing facts based on communications with the FDA with respect to the approval.

47. The true facts were first disclosed to investors shortly after the opening of trading on October 26, 2022 when the FDA published its Briefing Document for an October 28, 2022 Advisory Committee ("AdCom") Meeting, and again, on October 28, 2022 when the AdCom

vote 16-0 against recommending approval of omburtamab.

48. The disclosure of the true facts caused Y-mAbs common shares to plummet $11.56 a share from the closing price on October 25, 2022 of $15.17 a share to close on October 31, 2022 at $3.61 a share.

FACTUAL ALLEGATIONS

49. On October 5, 2000 after the close of the securities markets, Y-mAbs issued a press release informing investors that it had received a Refusal to File ("RTF") letter from the FDA regarding its Biologics License Application ("BLA") for omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma.

50. According to the press release, "[u]pon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control ("CMC") module and the Clinical module of the BLA require further detail. No additional non-clinical data have been requested or are required."

51. The press release added that "Y-mAbs is confident that it can address all points raised by the FDA, including providing the requested additional CMC information and supplementary data from Study 101, which will include tumor response data from patients with evaluable disease among the first 24 patients included in the protocol."

52. The press release also stated that the "Company will request a Type A meeting with the FDA as soon as possible, and plans to work in close dialog with the Agency in order to amend the BLA with the goal of resubmitting the BLA before the end of 2020."[2]

53. On a conference call conducted on October 6, 2020, beginning at 9:00 a.m., Moller reiterated that "There is no request [from the FDA] for additional clinical data that is not

[2] According to FDA guidance, a Type A meeting is "A meeting which is necessary for an otherwise stalled drug development program to proceed (previously referred to as a "special considerations" meeting)." Industry Meeting Type | FDA.

already available;" and that "shortly after the Type A meeting, we should be ready to put together the documents for refiling the BLA." Refinitiv Tr. at 3.

54. Moller added later on that call that:

> They requested 2 things. One thing was a different type of statistical comparison between the data from Study 03-133 and the old study with more than 100 patients and the historical controls. It's not a problem. We can do it, and we already started working on that this week. The other thing they specifically requested was tumor response data for patients from Study 101, where the tumor responses has been independently evaluated according to the RANO criteria for measuring tumor responses in the central nervous system.
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> So very clear, and we have everything, and I have no concern that the FDA will think, "Oh, that is not sufficient response." I think we are beyond that also. [Refinitiv Tr. at 5.]

55. Also on October 6, 2020, Y-mAbs filed a Form 8-K with the SEC, which attached the October 5, 2020 press release as Exhibit 99.1. The Form 8-K was signed by Defendant Gad.

56. Y-mAbs did not however publicly disclose the FDA's actual Refusal to File letter. According to the October 2022 Briefing Document, the actual text of the RTF letter (dated October 2, 2020) was markedly different than the description given by Y-mAbs in the October 5, 2020 press release and on the October 6, 2020 conference call. The actual RTF letter was described by the FDA in the Briefing Document (at 22) as follows:

> **FDA issued a RTF letter stating that application did not contain substantial evidence consisting of adequate and well-controlled investigations that ^{131}I-omburtamab is safe and effective for the treatment of pediatric patients with neuroblastoma that has relapsed to the CNS or LM.** FDA listed the following clinical reasons that the results of Study 03-133 did not support filing a BLA:
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> - The treatment effect of ^{131}I-Omburtamab cannot be objectively established or quantified based on the results from Study 03-133 compared to the reference rate derived from the CGCCR external control because there were no pre-specified statistical methods for matching analyses in place to assure comparability of the data from Study 03-133 to the CGCCR data. To provide a more accurate

reference rate for 3-year overall survival (OS), **data from Study 03-133 and the external control should be reanalyzed using a propensity score adjusted analysis (i.e. matching or IPTW) for important baseline characteristics** (such as prior receipt of craniospinal irradiation) and prognostic factors (such as patient age and MYCN status). Additionally, to adequately interpret the analysis and ensure adequate event rate estimates**, it will be important for the external control data to reflect a patient population and follow-up to that is comparable to Study 03-133**.

