CLASS ACTION COMPLAINT

Plaintiff John Solak ("Plaintiff"), individually and on behalf of all other persons similarly situated, by his undersigned attorneys, for his complaint against defendants, alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, inter alia, the investigation conducted by and through his attorneys, which included, among other things, a review of the defendants’ public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding Sanofi (sometimes referred to as the "Company"), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons other than defendants who purchased Sanofi contingent value rights ("CVRs" or "shares") between March 6, 2012 and November 7, 2013, inclusive (the "Class Period"), seeking to
recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under the Securities Exchange Act of 1934 (the “Exchange Act”).

2. Sanofi is a global pharmaceutical group engaged in the research, development, manufacture and marketing of healthcare products. Sanofi is the fifth largest pharmaceutical group in the world and the third largest pharmaceutical group in Europe. The company operates three main product segments: Pharmaceuticals, Human Vaccines, and Animal Health.

3. Many of the Company’s products are regulated by the United States Food and Drug Administration (“FDA”), which oversees the Company’s compliance with applicable rules and regulates the Company’s covered products such as vaccines and pharmaceuticals.

4. On or around February 16, 2011, Sanofi signed an agreement (the, “Merger Agreement”) to acquire Genzyme Corporation (“Genzyme”) and substantially all of Genzyme’s assets.

5. One of the most important drugs in development by Genzyme at the time of the acquisition was Lemtrada, a treatment for multiple sclerosis (“MS”). Sanofi (and Genzyme as its subsidiary) strongly touted the efficacy and safety of Lemtrada, by directing investors’ attention to two pivotal studies which the Company claimed demonstrated the safety and efficacy of Lemtrada.

6. In connection with the Genzyme acquisition, Sanofi agreed to amend the outstanding tender offer to acquire all of the outstanding shares of common stock of Genzyme (the “Genzyme Shares”) in order to increase the price per share from $69.00 to $74.00 in cash plus one CVR, per Genzyme Share, to be issued by Sanofi, subject to and in accordance with a CVR Agreement.
7. On March 30, 2011, Sanofi and the American Stock Transfer & Trust Company, LLC, as trustee entered into a CVR agreement governed by the laws of the State of New York and subject to the jurisdiction of the courts of the State of New York (the “CVR Agreement”) governing the terms of the CVRs.

8. Pursuant to the terms of the CVR Agreement, a holder of a CVR is entitled to cash payments upon the achievement of certain milestones, including based on U.S. regulatory approval of Lemtrada for treatment of MS, and on achievement of certain aggregate Lemtrada sales thresholds. The CVR Agreement set forth, in relevant part:

   Approval Milestone Payment. $1 per CVR upon receipt by Genzyme or any of its affiliates, on or before March 31, 2014, of the approval by the U.S. Food and Drug Administration of Lemtrada™ for treatment of multiple sclerosis.

   Product Sales Milestone #1 Payment. $2 per CVR if Lemtrada™ net sales post launch exceeds an aggregate of $400 million within specified periods and territories.

   Product Sales Milestone #2 Payment. $3 per CVR upon the first instance in which global Lemtrada™ net sales for a four calendar quarter period are equal to or in excess of $1.8 billion. If Product Sales Milestone #2 is achieved but the Approval Milestone was not achieved prior to March 31, 2014, the milestone payment amount will be $4 per CVR (however, in such event the Approval Milestone shall not also be payable).

   Product Sales Milestone #3 Payment. $4 per CVR upon the first instance in which global Lemtrada™ net sales for a four calendar quarter period are equal to or in excess of $2.3 billion (no quarter in which global Lemtrada™ net sales were used to determine the achievement of Product Sales Milestone #1 or #2 shall be included in the calculation of sales for determining whether Product Sales Milestone #3 has been achieved).

9. Throughout the Class Period, Defendants misrepresented to investors the efficacy and safety of the Company’s MS drug Lemtrada. The Company also misled investors regarding the design of its two Lemtrada pivotal trials, the 323 and 324 trials, specifically failing to
disclose that the trials contained high levels of placebo effect and observer bias which tainted the results, and thereby lowered the likelihood of approval of Lemtrada by the FDA.

10. On November 8, 2013, the FDA Advisory Committee on Peripheral and Central Nervous System Drugs issued a briefing report (the “Briefing Report”) in advance of its November 13, 2013 hearing. The Briefing Report sharply criticized the Company’s submission to the FDA, and found that “significant concerns exist regarding the safety profile of alemtuzumab [Lemtrada] and the adequacy of the efficacy data.”

