PhRMA Day Press Conference: November 18, 2014
Imperial Hotel

Speech of PhRMA Chairman – Ian Read

Good afternoon everyone. I am delighted to be here today as Chair of PhRMA representing the major biopharmaceutical companies in the world, including many Japanese companies – Takeda, Astellas, Daiichi-Sankyo, Eisai, Shionogi, and Otsuka.

Before taking your questions I want to spend a few minutes talking about the value the pharmaceutical industry creates for society, key priorities for the industry (including specific priorities here in Japan), and the industry's potential over the coming decade.

Over my career, I have seen the incredible impact our industry has made in improving and extending lives. We have been doing good and creating value for patients for decades.

Innovative new medicines and vaccines are possibly the most powerful levers for stemming the tide of illness and disability that directly threaten an aging population. They are a great value for the money, and also ensure the healthy development of growing populations in developing economies.

We have two examples that demonstrate this point: according to the World Health Organization (WHO), immunizations save an estimated 2.5 million lives every year. In addition, statins have not only improved people's lives - an academic peer reviewed article in Health Affairs demonstrated that between 1987 and 2008 alone, statins generated more than $1.3 trillion in social value. This means longer lives, less disability and more productivity for patients and their families. Of particular note, statins were invented by a Japanese researcher, Dr. Endo, in 1973.

We believe there are many more opportunities for the industry to create even more value through ongoing innovation…but we will need the right environment in which to operate - one that supports significant investment, great science and high risk.

It takes us 10 to 15 years of dedicated work to translate basic research to medicines that are safe and effective. Over the last year alone, the industry invested more than $50 billion in R&D, and since 2000 we have invested more than half a trillion dollars in R&D, more than any other industry.

PhRMA has four key priorities for creating the right environment. First, to preserve broad patient access to safe and effective medicines, including sustainable cost coverage of those medicines. Second, to support innovation through robust IP protection, both domestically and internationally. Third, we must ensure an evidence-based regulatory environment that is effective, efficient, and puts patients first. Finally, we must encouragea more transparent flow of information overall, with all key stakeholders (including payers, regulators and policy-makers) having full conversations, with access to real-world data, so the best decisions may be made.

These priorities address the most critical issues for enabling innovation and driving economic growth, throughcreating and supporting jobs, stimulating ongoing R&D, and raising the health and productivity of the workforce through delivery of the world's newest medicines.

Today the Japanese pharmaceutical industry employs 125,000 people and the foreign pharmaceutical companies employ another 40,000 people in Japan.

We know the Japanese government looks to our industry to promote economic growth, which can be achieved by having the right pricing and regulatory policies.

On the subject of pricing - I know there are unprecedented budget challenges facing Japan, especially with an aging population and an aging workforce. However, spending on pharmaceuticals has an important positive long-term budget impact. A recent study on the value of innovative medicines in Japan showed in the case of five new drugs, the overall financial benefit to the Japanese economy was 1.3- 1.5 trillion yen. This includes both the savings in treatment costs from using more innovative drugs and productivity benefits to the economy.

PhRMA appreciates the many significant improvements the government has made in recent years. This has increased our ability to bring the newest and most innovative medicines to Japanese patients.

For example the introduction four years ago of a new drug pricing system that rewards and encourages innovation was an important step. This system will shorten drug development and delivery timelines, promote innovation and investment, and ensure patients have prompt access to the world's newest and best medicines.

The two year renewal of the premium price system will help Japan's patients receive the world's best medicines. We ask that the government create long-term consistency by making this premium a regular part of the pricing system.

The amendment to the Vaccination law last year will provide greater access to important new vaccines for children and adolescents, and we are encouraged by the government's commitment to add additional vaccines to the list of recommended vaccines (including for adults).

The willingness of the Pharmaceuticals and Medical Devices Agency (PMDA) to look at new ways to speed up drug reviews is much appreciated. Under PDMA's improvements a total of 176 new medicines were introduced in the last 5 years, and review times for new medicines have decreased from 22 months to 11 months.Also I should note that our dialogue with PMDA is excellent and continues to deepen.

In addition we encourage further harmonization with international standards in clinical development, multiregional clinical trials, and risk management. PhRMA hopes MHLW and PMDA will be increasingly flexible in accepting data from other countries - in particular, from East Asian neighbors.

As an industrywe are committed to doing everything possible to ensure the safety of our drugs. We have been working closely with PMDA and the Ministry of Health Labor & Welfare (MHLW) on an

improved risk management system that went into effect a year ago.PhRMA will continue to offer our assistance and experience wherever it may be beneficial in all these areas.

Let's talk about the potential for the industry over the coming decade. The Japanese people are eagerly anticipating new medicines. According to a recent survey, "Perception of general public on medicines and pharmaceutical industry," conducted by the Japan Pharmaceutical Manufacturers Association in June 2014, 93% of respondents said the "development of new medicines is necessary even if it takes tremendous amount of time and money."The survey also revealed that respondents expect us to develop medicines for cancer, dementia, and Alzheimer's disease, and that the overall trust for the pharmaceutical industry was quite strong at 80.9%. Based on these results it's clear the pharmaceutical industry is respected and valued, in addition to being counted on to create the new medicines that people expect.

Fortunately,pipelines across the industry are deeper and better than they have ever been. Currently there are over 5,000 medicines in development globally.Potential first-in-class medicines make up 70% of the biopharmaceutical research pipeline, while potential first-in-class projects are particularly high in neurology (84%), cancer (80%) and psychiatry (79%).Many new medicines are currently in development for diseases that have not had a new therapy in ten years, and there are 158 medicines in development for ovarian cancer, 19 for sickle cell disease, and 41 for small cell lung cancer.

To deliver on the potential of the industries' pipeline requires an ecosystem - one in which there is ongoing collaboration between PhRMA, the government and healthcare providers. One example of this is Pfizer's drug Xalkori – the first therapy for advanced or locally metastatic ALK-positive non-small cell lung cancer. The ALK fusion gene was discovered by Dr. Hiroyuki Mano, a Japanese scientist. The approval of XALKORI took place only four years after the publication of the discovery by Dr. Mano. The collaboration between researchers, regulatory authorities (who recognized the value of small, highly targeted clinical trials) and doctors who understood the need for biomarker testing enabled this treatment to get to the right patients.

In summary, as an industry, we have a great responsibility to the patients we serve. They are counting on us to develop potential cures and new lifesaving treatments when it comes to surviving cardiovascular diseases, cancers, Alzheimer's, Parkinson's and neurological conditions. Through collaboration and commitment we can turn our opportunities into reality.