- Given the limitations associated with establishing and quantifying the treatment effect based on comparison of the 3-year OS rate observed in Study 03-133 to the 3-year OS rate derived from analyses of data from the CGCCR external control and from published literature, **direct evidence of the anti-tumor effect of ^{131}I-Omburtamab through assessment of overall response rate and duration of response as determined by a blinded independent radiology is needed to provide supportive evidence of the effectiveness of ^{131}I-Omburtamab** for the proposed indication. [Emphasis in the original.]

57. Defendants knew that Y-mAbs would have difficulty addressing the FDA's concerns, if possible at all, because the "statistical methods for matching analyses" were not "pre-specified" and the patient populations and treatment regimens for patients in Study 03-133 and CGCCR were not "comparable." Thus, any survival benefit achieved in the patient population in Study 03-133 could not be proven to be related to omburtamab.

58. The RTF letter did not contain new information provided by the FDA to Y-mAbs. Rather, as summarized in the Briefing Document (at 21), the FDA had met with and corresponded with Y-mAbs throughout 2017 to 2020, and had repeatedly advised Y-mAbs of its concerns that (i) the patient population in Study 03-133 was not comparable to the population in CGCCR, and (ii) interpretation of Study 101 would be "difficult" because it was a "single-arm trial."

59. Investor reaction to Y-mAbs's report of the Refusal to File letter was muted by

Defendants' statements of optimism that Y-mAbs "can address all points raised by the FDA." Y-mAbs's shares closed down $3.57 on October 6, 2020 (from $41.70 to $38.13 per share).

60. According to the Briefing Document (at 22), on November 3, 2020, a Type A meeting was held with Y-mAbs "to discuss the proposed plan to address filing issues described in the RTF letter." At that meeting, the "FDA expressed concern that the **CGCCR external control data may not be fit-for-purpose** as a direct comparator for the overall survival data from patients in Study 03-133 in that the patient populations may not be comparable. Specifically, **there appears to be an imbalance in receipt of radiation** treatment (more patients in the Study 03-133 received radiation, specifically craniospinal irradiation [CSI], compared to the patients in the CGCCR external control where no patients received CSI). FDA stated that given the uncertainties regarding the interpretation of overall survival results in Study 03-133, a single-arm study, **response data are needed** to support the antitumor effect of ^{131}I-omburtamab." [Emphasis in the original.]

61. Notwithstanding the skepticism reflected in the FDA's comments at the November 3, 3020 meeting, in Y-mAbs's earnings call for the third quarter of 2020, conducted on November 6, 2020, Defendant Moller, stated that:

> [I]t's pretty clear that on the Chemistry, Manufacturing, and Controls we have resolved all the issues that they have requested and we are ready to put that together in a resubmission package. [Refinitiv Tr. at 9.]

62. This statement in the November 6, 2020 earnings call was materially false and misleading because, as reflected in the FDA's comments at the November 3, 2020 meeting, it was not "clear" that Y-mAbs had resolved all the issues requested by the FDA.

63. According to the Briefing Document (at 22), on January 8, 2021, a teleconference was held with Y-mAbs "to discuss external control data that could serve as direct comparator to

data in Study 03-133 and response data in Study 101." During that teleconference:

- FDA referenced communication to Y-mAbs from 1/07/2021 which expressed concern that the CGCCR external control was not fit-for-purpose due to lack of granular patient-level data.

- FDA acknowledged that Y-mAbs had attempted to identify other sources including Children's Oncology Group and SIOPEN and that data on post-CNS relapse was not available.

- Due to the difficulties associated with obtaining patient-level data that would be of sufficient quality and granularity to serve as an appropriate external control, Y-mAbs expressed a preference for pursuing a clinical development strategy based upon demonstration of durable overall responses in patients with measurable disease enrolled in Study 101.

64. On February 17, 2021, Y-mAbs filed a Prospectus with the SEC for the secondary offering of 2,439,025 shares of T-mAbs common stock at $41.00 a share.

65. According to Y-mAbs's first quarter Form 10-Q, filed with the SEC on May 6, 2021, 2,804,878 shares were sold on the secondary offering at a price of $41.00 per share. The underwriters exercised the full over-allotment option of 365,853 shares.