11. The Briefing Report further disclosed the following concerns:

Dr. Mentari’s review discusses numerous safety concerns associated with the use of alemtuzumab for MS. These include the incidence of an array of autoimmune diseases including immune thrombocytopenia (ITP), autoimmune hemolytic anemia, immune pancytopenia, anti-glomerular basement membrane (Anti-GBM) disease, membranous glomerulonephritis, thyroid disorders, endocrine ophthalmopathy, acquired hemophilia A, type I diabetes mellitus, acute epitheliopathy of the retina, autoimmune skin disease, and undifferentiated connective tissue disorders, along with the incidence of malignancies, notably including thyroid cancer and melanoma. As these concerns are serious and potentially fatal, Dr. Mentari does not recommend approval of alemtuzumab unless substantial clinical benefit exists.

Dr. Marler’s review discusses various concerns associated with the data presented by the applicant in support of a demonstration of clinical benefit. These stem from issues involved with the adequacy of the design of the primary trials on which the application relies for support. In particular, Dr. Marler has grave concerns that the failure to blind patients and treating physicians in the open-label design of the trials introduced bias that confounds interpretation of their ostensible results. Because of these issues, Dr. Marler finds that the applicant has not submitted evidence from adequate and well-controlled studies to support the effectiveness of alemtuzumab for treating multiple sclerosis.

Dr. Yan’s review discusses the statistical aspects of the data presented by the applicant in support of a demonstration of clinical benefit, and largely reinforces the concerns of Dr. Marler. Dr. Yan also feels that troublesome design issues and the presence of bias
in the trials prevents reliance on their results, and that a valid, accurate, and interpretable effect on the two main clinical outcomes of interest, relapse rate and sustained accumulation of disability, has not been established. Dr. Yan finds, like Dr. Marler, that the applicant has not provided evidence from adequate and well-controlled studies in this application and that such studies still need to be conducted to establish the effectiveness of alemtuzumab for the treatment of patients with multiple sclerosis.

12. On this news, Sanofi’s CVRs declined $1.23 per share, or nearly 62%, to close at $0.77 per share on November 8, 2013 on volume of over 30 million shares.

13. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s CVRs, Plaintiff and other Class members have suffered significant damages.

JURISDICTION AND VENUE

14. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R § 240.10b-5.

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

16. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). Sanofi’s CVRs are traded in this District and many of the acts and practices complained of occurred in substantial part herein.

17. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.
PARTIES

18. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Sanofi CVRs at artificially inflated prices during the Class Period and was damaged thereby.

19. Defendant Sanofi is a French corporation maintaining its principal place of business at 54 Rue La Boetie, 75008 Paris, France. Sanofi's CVRs trade on the NASDAQ Global Market (“NASDAQ”) under the ticker symbol “GCVRZ.”

20. Defendant Christopher A. Viehbacher (“Viehbacher”) was, at all relevant times, the Company’s Chief Executive Officer (“CEO”).

21. Defendant David Meeker (“Meeker”) was, at all relevant times, the President and CEO of Genzyme.

22. Defendant Jerome Contamine (“Contamine”) was, at all relevant times, the Company’s Executive Vice President and Chief Financial Officer (“CFO”).

23. Defendants Viehbacher, Meeker and Contamine are referred to herein as the “Individual Defendants.”

SUBSTANTIVE ALLEGATIONS

BACKGROUND

24. Sanofi is a global pharmaceutical group engaged in the research, development, manufacturing and marketing of healthcare products. Sanofi is the fifth largest pharmaceutical group in the world and the third largest pharmaceutical group in Europe. The Company operates three main product segments: Pharmaceuticals, Human Vaccines, and Animal Health.

25. On or around February 16, 2011, Sanofi signed the Merger Agreement to acquire Genzyme and substantially all of Genzyme’s assets.
26. One of the most important drugs in development by Genzyme at the time of the acquisition was Lemtrada, a treatment for MS. Sanofi (and Genzyme as its subsidiary) strongly touted the efficacy and safety of Lemtrada by directing investors' attention to two pivotal studies that the Company claimed demonstrated the safety and efficacy of Lemtrada.

27. In connection with the Genzyme acquisition, Sanofi agreed to amend the outstanding tender offer to acquire all of the outstanding Genzyme Shares in order to increase the price per share from $69.00 to $74.00 in cash plus one CVR, per Genzyme Share, to be issued by Sanofi, subject to and in accordance with a CVR Agreement.

28. On March 30, 2011, Sanofi and the American Stock Transfer & Trust Company, LLC, as trustee entered into the CVR Agreement, governed by the laws of the State of New York and subject to the jurisdiction of the courts of the State of New York, governing the terms of the CVRs.

29. Pursuant to the terms of the CVR Agreement, a holder of a CVR is entitled to cash payments upon the achievement of certain milestones, including based on U.S. regulatory approval of Lemtrada for treatment of MS, and on achievement of certain aggregate Lemtrada sales thresholds. The CVR Agreement set forth, in relevant part:

Approval Milestone Payment. $1 per CVR upon receipt by Genzyme or any of its affiliates, on or before March 31, 2014, of the approval by the U.S. Food and Drug Administration of Lemtrada™ for treatment of multiple sclerosis.

