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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

BROOKE ABRAMS, On Behalf of ) No.  
Herself and All Others Similarly )  
Situated, ) COMPLAINT FOR VIOLATION OF  
 ) THE FEDERAL SECURITIES LAWS  
Plaintiff, )  
 )  
vs. )  
 )  
NOVARTIS AG, DANIEL VASELLA, )  
RAYMUND BREU, THOMAS )  
EBELING, PAUL HERRLING and )  
JAMES S. SHANNON, )  
 )  
Defendants. )  
 )  
\_\_\_\_\_ ) DEMAND FOR JURY TRIAL

## **INTRODUCTION AND OVERVIEW**

1. This is a class action for violations of the anti-fraud provisions of the federal securities laws on behalf of all purchasers of Novartis AG (“Novartis” or “the Company”) publicly traded securities between June 14, 2006 and July 17, 2007 (the “Class Period”), who were damaged thereby (the “Class”).

2. Novartis engages in the research, development, manufacture, and sale of health care products. The Company offers its products to physicians, pharmacists, hospitals, insurance groups, and managed care organizations primarily in the United States and Europe. Novartis was founded in 1895 and is headquartered in Basel, Switzerland.

3. Throughout the Class Period, Novartis failed to disclose adverse information regarding the Company’s research into a potential new cancer drug, Tassigna.

4. Investors who purchased Novartis securities during the Class Period suffered damages, as they purchased the securities at artificially inflated prices. The securities declined rapidly once the FDA disclosed the safety data for Tassigna, which defendants had known for several months.

## **JURISDICTION AND VENUE**

5. The claims asserted arise under §§10(b) and 20(a) of the Securities Exchange Act of 1934 (“1934 Act”) and Rule 10b-5. Jurisdiction is conferred by §27 of the 1934 Act. Venue is proper pursuant to §27 of the 1934 Act. Novartis is

headquartered in Basel, Switzerland, but has business units in this District, including Novartis Pharmaceuticals Corp., which is located in East Hanover, New Jersey. False statements were made in this District and acts giving rise to the violations complained of occurred in this District.

### **THE PARTIES**

6. Plaintiff Brooke Abrams purchased Novartis securities during the Class Period as set forth in the attached certification and was damaged thereby.

7. Defendant Novartis's headquarters are located in Basel, Switzerland. Novartis American Depositary Shares ("ADSs") trade under the symbol NVS on the New York Stock Exchange, an efficient market.

8. Defendant Daniel Vasella ("Vasella") was, at all relevant times, Chairman and Chief Executive Officer ("CEO") of the Company.

9. Defendant Raymund Breu ("Breu") was, at all relevant times, Chief Financial Officer ("CFO") of the Company.

10. Defendant Thomas Ebeling ("Ebeling") was, at all relevant times, CEO-Pharmaceuticals of the Company.

11. Defendant Paul Herrling ("Herrling") was, at all relevant times, Head of Corporate Research for the Company.

12. Defendant James S. Shannon ("Shannon") was, at all relevant times, Global Head of Pharma Development for the Company.

## SCIENTER

13. During the Class Period, the defendants had both the motive and opportunity to conduct fraud. They also had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, the defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of Novartis securities during the Class Period.

### FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

14. On June 14, 2006, the Company issued a press release entitled “Patients with treatment-resistant leukemia achieve high responses to Tasigna® (nilotinib) in first published clinical trial results,” which stated in part:

- *New England Journal of Medicine* publishes first evaluation of Tasigna, a promising next-generation targeted therapy, five years after issuing historic Glivec® Phase I data
- Tasigna *designed* to be a highly selective inhibitor of Bcr-Abl, the definitive cause of Ph+ CML, and its mutations
- More than 90% of patients with an unresponsive form of chronic myeloid leukemia (*CML*) in chronic phase treated with Tasigna achieved normal blood cell counts in less than five months

... First-ever published clinical trial data about the investigational drug Tasigna® (nilotinib) showed the compound helped more than 90% of patients diagnosed with an unresponsive form of leukemia, a life-threatening disease.

The data were published today in the *New England Journal of Medicine*.

In less than five months of treatment, 92% of patients with chronic phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) achieved a complete hematologic response with normal white blood cell counts after having shown resistance or intolerance to optimized Glivec® (imatinib)\* therapy.

