

# Attachment A

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3 **Introduction**

4 InterMune, Inc., first incorporated in 1998, is a biopharmaceutical company focused on  
5 developing and commercializing innovative therapies in pulmonology and hepatology.

6 During the Investigative Period (August 2002 through January 2003), InterMune derived  
7 the majority of its revenue from Actimmune® (interferon gamma-1b). Actimmune was  
8 approved by the United States Food and Drug Administration (“FDA”) for the treatment of  
9 chronic granulomatous disease and severe, malignant osteopetrosis. These diseases affect very  
10 small patient populations. The vast majority of Actimmune sales during the Investigative Period  
11 were attributable to prescriptions for the treatment of idiopathic pulmonary fibrosis (“IPF”), a  
12 debilitating, fatal lung disease for which there is no FDA-approved treatment and which afflicts  
13 approximately 83,000 Americans.

14 **Dissemination of Misleading Information Regarding Phase III Trial of Actimmune**

15 1. Commencing in October 2000 and through 2002 InterMune conducted a global  
16 Phase III clinical trial of Actimmune for the treatment of IPF that was designed to study whether  
17 Actimmune extended the time to disease progression or death. The primary endpoint was  
18 progression-free survival, measured from randomization of the test subjects either to disease  
19 progression or death, and, in addition, there were a number of secondary endpoints, including  
20 overall patient survival. In this clinical study, 330 IPF patients were studied in a double-blind,  
21 placebo-controlled trial conducted at 58 centers in the United States and Europe. Study  
22 participants received either a placebo or 200 micrograms of Actimmune injected subcutaneously  
23 three times per week. All patients were to remain in the trial until the last patient received 48  
24 weeks of therapy. Median treatment duration was 60 weeks.

25 2. On August 16, 2002, a select number of InterMune personnel received data from  
26 the clinical trial. On August 19, 2002, the data was also provided to the Data Monitoring  
27 Committee (“DMC”), which had been established in accordance with the protocol of the trial as  
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1 an independent committee that monitored safety and efficacy data throughout the trial in order to  
2 determine if it was scientifically and ethically appropriate to continue the trial, and to review data  
3 from the completed trial. The data showed that the trial failed to achieve statistical significance  
4 on the primary endpoint agreed between InterMune and the FDA, or any agreed upon secondary  
5 endpoint, including overall survival. After receiving the data, InterMune conducted some  
6 additional analysis of the mortality data that involved breaking the patient population into  
7 subgroups.

8           3. Certain senior InterMune personnel discussed these preliminary trial results,  
9 including the exploratory subgroup analysis, with representatives of the FDA in an informal  
10 telephone conference on August 27, 2002. The purpose of the call was to provide InterMune  
11 with the FDA reviewers' preliminary impressions of the data. The FDA representatives told  
12 InterMune that any substantive comments represented their own opinions and did not reflect the  
13 official opinion of the FDA. During the telephone conference, one FDA representative noted that  
14 the study failed to demonstrate efficacy on its primary endpoint. The FDA representative  
15 suggested that while the data appeared to show an optimistic trend on overall survival, because  
16 the data had failed to achieve statistical significance in the primary endpoint previously agreed  
17 with the FDA at the outset of the trial, it was the representative's opinion that the FDA was  
18 unlikely to approve the use of Actimmune for the treatment of IPF without further rigorous  
19 clinical testing.

20           4. On August 28, 2002, InterMune publicly announced the results of the Phase III  
21 clinical trial of Actimmune for the treatment of IPF in the form of a press release. Former  
22 employees of InterMune approved the press release, which was headlined "InterMune Announces  
23 Phase III Data Demonstrating Survival Benefit of Actimmune in IPF, with the subheading  
24 "Reduces Mortality by 70% in Patients With Mild to Moderate Disease." In the release,  
25 InterMune's then-President and CEO characterized the clinical trial results as indicating that  
26 "Actimmune may extend the lives of patients suffering from this debilitating disease" and further  
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1 stated that "Actimmune is the only available treatment demonstrated to have clinical benefit in  
2 IPF, with improved survival data in two controlled clinical trials."

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4 5. By letter dated September 5, 2002 to InterMune, the Chair of the DMC expressed  
5 his "serious concerns" with the August 28, 2002 press release. The letter reminded InterMune of,  
6 "the DMC's assessment that the trial had failed to establish benefit on the primary endpoint" and  
7 that there was no statistically significant evidence of benefit for any of the secondary endpoints.  
8 The letter also stated that the press release provided a "serious misrepresentation of results  
9 obtained from exploratory data subgroup analyses," referring specifically to the subheading and  
10 other statements concerning a survival benefit in the mild to moderate subgroup.

11 6. In approximately mid-October 2002, a specialty pharmacy that distributed  
12 Actimmune disseminated a fax concerning Actimmune for IPF to more than 2,000  
13 pulmonologists. Distribution of the fax had been approved by a former InterMune employee.  
14 The fax, like the August 28, 2002 press release, began with the headline, "InterMune Announces  
15 Phase III Data Demonstrating Survival Benefit of Actimmune in IPF," and continued with the  
16 subheading, "Reduces Mortality by 70% in Patients with Mild to Moderate Disease." The fax  
17 also included a copy of the InterMune press release.