Product Sales Milestone #1 Payment. $2 per CVR if Lemtrada™ net sales post launch exceeds an aggregate of $400 million within specified periods and territories.

Product Sales Milestone #2 Payment. $3 per CVR upon the first instance in which global Lemtrada™ net sales for a four calendar quarter period are equal to or in excess of $1.8 billion. If Product Sales Milestone #2 is achieved but the Approval Milestone was not achieved prior to March 31, 2014, the milestone payment amount will be $4 per CVR (however, in such event the Approval Milestone shall not also be payable).
Product Sales Milestone #3 Payment. $4 per CVR upon the first instance in which global Lemtrada™ net sales for a four calendar quarter period are equal to or in excess of $2.3 billion (no quarter in which global Lemtrada™ net sales were used to determine the achievement of Product Sales Milestone #1 or #2 shall be included in the calculation of sales for determining whether Product Sales Milestone #3 has been achieved).

MATERIALLY FALSE AND MISLEADING STATEMENTS MADE DURING THE CLASS PERIOD

30. The Class Period begins on March 6, 2012. On this day, Sanofi filed with the SEC an annual report on Form 20-F. The Form 20-F was signed by Defendant Viehbacher, and set forth the following, in relevant part:

Main compounds currently in Phase II or III clinical development:
In the Multiple Sclerosis field:

* * *

Alemtuzumab (Lemtrada™) — Humanized monoclonal antibody targeting CD52 antigen abundant on the surface of B and T lymphocytes leading to changes in the circulating lymphocyte pool.

Alemtuzumab targets patients with relapsing forms of Multiple Sclerosis (MS). The two Phase III studies demonstrating the safety and efficacy of alemtuzumab were completed in 2011. The first study, CARE-MS I, demonstrated strong and robust treatment effect on the relapse rate co-primary endpoint vs Rebif. The co-primary endpoint of disability progression (time to sustained accumulation of disability SAD) did not meet statistical significance. The second study, CARE-MS II, demonstrated that relapse rate and SAD were significantly reduced in MS patients receiving alemtuzumab as compared with Rebif. In both cases, safety results were consistent with previous alemtuzumab use in MS and adverse events continued to be manageable. The dossier is scheduled to be submitted to FDA review in the second quarter of 2012.

* * *

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a — 15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2011 based on the framework in “Internal Control — Integrated Framework” issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that assessment, management has concluded that the Company’s internal control over financial reporting was effective as of December 31, 2011 to provide reasonable assurance regarding the reliability of its financial reporting.
and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles.

There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

31. On April 24, 2012, the Company issued a press release reporting on data from the Phase III CARE-MS II trial. In that press release, Sanofi reported that Lemtrada significantly slowed disabilities in patients with MS. The press release set forth, in relevant part:

Accumulation of disability was significantly slowed in patients with multiple sclerosis (MS) who were treated with alemtuzumab versus Rebif® (high dose subcutaneous interferon beta-1a), as measured by the Expanded Disability Status Scale (EDSS), a standard assessment of physical disability progression. In addition, significant improvement in disability scores was observed in some patients treated with alemtuzumab from baseline and compared to patients treated with Rebif, suggesting a reversal of disability in these patients. In the trial, patients with pre-existing disability treated with alemtuzumab were more than twice as likely to experience a sustained reduction in disability than patients given Rebif.

CARE-MS II was a randomized Phase III clinical trial comparing the investigational drug alemtuzumab to Rebif in patients with relapsing-remitting multiple sclerosis (RRMS) who had relapsed while on prior therapy. The company announced in November that results for the co-primary endpoints of the trial were highly statistically significant.

Key disability data from the CARE-MS II trial presented today at the 64th Annual Meeting of the American Academy of Neurology include:

- The mean EDSS score for patients treated with alemtuzumab decreased over a two-year period, indicating an improvement in their physical disability, while the mean score for patients given Rebif increased, indicating a worsening of disability (-0.17 vs. 0.24; p < 0.0001).
- At two years, 29 percent of patients treated with alemtuzumab had experienced a six-month sustained reduction in disability, meaning their level of disability
improved, as compared to only 13 percent with Rebif (p=0.0002).

- There was a 42 percent reduction in the risk of six-month sustained accumulation (worsening) of disability (SAD) as measured by EDSS in patients treated with alemtuzumab compared to Rebif over two years of study (p=0.0084), as previously reported. This was a highly statistically significant result for this co-primary endpoint.

Key relapse data from the trial presented at AAN include:

- 65 percent of patients treated with alemtuzumab were relapse-free at two years, meaning they did not experience any relapses in the trial, compared to 47 percent with Rebif (47 percent risk reduction; p<0.0001).
- A 49 percent reduction in relapse rate was observed in patients treated with alemtuzumab 12 mg compared to Rebif over two years of study (p<0.0001), a highly significant result for this co-primary endpoint, as previously reported.