In more than a third of these patients, the Ph chromosome, the genetic abnormality that characterizes most cases of CML, was undetectable after treatment with Tasigna, as measured by standard laboratory methods. A total of 106 patients with Ph+ CML participated in this study: 33 patients in blast crisis, 56 patients in accelerated phase, and 17 patients in chronic phase. In addition, 13 patients with Ph+ acute lymphoblastic leukemia were included in the study.

Both Tasigna and Glivec inhibit Bcr-Abl, the definitive cause of Ph+ CML – in effect, shutting down production of the Ph chromosome. Tasigna was specifically designed to be a more selective inhibitor of Bcr-Abl and its mutations, which can cause resistance to treatment.

“By selectively inhibiting Bcr-Abl and its common mutations, Tasigna produced dramatic positive responses in patients who had limited treatment options,” said Hagop Kantarjian, MD, Professor of Medicine and Internist, Chair, Department of Leukemia, M.D. Anderson Cancer Center. “These extremely encouraging results reinforce the validity of treating this cancer by specifically targeting the one protein known to cause the disease.”

Patients in the most advanced phases of CML responded to Tasigna therapy. The overall rate of hematologic response (normalization of white blood cell counts) for patients in accelerated phase was 72% and the rate of cytogenetic response (reduction or elimination of the Ph+ chromosome) was 48%. Among patients in blast crisis, the response rates were 39% and 27%, respectively.

The study investigators concluded that Tasigna was generally well tolerated. Common adverse events included myelosuppression, transient indirect hyperbilirubinemia and skin rashes. Additionally, the investigators noted that Tasigna was usually not associated with common

toxicities seen with Glivec (e.g. fluid retention, superficial edema, weight gain), or rare cases of pleural and pericardial effusions.

\* Known as Gleevec® (imatinib mesylate) tablets in the U.S.

15. On July 17, 2006, the Company issued a press release entitled “Novartis generates strong sales and earnings growth in the first six months of 2006, growing faster than the world pharmaceuticals market,” which stated in part:

- New clinical data underscore potential of highly-rated Novartis pipeline, particularly for Galvus (type 2 diabetes), Rasilez and Exforge (hypertension), and Tasigna (cancer).

\* \* \*

- **Tasigna1** (nilotinib, formerly AMN107) achieved several important data milestones in the second quarter with the publication of Phase I clinical data in the “New England Journal of Medicine” as well as the presentation of interim results from an ongoing Phase II registration study during the American Society of Clinical Oncology (ASCO) annual meeting. The interim Phase II results found that 46% of patients with chronic phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) resistant or intolerant to optimized *Gleevec/Glivec* therapy achieved a major cytogenic response with *Tasigna* after six months of treatment. Both *Tasigna* and *Gleevec/Glivec* inhibit Bcr-Abl, the definitive cause of Ph+ CML. *Tasigna* was specifically designed to be a more selective inhibitor of Bcr-Abl and its mutations. Novartis has launched ENACT (Expanding Nilotinib Access in Clinical Trials) to provide expanded global access to *Tasigna*. Novartis plans to submit *Tasigna* for US and EU approval in late 2006 compared to earlier estimates for 2007.

16. On July 17, 2006, during the Q2 2006 earnings conference call, the Company made the following statements regarding Tasigna:

[Ebeling:] Tasigna, the next product in the segment, has a very competitive profile regarding its [efficacy], which you can see on 32 – and as well important, on page 33, an excellent tolerability profile.

\* \* \*

David Epstein [CEO, Oncology & Specialty Medicines]: . . . The biggest surprise actually for us at the ODAC meeting was learning about Sprycel’s overall side effect profile, which portends to have certainly more challenges than Gleevec, and at least on the surface would appear to be more difficult to tolerate than our new drug, Tasigna.

So I think it’s hard to give exact guidance. I think clearly, looking forward, Gleevec will slow, particularly into next year, and then once Tasigna launches, I would hope that we would see the franchise then pick up again.

\* \* \*

I will start with Tasigna. What we explained at the ASCO meeting was that we had changed the enrollment criteria into the study for advanced and [blast] crisis patients, those patients that had progressed on Gleevec, to reduce the number of QT millisecond elevations we would be willing to accept in the study went from 480 to 450, which is a modest change. Based upon that change, there have been no additional unexplained sudden deaths, despite the fact that we’ve enrolled another 300 plus patients into those clinical trials.

Additional work is still ongoing with Tasigna. In particular, we’re looking at QT prolongations in healthy volunteers to try to best understand if there’s any dose effect, which will then inform the dose and schedule to take into earlier-stage trials.