66. On February 26, 2021, Y-mAbs held its earnings call for the fourth quarter of 2020. Defendant Gad stated on the call that Y-mAbs had had several interactions with the FDA and further that a Type B meeting with the FDA had been scheduled for March 26, 2021.[3]

67. Defendant Moller, on the fourth quarter earnings call, stated:

> We have maintained a very close dialog with the FDA regarding the resubmission of the Omburtamab BLA, and have scheduled a Type B meeting next month, where we hope to reach a final agreement with the agency on the remaining details before initiating our rolling resubmission for Omburtamab BLA. We remain confident that we can address all points raised by the FDA, including providing the requested supplementary data from Study 101.

[3] According to FDA guidance, the purpose of a Type B meeting is "to acquaint FDA reviewers with the general information to be submitted in the marketing application, discuss appropriate methods for statistical analysis, discuss proposed format for data in the planned marketing application, to identify those studies that the sponsor is relying on as adequate and well-controlled, and to discuss any major unresolved problems (21 CFR 312.47)." Industry Meeting Type | FDA.

68. The Prospectus for the secondary offering and fourth quarter 2020 earnings call were materially false and misleading in that they failed to mention the continued concern expressed by the FDA that a single arm study (03-133) that did not analyze tumor response data lacked the substantial evidence of effectiveness necessary to receive approval.

69. According to the FDA Briefing Document (at 22), a Type B meeting was conducted on March 26, 2021 "where FDA again expressed concern that insufficient information was provided to determine whether the data from CGCCR are fit-for-purpose for establishment of a robust external comparator and outlined specific deficiencies." At that meeting:

> • FDA agreed to reassess the adequacy of the CGCCR external control after review of information provided in response to those deficiencies but stated that **if ultimately FDA cannot determine if the patient populations are similar enough or if the sample size derived from the external control data is too small to make statistical comparisons, an alternative clinical development program will need to be discussed.**
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> • Additionally, FDA stated that given the uncertainty regarding the interpretability of overall survival results in Study 03-133, a single-arm study, **compelling response data will likely be needed to support the anti-tumor effect of ^{131}I-Omburtamab, even if FDA determines that the data from the CGCCR external control are fit-for-purpose**. [Emphasis in the original.]

70. A further Type B meeting was conducted on June 1, 2021, where the FDA stated that given the complexity of this external control study design and the uncertainty introduced by the retrospective use of historical data to design an external control arm to appropriately isolate the treatment effect as well as multiple prior looks at the data sources,

> • The review of a marketing application supported by the proposed comparative analysis will be based on **FDA's overall assessment of the results of multiple analyses, including analyses of the pre-specified primary and secondary endpoints in addition to sensitivity analyses.**
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> **• FDA's determination regarding whether substantial evidence of effectiveness has been demonstrated will not rely solely on the results of a single analysis** of the primary efficacy endpoint or based on a single population. [Emphasis in the original.]

71. On June 23, 2021, Y-mAbs issued a press release stating that it had recently concluded a Type B meeting with the FDA regarding omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma. The press release stated that "[b]ased on our discussions with the FDA, we believe we now have a clearer path towards the resubmission of the omburtamab BLA to the FDA."

72. Notwithstanding the FDA's continuing skepticism that it would approve omburtamab, defendant Moller reiterated in the June 23, 2021 press release that "We are very pleased to be aligned with the FDA on the next step towards the resubmission of the Omburtamab BLA…."

73. According to the FDA Briefing Document (at 20), at a Type B meeting on September 14, 2021, the "FDA expressed outstanding concerns regarding the datasets, definitions and derivations of the variables. **FDA also stated that they will not be able to rely on a single population or primary analysis and will consider the totality of evidence** from several sensitivity analyses to objectively quantify the treatment effect." Emphasis in the original.

74. On November 5, 2021, Y-mAbs held its November 5, 2021 earnings call for the third quarter of 2021. During opening remarks, Defendant Moller stated:

> Based on feedback from the FDA at a Type B meeting in September, where we provided the FDA with additional detailed data and statistical analysis plan, we have recently requested a pre-BLA meeting. And we believe we are positioned to complete the submission during the course of the first quarter 2022, potentially allowing for FDA approval of Omburtamab in the fourth quarter of 2022. Needless to say, we are very pleased to be aligned with the FDA on the next steps. [Refinitiv Tr. at 4.]