In the CARE-MS II trial, alemtuzumab 12 mg was given as an IV administration a total of eight times over the course of the two-year study. The first treatment course of alemtuzumab was administered on five consecutive days, and the second course was administered on three consecutive days 12 months later. Rebif 44 mcg was administered by subcutaneous injection three times per week, each week, throughout the two years of study.

"Alemtuzumab is the first disease modifying therapy to show a significant effect both on relapse and disability endpoints over and above those of Rebif in a comparative trial," said Professor Alastair Compston, Chair of the Steering Committee overseeing the conduct of the study, principal investigator on the phase II and III clinical trials of alemtuzumab, and Head of the Department of Clinical Neurosciences at the University of Cambridge, United Kingdom. "The efficacy data from the CARE-MS trial program suggest that, if approved, alemtuzumab will be an important new treatment for relapsing MS patients with active disease."

Additional new data from the CARE-MS II study suggest that alemtuzumab provided significant improvement over Rebif across a number of imaging endpoints, consistent with the effects observed in the clinical endpoints. In MS, imaging can be used to track the development of lesions, or patches of inflammation in the central nervous system (CNS). Statistically significant
improvement was observed for alemtuzumab over Rebif in the percentage of patients with new or enlarging T2-hyperintense lesions (46 vs. 68; \( p<0.0001 \)) and with gadolinium-enhancing lesions (19 vs. 34; \( p<0.0001 \)). The change in T2-hyperintense lesion volume from baseline to year two, a secondary endpoint, was not significantly different (\( p=0.14 \)). In the trial, patients treated with alemtuzumab experienced less change in brain parenchymal fraction (BPF), a measure of brain atrophy or loss of neurons and the connections between them, compared to Rebif (-0.62 vs. -0.81) median percent change from baseline (\( p=0.012 \)), a significant result.

"We believe these ground-breaking results from CARE-MS II, including reversal of disability accumulation in some patients, achieved over the standard therapy Rebif, provide a message of hope for people living with MS," said David Meeker, M.D., President and CEO, Genzyme. "We are on track to submit alemtuzumab for review to U.S. and EU regulatory authorities in the second quarter of this year and are excited about the potential of bringing this important therapy to people living with MS who have unmet treatment needs."

The most common adverse events associated with alemtuzumab in the CARE-MS II study were infusion-associated reactions, which were generally mild to moderate. Infections were common in both groups, with a higher incidence in the alemtuzumab group. The most common infections included upper respiratory and urinary tract infections, cutaneous fungal infections and oral herpes. Serious infections occurred in 3.7 percent of the alemtuzumab group as compared to 1.5 percent of the Rebif group. Infections were predominantly mild to moderate in severity and none were fatal. [Emphasis added.]

32. On June 12, 2012, the Company issued a press release announcing that Sanofi had submitted a supplemental Biologics License Application (sBLA) to the FDA seeking approval of Lemtrada for treatment of relapsing MS. The press release, entitled "Genzyme Submits Applications to FDA and EMA for Approval of LEMTRADA™ (alemtuzumab) for Multiple Sclerosis," set forth, in relevant part:

Genzyme’s clinical development program for LEMTRADA included two Phase III studies in which results for LEMTRADA were superior to Rebif® (high dose subcutaneous interferon beta-
la) on clinical and imaging endpoints, including a reduction in relapse rate. In addition, as presented last month at the American Academy of Neurology meeting, some patients with preexisting disability treated with LEMTRADA in the CARE-MS II trial were more than twice as likely to experience a sustained reduction in disability over two years than patients treated with Rebif.

"There remains a large unmet treatment need for patients living with active disease and we believe that LEMTRADA, given its efficacy and unique dosing schedule, has the potential to transform the lives of patients with Multiple Sclerosis," said David Meeker, M.D., President and Chief Executive Officer, Genzyme.

The regulatory submissions for LEMTRADA include two-year controlled efficacy and safety data from both treatment-naive patients and those who relapsed while on therapy, with greater than five years of safety follow-up. Common adverse events associated with alemtuzumab were consistent across the Phase III program and included infusion-associated reactions and infections, which were generally mild to moderate in severity. Autoimmune adverse events were observed in some patients with cases being detected early through a monitoring program and managed using conventional therapies. [Emphasis added.]

33. On October 31, 2012, the Company issued a press release entitled “Genzyme Announces Publication of LEMTRADA (alemtuzumab) Pivotal Studies in The Lancet.” This press release announced clinical results from the Lemtrada CARE-MS I and CARE-MS II pivotal studies in patients with relapsing-remitting MS. The Company stated that Lemtrada was significantly more effective at reducing annualized relapse rates than the active comparator Rebif, and more patients on Lemtrada were relapse-free at two years.