18 7. During approximately September to October 2002, the same specialty pharmacy,  
19 again with the approval of a former InterMune employee, distributed a patient letter by mail to  
20 Actimmune patients, which was sent along with their Actimmune prescriptions. The patient  
21 letter was prepared by the specialty pharmacy's clinical staff from information, including the  
22 press release, provided by former InterMune personnel and provided the same misleading  
23 information about the results of the Phase III Actimmune trial results. The letter stated that "On  
24 August 28, 2002, InterMune, Inc. announced that preliminary data from its Phase III clinical trial  
25 of Actimmune (Interferon gamma-1b) injection for the treatment of [IPF] showed a statistically  
26 significant reduction in mortality by 70% in patients with mild to moderate IPF. Interferon  
27 gamma-1b is the first treatment ever to show any meaningful impact in this disease in clinical  
28 trials. These results indicate that Actimmune should be used early in the course of treatment of

1 this disease in order to realize the most favorable long-term survival benefit.” A former  
2 InterMune employee approved the final version of the patient letter.

3 8. Notwithstanding the fact that the Phase III trial failed to establish statistically  
4 significant benefits on its primary endpoint or any of its secondary endpoints, including overall  
5 survival, and notwithstanding the evaluation of the results by the FDA and DMC, certain former  
6 InterMune employees encouraged InterMune sales force personnel to inform physicians that  
7 Actimmune demonstrated a survival benefit in mild to moderate IPF patient populations, and  
8 certain former sales force personnel did so. Certain former sales personnel also distributed or  
9 showed the specialty pharmacy documents to physicians during sales visits.

#### 10 ASAP Registry

11 9. In 2001, InterMune established the “Actimmune Safe and Appropriate Use  
12 Program” (the “ASAP Registry” or the “Registry”), a registry that collected information about  
13 IPF patients taking Actimmune. As described in the Registry Services Agreement between  
14 InterMune and the third-party administrator of the Registry, the ASAP Registry was an  
15 observational database designed to obtain data on “variation in current diagnostic and therapeutic  
16 management of patients receiving Actimmune.” Information from the Registry was to be  
17 available “to InterMune and to participating physicians for research and analysis” and “as a basis  
18 for scientific presentations and publications.”

19 10. During the Investigative Period, the ASAP Registry was operated substantially by  
20 InterMune sales and marketing personnel. During the Investigative Period, InterMune sales  
21 representatives were the principal source of Registry enrollment, and were also the principal  
22 points of contact for physicians and their offices with respect to the Registry. Sales  
23 representatives received incentive payments for patients they enrolled.

24 11. Although one purpose the ASAP Registry was to gather data on Actimmune  
25 patients and make that data available to physicians who had patients enrolled in the Registry,  
26 InterMune did not share the data directly with physicians. InterMune provided a brief summary  
27 presentation at a scientific meeting in late 2002 in San Diego.

1 12. During the Investigative Period, there were a number of regulatory and operational  
2 issues raised by the third-party administrator concerning the ASAP Registry, including various  
3 issues relating to good clinical practices and the extent of InterMune sales representatives'  
4 participation in the operation of the Registry.

5 13. In the spring of 2002, an outside consultant was retained by InterMune to assess  
6 the ASAP Registry. In June 2002, the consultant issued a final audit report, which identified a  
7 number of problems with the Registry and concluded that absent significant changes, data from  
8 the Registry would most likely not be accepted by the regulatory authorities.

9 Sales Force

10 14. InterMune employed approximately sixty sales representatives focusing on  
11 pulmonology and, in particular, Actimmune, during the Investigative Period. The FDA had not  
12 approved Actimmune for the treatment of pulmonary disorders at that time.

13 15. In January 2001, InterMune acquired rights to Amphotec®, an anti-fungal drug  
14 approved by the FDA for the treatment of aspergillosis, including pulmonary aspergillosis.  
15 Amphotec was primarily administered in a hospital setting. Prior to the fall of 2002, InterMune's  
16 sales representatives had not marketed Amphotec for pulmonary aspergillosis outside the hospital  
17 setting. However, in the fall of 2002, sales force personnel relied on Amphotec for access to  
18 pulmonologists' offices, where the primary purpose for access to the offices was to discuss  
19 Actimmune for IPF.

20 16. InterMune's Sales Incentive Compensation Plan for 2002 provided that sales  
21 representatives would receive a quarterly bonus based on 7% of incremental Actimmune sales  
22 and 3.5% of incremental Amphotec sales. The Plan also provided that the bonuses paid to  
23 Regional Sales Directors were derived in part from the total earnings of the sales representatives  
24 in their regions.

25 17. During the Investigative Period several sales force personnel sometimes created  
26 and used their own marketing aids in discussions with physicians concerning Actimmune for IPF.  
27 For example, one former sales representative wrote and distributed an invitation letter to an  
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1 educational program, which one physician recipient characterized as “against the spirit of FDA  
2 regulations.”  
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