75. Moller's statement on the November 5, 2021 earnings call was materially false and would lead investors to believe Y-mAbs's purported alignment with the FDA would result in

FDA approval the following year.

76. According to the Briefing Document, a pre-BLA Type B meeting was held on January 13, 2022, "to discuss the plan to resubmit BLA 761176 based on the efficacy analyses using a propensity score model to evaluate OS in Study 03-133 compared with the external control group." At that meeting:

> • FDA stated that there was insufficient information to provide agreement on the efficacy package to support the BLA.
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> • FDA stated that the ability to satisfactorily audit the CGCCR external control database for the external control cohort would be a filing issue.
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> • Given the limitations of the external control cohort, FDA also strongly recommended submitting additional response rate data from Study 101 with the initial BLA submission. FDA noted that the assessment of responses in Study 101 appear to be limited by the washout period from prior therapies relative to the timing of the baseline scans, and the timing of onset of response following ^{131}I-Omburtamab, and that data from additional patients may strengthen the argument that there is a direct contribution from ^{131}I-Omburtamab.

77. On February 11, 2022, Y-mAbs issued a press release announcing completion of a pre-BLA meeting with the FDA for Omburtamab. Defendant Gad is quoted stating in the press release that "[w]e are pleased with the outcome of the pre-BLA meeting for Omburtamab providing a clear regulatory path forward for the resubmission of the BLA."

78. Additional reassurances were made by defendant Moller in the February 11, 2022 press release, by stating "We believe that we can resubmit the Omburtamab BLA by the end of the first quarter of 2022. We have been working closely with the agency to get to this point, and we will be applying for full approval. I am very grateful to the FDA and my team for the high-level constructive collaboration that has been exercised to get to this pivotal point."

79. On February 25, 2022, Y-mAbs held their earnings call for the fourth quarter of 2021. Defendant Moller stated:

> We had a pre-BLA meeting with the FDA on January 13, 2022, and we are working closely with the FDA on the resubmission of the Omburtamab BLA.
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> The agency had some final questions regarding access to the audit of historical data from the German database which we use a control group, and we have been working with the doctors responsible for the database to provide clarification on this matter. We are working diligently to meet all requirements for the FDA and expect to resubmit the entire Omburtamab BLA by the end of next month, first quarter 2022.
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> Needless to say we are very pleased to be aligned with the FDA on the next step and believe that if approved, Omburtamab will be a significant benefit to patients with central nervous system/leptomeningeal metastases from neuroblastoma.

80. Notwithstanding the FDA's continuing skepticism on approval, Moller's and Gad's continued reiteration of alignment with the FDA in public statements on February 11 and 25, 2022 falsely led investors to believe Omburtamab was on the path to approval by the FDA in 2022.

81. According to the Briefing Document (at 23), on March 21, 2022, "Y-mAbs agreed to follow up with a proposal for FDA to validate the data in the CGCCR external control dataset based on a potential audit de-identified records. Y-mAbs also agreed to submit details on the specific records that can be made available for validation."

82. On March 25, 2022, according to the Briefing Document, "Y-mAbs provided additional detail regarding the audit process for the CGCCR external control dataset" and "stated they welcomed the opportunity to discuss the proposal in a teleconference the following week."

83. On March 29, 2022, the "FDA thanked Y-mAbs for the response and agreed to follow up within 30 days." *Id.*

84. On March 31, 2022, "Y-mAbs elected to resubmit the BLA prior to reaching agreement with the FDA on the content of the application." *Id.*

85. On April 1, 2022, Y-mAbs issued a press release, stating that the company had

completed the resubmission of its BLA for omburtamab. Defendant Gad was quoted in the press release as stating that "I am excited to see the completion of Y-mAbs' second BLA submission in neuroblastoma."

86. The April 1, 2022 press release failed to disclose that Y-mAbs submitted the BLA "prior to reaching agreement with the FDA on the content of the application."

87. On April 27, 2022, Y-mAbs issued a press release stating that defendant Moller had stepped-down as CEO and that defendant Gad would replace Moller as interim CEO. As part of that transition, defendant Gad would cease being Board Chairman, but would remain a member of the Y-mAbs Board.