34. On January 28, 2013, the Company issued a press release entitled “Genzyme’s LEMTRADATM (alemtuzumab) Application for MS Accepted for Review by the FDA,” which announced that the FDA had accepted the Company’s sBLA file seeking approval of Lemtrada.
35. On or about March 7, 2013, the Company filed with the SEC an Annual Report on Form 20-F. The Form 20-F was signed by Defendant Viehbacher, and stated the following, in relevant part:

The main compound currently in Phase III clinical development in the multiple sclerosis field is Lemtrada (alemtuzumab), a humanized monoclonal antibody targeting CD52 antigen abundant on the surface of B and T lymphocytes leading to changes in the circulating lymphocyte pool. Alemtuzumab has been developed to treat patients with relapsing forms of MS. The two pivotal Phase III studies demonstrating the safety and efficacy of alemtuzumab were completed in 2011 and the results were published in the Lancet in November 2012. The first study, CARE-MS I, demonstrated strong and robust treatment effect on the relapse rate co-primary endpoint vs Rebif in treatment-naive MS patients. The co-primary endpoint of disability progression (time to sustained accumulation of disability: SAD) did not meet statistical significance. The second study, CARE-MS II, demonstrated that relapse rate and SAD were significantly reduced in MS patients receiving alemtuzumab as compared with Rebif in MS patients who had relapsed on prior therapy. Results from CARE-MS II also showed that patients treated with Lemtrada were significantly more likely to experience improvement in disability scores than those treated with Rebif, suggesting a reversal of disability in some patients. In both pivotal studies, safety results were consistent with previous alemtuzumab use in MS and adverse events continued to be manageable. Marketing applications for Lemtrada are currently under review by regulatory authorities.

* * *

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of December 31, 2012 based on the framework in “Internal Control — Integrated Framework” issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on that assessment, management has concluded that the Company’s internal control over financial reporting was effective as of December 31, 2012 to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles. . . .

There were no changes to our internal control over financial reporting that occurred during the period covered by this Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

36. On March 21, 2013, the Company issued a press release entitled “Effect of Genzyme’s LEMTRADA Maintained in Patients Beyond Two-Year Pivotal MS Studies,” which
announced interim results from the first year extensions study of Lemtrada. Therein, the Company reported, in relevant part:

In this analysis of the first year of the extension study, relapse rates and sustained accumulation of disability remained low among patients who had previously received Lemtrada in either of the Phase III CARE-MS I or CARE-MS II studies. In these pivotal studies, Lemtrada was given as two annual courses, at the start of the study and 12 months later. More than 80 percent of patients did not receive further treatment with Lemtrada during the first year of the extension study.

“These findings are important because they suggest that the benefits of Lemtrada as observed in the Phase III studies are maintained, even though most patients did not receive further dosing,” said Edward Fox, M.D., Director of the Multiple Sclerosis Clinic of Central Texas, who presented the study results today at the annual meeting of the American Academy of Neurology in San Diego, Calif.

The Phase III trials of Lemtrada were randomized, two-year pivotal studies comparing treatment with Lemtrada to Rebif (subcutaneous interferon beta-1a 44 mcg) in patients with relapsing-remitting MS who were either new to treatment (CARE-MS I) or who had relapsed while on prior therapy (CARE-MS II).

More than 90 percent of the patients who participated in the Phase III pivotal trials enrolled in the extension study. Patients who originally received Lemtrada were eligible to receive additional treatment in the extension study if they experienced at least one relapse or at least two new or enlarging brain or spinal lesions.

These interim results are from the first year of the extension study for patients who previously received Lemtrada in the two-year studies. Findings stated below are based on patients who enrolled in the extension study:

- More than half of patients (67 percent in CARE-MS I and 55 percent in CARE-MS II) who received Lemtrada in the pivotal trials and enrolled in the extension study were still relapse-free through the first year of the extension study.
In the first year of the extension phase, the annualized relapse rate for patients who received LEMTRADA in the pivotal trials was 0.24 and 0.25, comparable to the annualized relapse rate for those patients in CARE MS I and CARE-MS II, respectively.

Through year three, 72.4 percent of patients in CARE MS I and 70.0 percent in CARE MS II had improved or stable disability as measured by EDSS.

At three years, 88 percent and 80 percent of patients who received LEMTRADA in the pivotal trials, respectively, did not experience six-month confirmed sustained accumulation of disability.

"These results underscore the tremendous promise that LEMTRADA holds for MS patients," said David Meeker, M.D., Genzyme’s President and Chief Executive Officer. "We’re pleased to be able to present these three-year results that provide us with important new information about LEMTRADA and are consistent with the published results from our Phase II extension study."

Safety results from the first year of the extension study were reported for patients who received LEMTRADA in the Phase III pivotal studies. No new risks were identified. The frequency and type of common and serious adverse events in the first year of the extension study were generally similar to those in the Phase III pivotal studies. The most common adverse events during this period of time were infections, including predominantly mild to moderate upper respiratory and urinary tract infections.