17. On October 19, 2006, the Company issued a press release entitled “Novartis delivers dynamic sales and earnings growth in the first nine months of 2006, reaffirms outlook for record full-year results,” which stated in part:

- US and EU submissions completed for Galvus (type 2 diabetes) as well as Tekturna[2] and Exforge (hypertension), Tasigna (cancer) on track for US/EU submissions in 2006

\* \* \*

- **Tasigna[1]** (nilotinib, formerly AMN107) remains on track for US and EU submission as a new option for patients with resistance to treatment in certain forms of chronic myeloid leukemia. Interim Phase II results presented at the ASCO meeting in June found that 46% of patients with chronic phase Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) resistant or intolerant to optimized *Gleevec/Glivec* therapy achieved a major cytogenetic response with *Tasigna* after six months of treatment. Both *Tasigna* and *Gleevec/Glivec* inhibit Bcr-Abl, the definitive cause of Ph+ CML. *Tasigna* was specifically designed to be a more selective inhibitor of Bcr-Abl and its mutations.

18. On October 19, 2006, at the Q3 2006 earnings conference call, the

Company made the following statements regarding Tasigna:

[Eberling:] Together with [CIGNA], Gleevec has really, we are having now a very strong position in the (indiscernible) franchise. Dosing continues to go up, as is illustrated on Page 32, and we are progressing as planned with Tasigna.

\* \* \*

Page 37-38, you can see the latest on our late-stage pipeline. I judge this as that we have not experienced any major setbacks on those 12 late-stage projects. Most projects advance very well and especially our key late-stage projects. Galvus, Tekturna, Exforge and Tasigna are continuing to develop in line with our expectations.

\* \* \*

[Breu:] Regarding your question on Tasigna, we'd like to update you at a pipeline date in November. I believe you also asked me about the TOPS trial which is the head-to-head comparison of 400 versus 800 mg of Gleevec and de novo CML. We are on track to finish accrual into that trial by the end of '06, which would indicate data sometime in 2008.

19. On December 11, 2006, the Company issued a press release entitled “Pivotal submission data shows Tasigna® achieved impressive response rates in chronic myeloid leukemia patients no longer helped by Glivec®,” which stated in part:

- New data support US and EU submissions of next-generation targeted therapy offering hope to patients with resistance or intolerance to Glivec
- Tasigna shown to have impressive efficacy and manageable safety profile, with patients intolerant to Glivec rarely experiencing same side-effects on Tasigna
- About one of two patients treated with Tasigna had significantly reduced or no presence of cells with the defective chromosome that causes this blood cancer

. . . New clinical data presented today demonstrated that Tasigna® (nilotinib) eliminated or significantly reduced the presence of blood cells containing a defective chromosome in approximately half of adult patients with a form of life-threatening leukemia who developed resistance or intolerance to treatment with Glivec® (imatinib).

The reductions achieved in these patients resistant to Glivec, one of the first oncology drugs developed based on an understanding of how some cancer cells work, may be the highest ever reported with a targeted therapy at a minimum of six months follow-up.

The Phase II data, which forms the basis for US and EU regulatory submissions completed earlier in 2006, showed that the use of Tasigna in patients with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) reduced or eliminated the presence of this defective chromosome in 51% of Glivec-resistant patients in chronic phase of this disease and led to normalized white blood cell counts in 74% of these patients.

The study also showed a similar magnitude of elimination or reduction of these defective cells in 55% of intolerant patients. Data from

this trial were presented today at the American Society of Hematology annual meeting.

Novartis has filed applications with both the US Food and Drug Administration (FDA) and European Medicines Agency (EMA) for Tasigna as a therapy for adult patients with chronic or accelerated phase Ph+ CML with intolerance and/or resistance to Glivec.

Tasigna was developed by Novartis as a next-generation targeted therapy based on the success of Glivec. Although data from the landmark IRIS trial – the largest-ever conducted in CML patients – demonstrated that nearly 90% of chronic-phase Ph+ CML patients taking Glivec were alive at five years, a small subset of patients develop resistance or cannot tolerate this therapy.

Both Tasigna and Glivec are designed to inhibit production of cells containing the Philadelphia chromosome by inhibiting the Bcr-Abl protein. Bcr-Abl is recognized as the key cause and driver of the proliferation of white blood cells that characterizes Ph+ CML.