88. On May 10, 2022, in introductory remarks for the first quarter 2022 conference call, defendant Gad stated that Y-mAbs "saw a great start to 2022 … notably the resubmission of the BLA for omburtamab in Q1, as promised." Refinitiv Tr. at 2.

89. Defendant Gad added on the call that:

> We are thrilled with our recent resubmission of the omburtamab BLA for the treatment of CNS/leptomeningeal metastases for neuroblastoma. As you might recall, we had the pre-BLA meeting with the FDA in January of this year and confirmed our path towards our March BLA resubmission, which we ultimately achieved. We are hopeful that omburtamab will be approved given the meaningful improvements in overall survival rate, which data has significantly matured with time. [*Id.* at 4.]

90. On May 31, 2022, Y-mAbs issued a press release announcing that the BLA for omburtamab had been accepted for priority review by the FDA. The press release stated that the FDA had set an action date of November 30, 2022 to determine whether to approve the BLA and that the FDA had indicated that it was planning to hold an advisory committee meeting in October 2022 to discuss the application.

91. On August 9, 2022, Y-mAbs held its earnings call for the second quarter of 2022.

Defendant Gad stated on the call (Refinitiv Tr. at 4-5) that "[w]e are optimistic about the potential approval based on meaningful improvement in overall survival rates and unparalleled efficacy in patients with CNS metastases from neuroblastoma."

92. Defendant Rajah, Y-mAbs's Chief Medical Officer, stated on the call (*id.* at 10-11) that:

> [T]he headline news around efficacy concludes that there is a clear benefit -- clinical benefit in terms of response rates and survival with a manageable safety profile. For example, in the 03-133, where, as you know, we looked at the overall survival, progression-free survival and we did an indirect comparison with an external control arm to serve as an appropriate comparator. Preliminary data has shown that the overall survival difference doing the indirect comparison the need in overall survival has a difference of roughly 15 months in the control arm versus 43 months in the actual interventional arm, albeit taking to account these are indirect comparisons.
>
> Moving to the 101 study, where the primary endpoint was response rates. Here, the primary aim is to look at individual patients, looking at response rate at 6 months after initiation of treatment. Here, we have shown certainly in those patients with measurable disease, which is about 20 patients. Roughly 14 patients had a level of disease control, which includes complete response, partial response as well as stable disease.
>
> So I think combined with these 2 studies, we believe that there is clearly a signal of clinical benefit for these patients who really have no alternative treatments, with a very poor prognosis.
>
> * * *
>
> And I should add that all of these points we have been involved in a number of discussions – ongoing discussions with the FDA. And the team are confident we are able to address these, not just the clinical arguments, but also the statistical arguments with a high degree of confidence I should add because I think we are – our case largely of course looks at the data that we have, the 03-122 data is the single largest study in this patient population. And given the fact this is a rare disease in an area of unmet medical need with very poor prognosis we also believe the FDA and the AdCom will look at this as an area where flexibility needs to be applied in making any judgments around risk benefits assessments.
>
> And in their own guidance, they do provide statements where they allow for this flexibility in determining effectiveness of drugs in rare diseases. So that's really what I expect the discussion to go like in the AdCom.

93. Rajah's statements during the earnings call were materially false and created the misleading impression that Y-mAbs had addressed all arguments previously made by the FDA and that the FDA would apply flexibility in determining the effectiveness of omburtamab.

94. On September 1, 2022, after the close of trading, Y-mAbs issued a press release announcing that that the FDA had scheduled a meeting of its Oncologic Drugs Advisory Committee for October 28, 2022. Defendant Gad was quoted in the press release as stating: "This is another key step towards providing a potential treatment for pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma."

95. The true facts were first revealed on October 26, 2022, shortly after the opening of trading, when the FDA publicly released its Briefing Document for the Advisory Committee Meeting.