There were two deaths. One, as previously reported, was from sepsis. The other was presumed accidental and deemed unrelated to study treatment. The cumulative incidence of autoimmune thyroid disease over three years was 29.9 percent, as expected based on the Phase II study experience.

Additionally, over three years, approximately 1 percent of patients developed immune thrombocytopenia (ITP) and 0.3 percent developed nephropathy, all of whom responded to treatment.

These cases were detected early through routine monitoring. Patient monitoring for autoimmune disorders is incorporated in all Genzyme-sponsored trials of LEMTRADA. [Emphasis added.]
37. The statements contained in §§ 30-36 were materially false and misleading at the time they were made because Defendants misrepresented and/or failed to disclose the following adverse facts, which were known to Defendants or recklessly disregarded by them:

(a) that Defendants had materially misrepresented the safety and efficacy of Lemtrada in statements to investors and the public;

(b) that the design of the Lemtrada 323 and 324 trials had been materially misrepresented to investors and the public, with Defendants failing to disclose that the trials contained high levels of placebo effect and observer bias, which tainted the results and thereby lowered the likelihood of Lemtrada approval by the FDA;

(c) that the Company lacked adequate internal controls; and

(d) that as a result of the foregoing, Defendants lacked a reasonable basis for their positive statements about Lemtrada and its prospects.

THE TRUTH IS REVEALED

38. On November 8, 2013, the FDA Advisory Committee on Peripheral and Central Nervous System Drugs issued the Briefing Report in advance of its November 13, 2013 hearing. The Briefing Report sharply criticized the Company’s submission to the FDA, and found that, “significant concerns exist regarding the safety profile of alemtuzumab [Lemtrada] and the adequacy of the efficacy data.”

39. The Briefing Report further disclosed the following concerns:

Dr. Mentari’s review discusses numerous safety concerns associated with the use of alemtuzumab for MS. These include the incidence of an array of autoimmune diseases including immune thrombocytopenia (ITP), autoimmune hemolytic anemia, immune pancytopenia, anti-glomerular basement membrane (Anti-GBM) disease, membranous
glomerulonephritis, thyroid disorders, endocrine ophthalmopathy, acquired hemophilia A, type 1 diabetes mellitus, acute epitheliopathy of the retina, autoimmune skin disease, and undifferentiated connective tissue disorders, along with the incidence of malignancies, notably including thyroid cancer and melanoma. As these concerns are serious and potentially fatal, Dr. Mentari does not recommend approval of alemtuzumab unless substantial clinical benefit exists.

Dr. Marler’s review discusses various concerns associated with the data presented by the applicant in support of a demonstration of clinical benefit. These stem from issues involved with the adequacy of the design of the primary trials on which the application relies for support. In particular, Dr. Marler has grave concerns that the failure to blind patients and treating physicians in the open-label design of the trials introduced bias that confounds interpretation of their ostensible results. Because of these issues, Dr. Marler finds that the applicant has not submitted evidence from adequate and well-controlled studies to support the effectiveness of alemtuzumab for treating multiple sclerosis.

Dr. Yan’s review discusses the statistical aspects of the data presented by the applicant in support of a demonstration of clinical benefit, and largely reinforces the concerns of Dr. Marler. Dr. Yan also feels that troublesome design issues and the presence of bias in the trials prevents reliance on their results, and that a valid, accurate, and interpretable effect on the two main clinical outcomes of interest, relapse rate and sustained accumulation of disability, has not been established. Dr. Yan finds, like Dr. Marler, that the applicant has not provided evidence from adequate and well-controlled studies in this application and that such studies still need to be conducted to establish the effectiveness of alemtuzumab for the treatment of patients with multiple sclerosis. [Emphasis added.]

40. On this news, Sanofi’s CVRs declined $1.23 per share, or nearly 62%, to close at $0.77 per share on November 8, 2013 on volume of over 30 million shares.

41. On November 14, 2013, The Boston Globe published an article entitled “Genzyme MS Drug Gets Mixed Review.” This article revealed, in relevant part:

A panel of medical specialists convened to advise US regulators concluded Wednesday that safety concerns about Genzyme’s much-anticipated multiple
sclerosis drug don’t mean it can’t be approved for sale to patients who have tried other MS treatments.

But the Food and Drug Administration advisory committee also said the clinical trials of Genzyme’s drug, called Lemtrada, were flawed. That raised the question of whether the FDA will sign off on a medicine that — while eagerly awaited by many patients — underwent clinical studies deemed inadequate.

The advisory panel, in a daylong meeting in Silver Spring, Md., peppered representatives of Cambridge-based Genzyme and the FDA with questions about an FDA staff report that suggested Lemtrada may be too dangerous to approve because data linked it to side effects such as rashes and bleeding and a higher long-term risk of thyroid cancer.

In the end, the panel took a series of seemingly contradictory votes that generated as much confusion as guidance. The advisers, by an 11-to-6 vote, accepted the view of FDA staffers that there was “bias” in Genzyme’s clinical trials because the company didn’t keep patients from knowing whether they were taking Lemtrada or another drug.