While Tasigna and Glivec target the same pathways, the strategy behind the Tasigna research program was to design a preferentially Bcr-Abl targeted therapy that would be more potent against Glivec mutations but avoid the potential side effects of less targeted agents.

“These exciting data demonstrate that Tasigna has the potential to offer a compelling new treatment option for patients with Ph+ CML. Designing Tasigna to be an even more targeted Bcr-Abl inhibitor than Glivec appears to be providing impressive efficacy results with a manageable safety profile,” said David Epstein, CEO and President of Novartis Oncology. “We look forward to further exploring the potential benefits of Tasigna through our broad Phase III clinical trial program in earlier CML settings.”

### Study details

The open-label Phase II study was designed to evaluate the safety and efficacy, as defined by hematologic (normalization of white blood cell counts) and cytogenetic (reduction or elimination of the Ph+ chromosome) response rates of Tasigna administered to Glivec-resistant or intolerant patients with Ph+ CML in chronic phase and accelerated phase. The 316 chronic-phase patients in the Phase II study were heavily

pre-treated for Ph+ CML, with a significant majority (72%) having received at least 600 mg of Glivec as well as having been treated earlier with interferon (65%) and hydroxyurea (83%).

Among 279 assessable patients (i.e., those patients with at least six months of follow up) with chronic-phase disease, major cytogenetic response was observed in 145 (52%) of which 96 (34%) were complete. Complete hematologic response was reported in 137 (74%) of 185 assessable patients. In patients with at least 10 months follow up, the median time to cytogenetic response was 2.8 months (range 1 to 11), and the median time to complete hematologic response was 1.0 (range 1 to 8) months.

Among 64 patients with accelerated-phase disease, major cytogenetic response was observed after at least eight months follow-up in 23 (36%), of which 14 (22%) were complete. Confirmed hematologic response occurred in 38 (59%), of which 15 (23%) were complete. The median time to cytogenetic response was 2.0 months (range 1 to 8), and the median time to complete hematologic response was 1.0 (range 1 to 3) months.

The Phase II study showed an acceptable tolerability profile with a low incidence of events related to fluid retention such as edema, a side effect common with other tyrosine kinase inhibitors. The most frequent Grade 3 or 4 adverse events were primarily hematological in nature and include neutropenia and thrombocytopenia. Elevations were seen in bilirubin, liver function tests, lipase enzymes and blood sugar, which were mostly transient and resolved over time. These cases were easily managed and rarely led to discontinuation. Pancreatitis was reported in less than 1% of cases.

The study also showed virtually no non-hematologic cross-intolerance between Glivec and Tasigna. (Cross-intolerance occurs when patients cannot tolerate two different drugs because of the same side effects.) Causes of non-hematologic intolerance to Glivec, which occurred in 95 patients, included Grade 3 or 4 rash/skin toxicity, fluid retention, gastrointestinal intolerance, liver toxicity, and myalgia/arthritis. When treated with Tasigna, none of these patients experienced severe rash/skin toxicity, fluid retention or myalgia/arthritis. One patient each experienced severe gastrointestinal intolerance and liver toxicity.

## About Tasigna

Discovered in the biomedical research facilities of Novartis, Tasigna (nilotinib, formerly AMN107) entered Phase I clinical studies in 2004 just 21 months after it was first synthesized in August 2002.

As an investigational compound, the safety and efficacy profile of Tasigna has not yet been established. Access to Tasigna is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the compound's potential benefits and risks and data has been filed with regulatory authorities.

20. On December 11, 2006, at the American Society of Hematology Annual Meeting and Exposition, the Company made the following statements regarding Tasigna:

David Epstein [President, CEO of Oncology]: . . . There's much we could talk about for our business, but given that we recently reviewed our pipeline at Pipeline Day I thought we would focus on the three medicines that have made the most news at the ASH meeting which are Glivec, Tasigna and PKC412

\* \* \*

But focusing back on CML, our Company believes that this is a market segment that is attractive, that patients will continue to need new therapies to get maximum long-term survival. And we know that not every patient is currently well controlled with the available marketed agents. And as a result we continue to do R&D in this area and focusing particularly on more targeted Abl inhibitors and that will be Tasigna, I will give you some detail on that.

\* \* \*

If you turn now to page 15, I believe you saw this one at Pipeline Day, but just to remind you, we have indeed filed new drug applications in Europe, in the U.S., Switzerland as well as other countries. We have formal acceptance from the EMEA and we should hear from FDA in the next couple of days about hopefully their formal acceptance as well. The only new data on this slide for you that you haven't seen before is that

over 1,500 patients have now been treated with Tasigna. So we think we're getting quite a good handle on its efficacy and an ability profile.