96. In the Briefing Document, the FDA review team identified three key issues with the application submitted by Y-mAbs: "(1) The external control population is not fit-for-purpose as a comparator due to substantive differences between the study and control populations that limit the ability to attribute survival differences to the effect of Omburtamab; (2) recognizing the level of evidence provided and need for regulatory flexibility, FDA performed additional analyses to examine bias and results reinforce that differences in survival cannot be reliably attributed to Omburtamab; (3) the application does not include reliable response rate data to provide supportive evidence of the treatment effect of Omburtamab."

97. The Briefing Document also brought to light (at 23) Y-mAbs's election to resubmit the BLA on March 31, 2022 prior to reaching agreement with the FDA on the content of the application.

98. An October 26, 2022 Cowen analyst report recognized that Defendants had

previously misrepresented the degree of the FDA's acceptance of Y-mAbs's submissions:

> Given the FDA's document today, it appears as though the Agency continued to have concerns at each meeting and YMAB resubmitted the application "prior to reaching agreement with the FDA on the content of the application with respect to the plan for audit of the external control data and information submitted regarding the type of doses of CS-directed radiation therapy."

99. Y-mAbs's stock price fell $4.16 per share on October 26, 2022 (from $15.17 to $11.01) as a result of the revelations of true facts in the FDA's Briefing Document. Trading volume was extraordinarily high at 2.1 million shares.

100. As news of the FDA's Briefing Document spread, the stock continued its rapid decline. On October 27, 2022, Y-mAbs common stock declined by an additional $2.16 per share on October 27, 2022 (from $11.01 to $8.85). Y-mAbs shares were trading at $8.93 on October 28, 2022 when trading was halted for the AdCom.

101. On Friday, October 28, 2022, after the close of trading, Y-mAbs filed a Form 8-K with the SEC. The Form 8-K informed investors that the AdCom had voted 16 to 0 that Y-mAbs had not provided sufficient evidence to conclude that Omburtamab improved overall survival. The grounds for denial were precisely the same grounds that Y-mAbs was apprised of by the FDA during their 2020 bid for BLA approval as follows:

> These review issues result in a large degree of uncertainty regarding whether the observed differences in overall survival between the Study 03-133 and external control populations are due to Omburtamab or whether they are due to differences in other anticancer treatment, supportive care regimens, unknown differences between the two populations, or a combination of these factors. [Briefing Document at 45]

102. Y-mAbs common stock closed on Monday, October 31, 2022, in the aftermath of disclosure of the true facts occasioned by the release of the Briefing Document and the AdCom hearing and vote, at $3.61.

B. Scienter

103. By virtue of Y-mAbs's meetings with the FDA, Defendants had actual knowledge that the FDA would not approve the BLA for omburtamab without the demonstration of substantial evidence of effectiveness through adequate and well-controlled studies. As summarized by the FDA in its Briefing Document (at 20):

> FDA met with Y-mAbs multiple times to discuss the issues outlined in the RTF letter and to reach agreement on how to address each issue. FDA repeatedly expressed concerns that the CGCCR external control data may not be fit-for-purpose as a direct comparator for the overall survival data from patients in Study 03-133 because the patient populations may not have sufficient comparability for a valid comparison. FDA also repeatedly noted that direct evidence of the anti-tumor effect of ^{131}I-Omburtamab through assessment of overall response rate and duration of response as determined by a blinded independent radiology committee is needed to provide supportive evidence of the effectiveness of ^{131}I-Omburtamab.
>
> On March 31, 2022, Y-mAbs elected to resubmit the BLA prior to reaching agreement with the FDA on the content of the application.

104. Defendants were financially motivated to misrepresent the truth and artificially inflate the market price of Y-mAbs stock. Among other things, during the Class Period, Y-mAbs conducted a secondary offering on February 17, 2021 – selling 2,804,878 million shares of YMAB common stock at $41.00 per share, for gross proceeds of $115 million.

105. From 2019 through the first quarter of 2022, defendant Gad realized gross proceeds of $ $43.0 million from sales of Y-mAbs common stock on the open market. In the first quarter of 2022 alone, Gad realized gross proceeds of $7.0 million from insider sales to satisfy a margin loan.

COUNT 1

Against Defendants for Violation of Sections 10(b) of The Exchange Act and Rule 10b-5 Thereunder

106. Plaintiff incorporates each of the foregoing paragraphs as if fully set forth herein.

107. Defendants participated in a course of conduct involving misrepresentation and concealment of adverse material information about the business of Y-mAbs as specified herein.

108. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of fraudulent conduct as alleged herein in an effort to assure investors of Y-mAbs's progress, which included the making of, or the participation in the making of, untrue statements of material facts and omitting to state material facts necessary in order to make the statement made about Y-mAbs and its business, in light of the circumstances under which they were made, not misleading. This conduct operated as a fraud and deceit upon the purchasers of Y-mAbs common stock during the Class Period.

109. Had Plaintiff and the other members of the Class known of the material adverse information not disclosed by Defendants, or had they been aware of Defendants' material misstatements, they would not have purchased Y-mAbs's common stock at artificially inflated prices.

110. Plaintiff and the Class were injured because the risks that materialized were risks of which they were unaware as a result of Defendants' misrepresentations, omissions and other fraudulent conduct alleged herein. The decline in the price of Y-mAbs's common stock was caused by the public dissemination of the true facts, which were previously concealed or hidden. Absent Defendants' wrongful conduct, Plaintiff and the Class would not have been injured.

111. The price of Y-mAbs common stock declined materially upon public disclosure

of the true facts which had been misrepresented or concealed, as alleged in this complaint. Plaintiff and other members of the Class have suffered substantial damages as a result of the wrongs alleged herein.

112. By reason of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

COUNT 2

Against Defendants Gad and Moller for Violation of Section 20(a) of the Exchange Act

113. Plaintiff incorporates each of the foregoing paragraphs as if fully set forth herein.

114. Defendants Gad and Moller were able to and did control, directly or indirectly, the content of the aforesaid public statements disseminated by Y-mAbs. With knowledge of the falsity of the statements contained therein and in reckless disregard of the true status of the FDA analysis of omburtamab, defendants Gad and Moller caused the complained of misstatements and omissions of material fact as alleged herein, and knowingly or recklessly failed in their duty to update or correct misleading statements issued by them or on their behalf.

115. Defendant Gad had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or acted with reckless disregard for the truth in that he failed to ascertain and disclose such facts, even though such facts were available to him.

116. By virtue of his position as Chief Executive Officer of Y-mAbs during a crucial portion of the Class Period, defendant Moller had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or acted with reckless disregard for the truth in that he failed to ascertain and disclose such facts, even though such facts were available to him.

117. In particular, defendants Gad and Moller had direct involvement in the day-to-day operations of the company and therefore had the power to control or influence the particular

statements giving rise to the securities violations as alleged herein, and exercised the same.

118. As set forth above in Count I, Y-mAbs violated Section 10(b) and Rule 10b-5 promulgated thereunder by its acts and omissions as alleged in this Complaint.

119. As a result of the deceptive practices and false and misleading statements and omissions, the market price of Y-mAbs's common stock was artificially inflated during the Class Period. In ignorance of the false and misleading nature of the representations described above and the deceptive and manipulative devices employed by Defendants, Plaintiff and the other members of the Class, in reliance on either the integrity of the market and/or directly on the statements and reports of Defendants, purchased Y-mAbs's common stock at artificially inflated prices.

120. By virtue of their positions as Chairman (Gad) and Chief Executive Officers of Y-mAbs (Gad and Moller), Gad and Moller are liable for the company's violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, as alleged in Count I, pursuant to Section 20(a) of the Exchange Act.

121. Plaintiff and the other members of the Class have been damaged by the violations as described in this Count and seek recovery for the damages caused thereby.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, on behalf of himself and the other members of the Class, prays for judgment as follows:

1. Declaring this action to be a proper class action maintainable pursuant to Rule 23(b)(3) of the Federal Rules of Civil Procedure and declaring Plaintiff to be a proper Class representative;

2. Awarding Plaintiff and the other members of the Class damages suffered as a

result of the wrongs complained of herein, together with appropriate interest;

3. Awarding Plaintiff and the other members of the Class their costs and expenses of this litigation, including reasonable attorneys' fees and expert fees and other costs and disbursements; and

4. Awarding Plaintiff and the other members of the Class such other and further relief as may be just and proper under the circumstances.

JURY DEMAND

Plaintiff demands a trial by jury for all claims so triable.

Dated:

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