“We indicated our discomfort with the clinical trial as designed,” Dr. Billy Dunn, acting deputy director of the FDA’s Division of Neurology Products, told the advisers.

But the committee, through a 12-to-6 vote, said Genzyme provided substantial evidence that Lemtrada worked for patients with relapsing MS, a potentially debilitating autoimmune disease that affects the brain and central nervous system of an estimated 400,000 people in the United States and 2.5 million worldwide.

By a 17-to-0 vote, the panel concluded that Lemtrada’s safety concerns shouldn’t preclude its approval for patients for whom other drugs aren’t effective. At the same time, it voted 16-to-0 that Genzyme’s drug should not be allowed for sale in the United States as a so-called first-line treatment for newly diagnosed MS patients. (Members of the panel abstained from some votes.)

While the panel pored over evidence from clinical trials, it also heard from MS patients, some of whom had taken Lemtrada in trials and testified it had been safe and effective. Panelists also heard from patient advocates, who noted other approved medicines also carry safety risks.

“If one of your family members had MS, wouldn’t you want them to have a choice?” said Melissa Burdick. “We, as patients, deserve the right to have a choice of therapy.”

While saying the data didn’t justify Lemtrada’s approval as a first-line therapy, panel member Dr. Robert R. Clancy, professor of neurology and pediatrics at the
University of Pennsylvania School of Medicine, agreed patients should have the right to make decisions about the risks and benefits of Lemtrada in consultation with their doctors. “There are individuals who know what their own circumstances are (and) . . . are willing to roll the dice,” he said.

Unlike other MS treatments, Lemtrada is administered intravenously for five days the first year of use, and for three days the next year. After that, many patients no longer need treatments for years, according to Genzyme’s clinical studies. The drug, which played a pivotal role in Genzyme’s acquisition in 2011 by French drug maker Sanofi SA, was approved by European regulators in September for both new patients and those who have taken other drugs.

Shares of Sanofi dipped and rose by a fraction in after-hours trading on the New York Stock Exchange, reflecting investor confusion over Lemtrada’s fate. The drug had been expected to compete with treatments such as Tysabri, made by Weston-based Biogen Idec Inc., in an MS market estimated at as much as $13 billion annually.

FDA spokeswoman Tara Goodlin said the agency doesn’t disclose when it might take action on a drug application. But she stressed the FDA isn’t bound by advisory panel votes.

“The advisory committee provides advice to the FDA,” she said. “We take the committee’s advice into consideration when reviewing an application, but the ultimate decision lies with the FDA.” [Emphasis added.]

**ADDITIONAL SCIENTER ALLEGATIONS**

42. As alleged herein, Defendants acted with *scienter* in that Defendants knew, or recklessly disregarded, that the public documents and statements they issued and disseminated to the investing public in the name of the Company or in their own name during the Class Period were materially false and misleading. Defendants knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements and documents as primary violations of the federal securities laws. Defendants, by virtue of their receipt of information reflecting the true facts regarding Sanofi, and their control over, and/or receipt and/or modification of, Sanofi’s and/or its subsidiaries’ allegedly materially misleading misstatements, were active and culpable participants in the fraudulent scheme alleged herein.
43. Defendants knew and/or recklessly disregarded the false and misleading nature of the information which they caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and complicity or, at least, the reckless disregard of personnel at the highest levels of the Company, including the Individual Defendants.

44. The Individual Defendants, because of their positions with Sanofi and/or its subsidiaries, controlled the contents of the Company’s public statements during the Class Period. Each defendant was provided with or had access to copies of the documents alleged herein to be false and/or misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, these defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations that were being made were false and misleading. As a result, each of these defendants is responsible for the accuracy of Sanofi’s corporate statements and is therefore responsible and liable for the representations contained therein.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

45. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired Sanofi CVRs during the Class Period (the “Class”) and were damaged thereby. Excluded from the Class are defendants herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.
46. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Sanofi CVRs were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Sanofi or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

47. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

48. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

49. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by defendants' acts as alleged herein;
- whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Sanofi;
- whether the Individual Defendants caused Sanofi to issue false and misleading financial statements during the Class Period;
- whether defendants acted knowingly or recklessly in issuing false and misleading financial statements;
• whether the prices of Sanofi CVRs during the Class Period were artificially inflated because of the defendants’ conduct complained of herein; and

• whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

50. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

51. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

• defendants made public misrepresentations or failed to disclose material facts during the Class Period;

• the omissions and misrepresentations were material;

• Sanofi CVRs are traded in efficient markets;

• the Company’s CVRs were liquid and traded with moderate to heavy volume during the Class Period;

• the Company traded on the NASDAQ, and was covered by multiple analysts;

• the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company’s CVRs; and

• Plaintiff and members of the Class purchased and/or sold Sanofi CVRs between the time the defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

52. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.
LOSS CAUSATION/ECONOMIC LOSS

53. During the Class Period, as detailed herein, Defendants made false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of Sanofi’s CVRs and operated as a fraud or deceit on Class Period purchasers of Sanofi’s CVRs by misrepresenting the safety and efficacy of Lemtrada, as well as the design of the clinical trials. As Defendants’ misrepresentations and fraudulent conduct became apparent to the market, the price of Sanofi’s CVRs fell precipitously, as the prior artificial inflation came out of the price. As a result of their purchases of Sanofi’s CVRs during the Class Period, plaintiff and other members of the Class suffered economic loss, i.e., damages, under the federal securities laws.