If you turn now to page 16, I think it's important to get a sense of the types of patients we enrolled in our Tasigna trial so that you can put this data into context when you're looking at other CML trials with other agents. We set a relatively high bar for Glivec resistance; you can read the details on the page, but in particular patients needed to be treated with the 600 milligrams of imatinib for three months. In addition, patients had to have losses of complete hematologic response with WBCs greater than 20,000. So it was quite hard to declare imatinib resistance, so as a result we believe we have fairly sick patients in our trial. In fact, the vast majority of these patients also had failed interferon and/or hydroxyurea.

If you look at page 17 and you look at the definition that we used for the intolerant population, the patients that we chose for our trial had to be without a major cytogenetic response. They needed to have stopped therapy due to persistence AEs and without a major cytogenetic response. Unlike other trials that have reported this meeting which allowed patients who had a response – a cytogenetic response to then go on to the next therapy and then to be declared as successes in those trials. So it's important to compare numbers like versus like.

If you turn now to slide 18, what you see is the data from the chronic phase Glivec resistant intolerant patients that were treated with Tasigna. We see at eight months of median follow-up all these patients were treated for at least six months, that 74% of the patients had a complete hematologic response. Overall the major cytogenetic response rate was unimpressive, 52%, and the complete cytogenetic response rate was already 34% at this median follow-up. What's important to point out I think are the imatinib resistant patients; and remember the very difficult hurdle that we set to be declared imatinib resistant. And what you see there is that these patients at this short follow-up, already 51% of them had achieved a major cytogenetic response which gives us considerable hope for the value this therapy is going to bring.

If you go to page 19, there is some data, updated data that was reported at this meeting for another drug in this category. And what you see is at the eight-month follow-up they reported only a 39% major cytogenetic response rate in a similar group of patients. Remember, our definition was more challenging. And then by 15 months, it took all the

way to 15 months before they achieved numbers that were quite comparable to the Tasigna figures.

Turning now to slide 20, I want to take you a little bit through the tolerability profile because I think this is one area that greatly distinguishes Tasigna from other therapies and when I say other therapies I mean both Glivec as well as competing therapies. And what you see on page 20 is that when you look at hematologic adverse events, looking at grade 3 and 4 events, these numbers are routinely – very few patients experience grade 3 or grade 4 events. Actually these are not hematologic events, I'm sorry.

Turning now to page 21, looking at the biochemistries, you see once again generally manageable changes in biochemistry. For many of these patients they would have an abnormality for a period of time and then it would resolve over time. The highest numbers here are in the areas of lipase elevation and hyperglycemia as well as hypophosphatemia.

Looking at page 22, we speak here and we take a look at the various types of fluid retention in patients – on CML patients. As I said earlier, it's striking to see the differences between Tasigna and the other drug. You'll remember, as I said earlier, Glivec has fairly significant rates of peripheral edema which are certainly not life threatening but can be annoying for the patient, and dasatinib has, as reported this meeting, quite significant rates of pleural effusion. And what we see here in looking in terms of grade 3/4 events, almost no patients had these events on Tasigna. And even when you look at all grades of events the numbers were quite, quite low.

Turning now to page 23, another feature about the tolerability profile about Tasigna gives us also a lot of hope and encouragement is that very low rates across intolerance of Glivec. In other words, if a patient had significant tolerability problems, for example grade 3/4 tolerability issues with rash or fluid retention or GI intolerance on Glivec when they were switched to Tasigna, in almost all patients those AEs did not reoccur. You can see for GI intolerance it was one out of 16 and liver toxicity one out of 13. So this will give physicians an alternative if a patient wants a drug that's going to not have the same tolerability issues and probably won't risk some of the fluid retention events that we see with the other drugs.

Turning to page 24, we've had a lot of questions about QT prolongation with Tasigna. During the Pipeline Day we reported the results from the healthy volunteer study and I want to show you here the results from the actual CML patients. When you're looking at the clinical findings we see the mean change in QT interval of about 5 milliseconds as a time average figure. In addition we see that only three of 316 patients had an interval of greater than 500 milliseconds and that only six out of 316 patients had a change that was greater than 60 milliseconds from baseline and no patients had Torsades. So there is some prolongation of QT. It does not seem, at least for the vast majority of patients, to be that meaningful.

