Press Conference – March 11, 2014

Tony Alvarez, Chairman of the Japan-Based Executive Committee of PhRMA

Opening Statement (as prepared for delivery)

[Slide 1: Opening Title]

Good afternoon. My name is Tony Alvarez, and I am the President of MSD Japan and the newly elected Chairman of the Japan-Based Executive Committee of PhRMA. Thank you all for joining me this afternoon.

Let me first recognize that today is the third anniversary of the Great East Japan Earthquake and the devastation that followed. The Japanese people have shown, once again, how incredibly resilient they are – and the world continues to look on with admiration. The suffering of so many, and the amazing acts we have seen of giving and caring, is something no one can ever forget.

Turning to the pharmaceutical industry and healthcare in general, I would like to make a few remarks and then I would be happy to answer your questions.

[Slide 2]

I was educated as a pharmacist. I have spent over thirty years in the pharmaceutical industry, including the last eight years in Japan, and I have never been prouder of the contribution our industry has made to public health globally and in Japan. The benefits of our innovations affect the lives of everyone in this room, our families, and our friends. This includes improvement in the quality of life, prevention of debilitating disease, amelioration of the effects of disease, lengthening the period that we can lead a healthy life, enhancing our ability to be part of a productive workforce, and contributing to the overall growth of the Japanese economy.

I salute the Abe Administration for putting promotion of innovation in the healthcare area, including pharmaceuticals, as one of its top priorities. PhRMA published several studies last year that illustrated the contribution that innovation makes to society.

[Slide 3]
One study analyzed five of the 176 drugs approved over a recent five year period and concluded that the economic value of those five drugs was 1.3-1.5 trillion yen, divided into 800-950 billion yen in saved medical costs and 500-550 billion yen in productivity gains for the society.

[Slide 4]
Another study looked at new drugs and innovation, analyzing drugs approved in 12 disease areas over the past six years. This study demonstrated, from the perspective of patients and healthcare providers, how these newly approved drugs helped save and improve lives.

Together, these studies demonstrate very clearly and in detail the importance of innovation. We provided you with these studies last year at media meetings, and they are both available on our website.

[Slide 5]
Let me now review the past year from a perspective of how the changes in Japan's healthcare policy have positively impacted the promotion of innovation in healthcare. I will also point out further changes that we believe are necessary and that we will work hard to promote over the coming years.

[Slide 6]
First, let me discuss regulatory issues. I salute the efforts of PMDA, under the leadership of Dr. Tatsuya Kondo and with the hard work of hundreds of professionals on its staff, to increase the speed of approval of new drugs.

[Slides 7]
PMDA exceeded its goals this past year – 12 months for approval of drugs subject to regular review and nine months for those subject to priority review. PMDA celebrated its tenth anniversary last month, and these developments demonstrate the remarkable changes PMDA and its professional staff have made during this period.

We have seen some progress in the use of foreign data in PMDA's approval process and welcome that, although we would like to see more success in the

tripartite efforts among Japan, South Korea, and China. We are pleased that the regulatory environment has become more conducive to our companies including Japan in multiregional clinical trials. This is important to us and important to Japanese drug development. And I want to acknowledge that in the draft of its next five year plan, PMDA has included a commitment to measure review times based on a target proportion of 80% for regular products in 2017 and for priority products in 2018. We have been requesting this change for several years and I thank PMDA for making this commitment.

[Slide 8]
Second, let me turn to pricing issues. The decisions made over the past few months by Chuikyo on drug pricing were difficult, and we congratulate MHLW in its efforts to find a balance among many diverse, and often conflicting, interests. The decision to extend the innovative price premium for another two years was an important one, demonstrating the government's commitment to promote innovation and ensure that Japanese patients will receive promptly the newest and best drugs being developed now and in the future. Japan should be proud of this new price premium and its impact on promoting new drug development in this country. As you all know, we had recommended that this premium be made a regular part of the NHI system. Given the long time frames of drug development, we continue to believe that is the best course to ensure continued investment in innovation.

[Slides 9]
We provided Chuikyo with the data gathered from a survey of 21 companies. The survey results clearly show the impact that the price premium has had on promoting innovation, reducing the drug lag, and ensuring future drug development in Japan.

[Slide 10]
For example, the lag in submitting an NDA in Japan compared to the US and Europe was dramatically shortened from 30 to 17 months after the introduction of the premium price system. If the premium price system is maintained, this lag is expected to be shortened even more to 4 months.

[Slide 11]
As you know, new drug development involves a significant amount of business risk-taking, but the survey results also showed the more companies were willing to take that risk to start various drug development initiatives since the premium price system was introduced in 2010.

Over the coming two years, PhRMA will provide Chuikyo and the government with further data that demonstrate the continuing importance of the price premium in promoting innovation and investment in Japan and in contributing to this nation's economic growth.

We were disappointed by several other pricing decisions, however. We believe that the revisions of average foreign price adjustment rule will improperly reflect the variations among foreign prices and the influences of foreign exchange fluctuations. This will inhibit the promotion of innovation and investment in Japan. The failure to address the anti-innovation rule on repricing for market expansion is puzzling to us as this rule runs counter to the government's pro-innovation policies.

Also, the failure to address the 14-day limitation on prescriptions during the first year after approval for all medicines is a major disappointment. This rule, that does not exist anywhere else in the world, requires patients to visit doctors in person every two weeks, which reduces convenience and increases costs. Now that Japan has strengthened its risk management systems and maintains a robust Post Marketing Surveillance program, the 14-day rule should be revised or repealed.

We pledge to work hard the next two years to explain why these anti-innovation policies should be reversed.