COUNT I

(Against All Defendants For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder)

54. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

55. This Count is asserted against defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

56. During the Class Period, defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to,
and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Sanofi CVRs; and (iii) cause Plaintiff and other members of the Class to purchase Sanofi CVRs at artificially inflated prices. In furtherance of this unlawful scheme, plan and course of conduct, defendants, and each of them, took the actions set forth herein.

57. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Sanofi CVRs. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about Sanofi’s finances and business prospects.

58. By virtue of their positions at Sanofi, defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to defendants. Said acts and omissions of defendants were committed willfully or with reckless disregard for the truth. In addition, each defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

59. Information showing that defendants acted knowingly or with reckless disregard for the truth is peculiarly within defendants’ knowledge and control. As the senior managers and/or
directors of Sanofi, the Individual Defendants had knowledge of the details of Sanofi’s internal affairs.

60. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Sanofi. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to Sanofi’s businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Sanofi CVRs was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Sanofi’s business and financial condition, which were concealed by defendants, Plaintiff and the other members of the Class purchased Sanofi CVRs at artificially inflated prices and relied upon the price of the CVRs, the integrity of the market for the CVRs and/or upon statements disseminated by defendants, and were damaged thereby.

61. During the Class Period, Sanofi CVRs were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased Sanofi CVRs at prices artificially inflated by defendants’ wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased said CVRs or would not have purchased them at the inflated prices that were paid. At the time of the purchases by Plaintiff and the Class, the true value of Sanofi CVRs was substantially lower than the prices paid by Plaintiff and the
other members of the Class. The market price of Sanofi CVRs declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

62. By reason of the conduct alleged herein, defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

63. As a direct and proximate result of defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's CVRs during the Class Period, upon the disclosure that the Company had disseminated false financial statements to the investing public related to its prospects for FDA approval.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against The Individual Defendants)

64. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

65. During the Class Period, the Individual Defendants participated in the operation and management of Sanofi, and conducted and participated, directly and indirectly, in the conduct of Sanofi's business affairs. Because of their senior positions, they knew the adverse non-public information regarding Sanofi.

66. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Sanofi's financial condition and results of operations, and to correct promptly any public statements issued by Sanofi which had become materially false or misleading.
67. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which Sanofi disseminated in the marketplace during the Class Period concerning Sanofi's financial prospects. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Sanofi to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Sanofi within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of Sanofi CVRs.

68. Each of the Individual Defendants, therefore, acted as a controlling person of Sanofi. By reason of their senior management positions and/or being directors of Sanofi, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Sanofi to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of Sanofi and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

69. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Sanofi.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;
C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: December 11, 2013

Harwood Feffer LLP

By: 

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Telephone: (484) 588-5516
Facsimile: (484) 450-2582

Counsel for Plaintiff
CERTIFICATION

I, John Solak, ("Plaintiff") declare, as to the claims asserted under the federal securities laws that

1. Plaintiff has reviewed the complaint and authorizes its filing.

2. Plaintiff did not purchase the security that is the subject of this action at the direction of Plaintiff’s counsel or in order to participate in any private action.

3. Plaintiff is willing to serve as a representative party on behalf of the class, either individually or as part of a group, including providing testimony at deposition or trial, if necessary. I understand that this is not a claim form, and that my ability to share in any recovery as a member of the class is not dependent upon execution of this Plaintiff Certification.

4. Plaintiff’s purchase and sale transaction(s) in the Sanofi (NASDAQ: GCVRZ) security that is the subject of this action during the Class Period is/are as follows:

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(Please list additional purchase and sale information on a separate sheet of paper, if necessary)

5. Plaintiff has complete authority to bring a suit to recover for investment losses on behalf of purchasers of the subject securities described herein (including Plaintiff, any co-owners, any corporations or other entities, and/or any beneficial owners).

6. During the three years prior to the date of this Certification, Plaintiff has not sought to serve or served as a representative party for a class in an action filed under the federal securities laws, except as described below_________________________________.

7. Plaintiff will not accept any payment for serving as a representative party on behalf of the class beyond Plaintiff’s pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the class as ordered or approved by the court.

I declare under penalty of perjury that the foregoing is true and correct.

Executed this 27th day of November, 2013.

John Solak
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