\* \* \*

Turning now to page 29, we get a first glimpse of the potential future for Tasigna and here investigators reported on additional follow-up from the M.D. Anderson studies looking at 400 milligrams BID Tasigna in newly diagnosed chronic myeloid leukemia patients. And you see that now at nine months, 11 of these patients have been followed up for nine months and we continue to have a 100% complete cytogenetic response rate which of course is very good. Patient numbers are small so we need to be cautious. But very, very encouraging. These responses occur very rapidly and the toxicity profile continues to be very favorable.

Based upon this data we are designing a Phase III program in both newly diagnosed patients as well as patients who have not gotten the kind of response that we would like in the chronic phase. Those trials will start during the first half of 2007 and we hope to have more to say about them as we move into next year.

So in short, with Tasigna we are very pleased with the results. We are very opportunistic about the long-term potential of Tasigna. We hope to be able to launch Tasigna in Switzerland, the U.S. and Europe during the next year as well as many other markets.

\* \* \*

Turning now to page 35, I just want to wrap up and once again share with you our overall pipeline. I won't go through that again today. Those of you who were not at Pipeline Day, I would reference you to those documents. If you don't have them, our Investor Relations department would be happy to provide them. I would say our greatest

challenge in Novartis oncology is not lack of work, but rather moving these products through the development phase with speed and quality. I hope that the experience that we've gained with programs like Glivec, Zometa, Femara and Tasigna will pave the way for future successes.

. . . There will be quite a bit of news flow during 2007. And just to share with you what we believe will be some of the key events. We expect the first regulatory decisions for Tasigna, the initiation of the new Tasigna registration trial as well as new registration studies for PKC, Tasigna in GIST, LBH589 and refractory CML and multiple myeloma, not to mention the CTCL trial that's just getting underway, SOM230 in refractory carcinoid tumors, Acromegaly, in addition the Cushing's trial which is now underway. And then RAD001 refractory carcinoid tumors as well as the renal trial that's underway.

\* \* \*

Graham Parry [Merrill Lynch Analyst]: Thanks for taking my questions. I've got three questions. Firstly, I was wondering if you could comment on the three cases of pancreatitis seen in the Tasigna Phase II study in terms of severity, history and whether that led to dose adjustments or discontinuation? Secondly, I was just wondering if you're aware of any similar data for spy cell on the QT issues that you've mentioned with Tasigna. Is there anything published on that you're aware of for spy cell?

\* \* \*

Dr. Diane Young [Head of Global Medical Affairs]: In terms of the pancreatitis, as was noted, there were lipase elevations seen in a fraction of the patients with Tasigna. Actually very few cases of pancreatitis; some of those were just made on x-ray diagnosis without a lot of clinical symptoms, so really were not a significant problem for the patients.

\* \* \*

Rachna Upadhyia [Bear Stearns Analyst]: Good afternoon. Thank you very much for taking my questions. Just a quick question on the mechanism of action of Nilotinib. Can you explain why you don't get peripheral edema or pleural effusions with Nilotinib whereas obviously these are issues with Glivec and with Sprycel. And the second question

is if you could just explain also why you get an increase in lipase elevation with Nilotinib? Thanks.

David Epstein: In terms of the first, you're probably aware that Glivec is actually a quite potent PDGF inhibitor and Tasigna actually is not. Tasigna was designed to be more selective for Abl. We think that – we can't prove it conclusively – we think that is the reason patients have peripheral edema on Glivec and much lower rates on Tasigna. When it comes to dasatinib, some have speculated that the pleural effusions related, but we don't necessarily believe it because we don't see it with Glivec. So another theory that I've heard, but obviously not proven is that one of the up to other 30 kinases that are being inhibited may somehow play a role. Is there anything we can say about lipases, Diane, do we know?

Dr. Diane Young: We do not know why we observed asymptomatic lipase elevations.

David Epstein: So for lipases, we just don't know at this time.

Rachna Upadhyia: And sorry, one follow-up question if I may which is actually on the start of trial. Would you expect the hematological responses to follow that of the cytogenetic responses that we've seen? Obviously it is a competitive study and I realize that. But it's just that it seems sort of somewhat surprising that we didn't see that data presented today?

David Epstein: I think I'd rather not comment on that trial. We have some issues with its design and I think it's hard to really make much of it. I think you'll have to go back to them.