[Slide 12]
Third, I would like to talk about vaccines. We welcome recent changes in vaccine policy and regulations. Vaccination, as most of you know, is widely recognized, after clean water and sanitation, as the single most cost effective disease prevention measure. Last year, amendments to the Immunization Law established a new process of policy making and evaluation for vaccines, added

three new vaccines to the list of recommended vaccines, and outlined a pathway for subsequent vaccines to be included on the recommended list and used by citizens. Recently, the Vaccine Committee recommended that two additional vaccines, including one for adults, be added to the routine immunization program in October. The changes are all important in preventing disease in Japan.

However, there is still a major challenge in developing the proper level of awareness of the need for vaccinations among the general public. Solving this challenge is a top priority of PhRMA and, I might add, of many others in Japan.

[Slide 13]
PhRMA published a Vaccine Fact Book several years ago to provide people in Japan with basic information about vaccines. We will publish another fact book soon that will focus on vaccine development in Japan and the benefits of vaccines, and we plan to disseminate this information as widely as possible. We will hold a joint symposium with the Japan Medical Association in May that will focus on how to increase awareness of the importance of vaccines. Finally, for the past four years, in a partnership with the U.S. government, we have brought key officials in charge of American vaccine policy from the Department of Health and Human Services and the Centers for Disease Control and Prevention to share best global practices with the government, Diet members, key medical leaders concerned with vaccines, and you in the media. We will hold the fifth annual program later this year.

[Slide 14]
The fourth area I would like to discuss is the role that the pharmaceutical industry plays as a key element in Japan's economic growth strategy. Much of the discussion about this seems to focus on increasing the export ability of the Japanese pharmaceutical industry. We welcome changes that will enhance the strength of the Japanese industry, including their export abilities. After all, our companies have important strategic relationships with many Japanese drug companies, and their strength is our strength.

But exporting is really only a tiny part of the picture of what the domestic and global pharmaceutical industry contributes to Japanese economic growth. Although manufacturing is important and involves cutting edge high technology,

drug discovery and development is inherently an intellectual process. Basic science is done in industry, university, and research institute laboratories. It then needs to move out of the laboratory into the clinical development process and, eventually, into the market. This process is called translational research and, without it, no patient will ever receive the benefits of those amazing laboratory discoveries. It is the intellectual ability of researchers and technicians that allows a drug to move thru the myriad steps in this complex, long, and expensive process.

The increase in clinical development being done in Japan by foreign pharmaceutical companies adds to the intellectual capacity of the nation. Researchers in laboratories learn about the clinical development process. Clinicians and other healthcare providers are exposed to global best practices through increased participation in clinical trials.

It is widely recognized that Japan has fallen behind in the area of translational research. The decision to create the Japan Medical Research and Development Agency, known popularly as the Japan NIH or National Institutes of Health, is welcome news as it tries to centralize the government budget for research and make those investment decisions more strategic. That is an important step, but much more needs to be done.

[Slide 15]
PhRMA is trying to help. We began a program to send eight young researchers to the United States every year for two weeks to study how translational research is being done and to help them develop contacts and a network with American researchers and institutions that are leading the way. The first group went in September and we have begun the recruitment process for the next group to visit the United States later this year.

We held a symposium last August to make younger researchers in Japan aware of the importance of translational research, and we will continue this program yearly.

I cannot exaggerate the importance of developing translational science to make Japan a pharmaceutical global powerhouse.

Another critical contribution that the pharmaceutical industry makes to economic growth in Japan is thru increasing productivity. There is no growth without higher productivity. A healthier workforce, including a healthier older population that can continue working longer, translates directly into economic growth. And the studies I mentioned earlier show how the products discovered, developed, and marketed by our industry contribute significantly to greater productivity in Japan with its aging population.

[Slide 16]
Finally, let me touch on the issue of ethics. Our industry serves patients, first and foremost. A patient, and his or her physician, must have confidence in the company providing the powerful medicine needed by that patient to get better or to manage or prevent a disease. Trust is at the forefront of our relationship with patients and healthcare providers.

[Slide 17]
JPMA does a survey of Japanese citizens to understand how they view the pharmaceutical industry. In the most recent survey in 2012, 85.6 percent of the public believed that the pharmaceutical industry is reliable. We must and will make every effort to maintain that high level of public trust and confidence.

Last year, domestic and foreign pharmaceutical companies in Japan, following voluntary guidelines prepared by JPMA, published information about payments to healthcare providers on our individual company websites. We welcome JPMA's leadership in promoting this increased transparency for our industry.

In our own effort to ensure public confidence and trust, the Japan-Based Executive Committee of PhRMA is issuing today a paper setting forth suggested principles for industry support of Investigator Initiated Trials. Although pharmaceutical companies conduct or sponsor a significant portion of clinical research in Japan and throughout the world, many important studies are sponsored or conducted by independent researchers and institutions, sometimes with support from pharmaceutical companies.

This research, like company-sponsored research, must be conducted

responsibly and in accordance with internationally recognized standards. It is important to distinguish between a study sponsored by a pharmaceutical company and a study where a pharmaceutical company is providing support for an investigator initiated study. These principles we published today involve the latter, and we have included the full document in your packet.

[Slide 18]
In conclusion, PhRMA supports promotion of healthcare innovation by the Abe administration and PMDA efforts in accelerating new drug approvals. We will do everything necessary to make premium pricing a permanent law and continue to work with all parties to revise “market expansion re-pricing” and the “14-day prescription limit” on new drugs. PhRMA will continue to promote drug discovery innovation in Japan.

Thank you for listening. Now I am happy to answer your questions.