21. On January 18, 2007, the Company issued a press release entitled “Novartis strategic healthcare portfolio drives sustained strong performance with record full-year results in 2006,” which stated in part:

- **Tasigna[1]** (nilotinib) was accepted in late 2006 for both US and EU regulatory review as a new option for patients with resistance and/or intolerance to treatment in certain forms of chronic myeloid leukemia. Phase II registration data, presented in December at the American Society of Hematology annual

meeting, showed that *Tasigna* had impressive efficacy and a manageable safety profile, with patients intolerant to *Gleevec/Glivec* rarely experiencing the same side-effects on *Tasigna*. About half of patients treated with *Tasigna* had significantly reduced or no presence of cells with the defective chromosome that causes this blood cancer. Both *Tasigna* and *Gleevec/Glivec*, another Novartis medicine, inhibit Bcr-Abl, the definitive cause of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML). *Tasigna* was designed to be a more selective inhibitor of Bcr-Abl and its mutations.

22. On April 23, 2007, at the Q1 2007 Novartis Corporation Earnings & Sales Conference Call, the Company made the following statements regarding *Tasigna*:

Alexandra Hauber [Bear Stearns Analyst]: . . . And also wondering whether we could get an update on the number of patients which are currently enrolled into the expanded access program for *Tasigna*.

\* \* \*

David Epstein: . . . Regarding *Tasigna*, we have almost 300 clinical trial sites open, and there are just over 700 patients that have been dosed so far in the expanded access program.

\* \* \*

[Breu]: . . . I think in terms of the growth outlook, certainly we will have in the second half of 2008 you will see an acceleration of growth, and that is partly driven by the fact that the negatives basically happen already – will happen in the second half of 2007, so if we go into the second half of 2008 you will see then a comparison versus a lower base. Then we have seen the washout of Lamisil and Trileptal generics, and of the Zelnorm marketing suspension. And against this, you have to basically allocate the gross benefit of our several launches. Especially here, I think Exforge, Exjade, Tekturna, *Tasigna*, Aclasta, a lot of products where I think we are maybe a little bit got more optimistic than the market, and the market has maybe still [probabalized] the launches, and not converted into sales which are unprobabalized. The products

have been approved and are about to be launched. Okay, and then Mark, your question regarding the breakdown of the \$54 million, I think approximately \$39 million are sales return, and the remainder is provisions for the cost of the suspension into recall.

\* \* \*

Tim Anderson [Prudential Securities Analyst]: I have some pipeline questions. In looking at Bristol-Myers Sprycel not gaining a lot of traction. It says either that the Glivec failure market is a small one, or that their unique product just isn't gaining traction because of its attributes. But I'm wondering what this says about Tasigna's commercial potential. So maybe you can just talk about Tasigna and how you see that layering into the marketplace alongside Glivec.

\* \* \*

David Epstein: I would encourage you to look at Glivec and Tasigna together and look at the combined market potential, which we said could exceed \$3.5 billion. It is indeed difficult to tell you exactly how much of that market potential will be Tasigna and how much would be Glivec. A lot will depend upon how Tasigna performs in the de novo and suboptimal studies that will start during the second quarter of this year.

It is indeed true that patients who have truly progressed on Glivec certainly to the accelerated or blast stage is a small market, because patients do so very well on Glivec. And I do believe Tasigna has a good combination of both efficacy and safety, which will allow physicians to consider using it when perhaps in some cases they are uncomfortable with the side effects of the competing drug.

23. On July 17, 2007, the Company issued a press release entitled "Novartis delivers strong performance in first half of 2007," which stated in part:

**Tasigna** (nilotinib) is awaiting regulatory decisions in the US, Europe and Switzerland as a new targeted cancer therapy for patients with a form of the life-threatening blood cancer chronic myeloid leukemia (CML) who are resistant or intolerant to treatment with *Gleevec/Glivec* (imatinib). A submission was completed in Japan during the 2007 second quarter. Also planned for 2007 are the start of Phase III

studies in newly diagnosed CML patients and patients responding sub-optimally to other therapies. A registration study is already underway in patients with gastrointestinal stromal tumors (GIST). Both *Tasigna* and *Gleevec/Glivec* inhibit Bcr-Abl, the definitive cause of Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML). *Tasigna* was designed to be a more selective inhibitor of Bcr-Abl and its mutations. In the US, the FDA requested on July 16 a three-month extension in the regulatory review period.

24. On July 17, 2007, at the Interim 2007 Novartis Corporation Sales & Earnings Conference Call, the Company made the following statements regarding *Tasigna*:

[Ebeling]: *Tasigna* had positive clinical newsflow, and here we expect a decision both by FDA and EMEA in quarter four.

\* \* \*

Andrew Baum [Morgan Stanley Analyst]:

\* \* \*

On the same theme of new products, just maybe some color on the *Tasigna* delay, whether it is cardiovascular safety.

\* \* \*

David Epstein . . . : During the course of the *Tasigna* review, we submitted additional data on the patients originally in the NDA, as well as additional patients to the NDA. And the FDA advised us simply that they want more time to review that new data and run some additional analyses. There is no one specific point that they seem to be focused on. Rather they are still coming to grips with the overall benefit risk profile for the drug. We think the three months should be enough time to finish that analysis.

\* \* \*

Alexandra Hauber [Bear Stearns Analyst]:

\* \* \*

And just a follow-up question to Andrew's question. David, you said you did submit additional Tasigna data. Was that data submitted on FDA request or just on your own motivation?

\* \* \*

David Epstein: Regarding Tasigna, the file I must say was a little bit on the light side with the initial submission. The chronic phased patients, there was under eight months of follow-up data with the additional data that was submitted at the 120-day update. We now have almost a year's worth of data in the chronic phase, and we feel that this data set is more robust for the FDA to take its final decision.

\* \* \*

I think as I have said before, to get a new frontline CML drug, you need to have really an extraordinarily good balance of efficacy and safety, which Glivec has demonstrated now with over five years' data. So it is unclear whether any other drug will get into the first-line setting.

Having said that, we think Tasigna does have a shot, and we will start Phase III trials in de novo CML patients later this year.

25. As a result of this disclosure, Novartis's share price declined from \$55.45 to \$53.36 in two days.

### **LOSS CAUSATION/ECONOMIC LOSS**

26. During the Class Period, as detailed herein, defendants made false and misleading statements by means of concealment and obfuscation of critical clinical trial data and engaged in a scheme to deceive the market. This artificially inflated Novartis's share price and operated as a fraud or deceit on the Class. Later, when defendants' prior misrepresentations and fraudulent conduct became apparent to the market, Novartis's share price fell precipitously, as the prior artificial inflation came out of the share price over time. As a result of their purchases of Novartis securities

during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

### **NO SAFE HARBOR**

27. Novartis's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

28. The defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Novartis who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made. On the contrary, such statements concealed critical data about the prospects of an important drug candidate.

### **APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET**

29. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company's securities traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's shares; and

(e) Plaintiff and other members of the Class purchased Novartis securities between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

30. At all relevant times, the market for Novartis securities was efficient for the following reasons, among others:

(a) As a regulated issuer, Novartis filed periodic public reports with the SEC; and

(b) Novartis regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

## COUNT I

### **For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

31. Plaintiff incorporates ¶¶1-30 by reference.
32. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.
33. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:
  - (a) Employed devices, schemes, and artifices to defraud;
  - (b) Made untrue statements of material facts or 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; or
  - (c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Novartis securities during the Class Period.
34. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Novartis securities. Plaintiff and the Class would not have purchased Novartis securities at the prices they

paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

35. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Novartis securities during the Class Period.

## **COUNT II**

### **For Violation of §20(a) of the 1934 Act Against All Defendants**

36. Plaintiff incorporates ¶¶1-35 by reference.

37. The Individual Defendants acted as controlling persons of Novartis within the meaning of §20 of the 1934 Act. By virtue of their positions and their power to control public statements about Novartis, the Individual Defendants had the power and ability to control the actions of Novartis and its employees. Novartis controlled the Individual Defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

### **CLASS ACTION ALLEGATIONS**

38. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased Novartis securities during the Class Period (the "Class"). Excluded from the Class are defendants, directors and officers of Novartis and their families and affiliates.

39. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial

benefits to the parties and the Court. Novartis had more than 2.3 billion shares outstanding, owned by thousands of persons.

40. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether the 1934 Act was violated by defendants;
  - (b) Whether defendants omitted and/or misrepresented material facts;
  - (c) Whether defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
  - (d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;
  - (e) Whether the prices of Novartis securities were artificially inflated;
- and
- (f) The extent of damage sustained by Class members and the appropriate measure of damages.

41. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

42. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

43. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

### **PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding plaintiff and the members of the Class damages and interest;
- C. Awarding plaintiff's reasonable costs, including attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

### **JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: October \_\_, 2007

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