CEOs Round Table Discussion on the Changing Face of R&D
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Good morning everyone. It's a pleasure to represent Sanofi and our peers in the research-based pharmaceutical industry.

I would like to thank Greg D'Avignon and the BBCA (Business Council of British Columbia) for including me in this event.

Over the decades our industry has conquered a lot of new territory in healthcare.

We have discovered and brought to market products that give people back their health, allow them to hold jobs and enjoy life with their families.

Historically, the pharma industry has made these things possible, and enjoyed great success, by building robust internal R&D organizations and investing heavily in the discovery of chemical entities (small molecules) to treat disease.

Many of these products become blockbusters, household names that proved very effective in treating large segments of the population.

This approach led to a lot of very tangible improvements in people's lives.

The death rates for many prevalent conditions (cardiovascular disease, HIV and asthma) have been reduced over the last 30 years thanks in large part to pharmaceutical interventions. For example, pharmaceutical interventions have helped to reduce the death rate from heart disease by 74%, and from HIV/AIDs by 78%.

As successful as it was in the past, our old R&D model is no longer productive as it once was. Successful blockbusters are harder than ever to replace. Companies have been investing more and more in R&D, but fewer products are actually reaching the patient.

It now costs $1 billion and takes from 10 to 12 years to bring a product to market. Our industry association estimates that only 1 in every 5,000 molecules studied ever makes it to market.

Drug discovery is becoming more complex. Thanks to a better understanding of genotypes and biomarkers, we are now able to link treatments to genetically homogenous patient groups.

This is a first step towards personalized medicine in which therapies are tailored to the individual patient.

These technologies are leading to a major shift in focus – away from "one-size-fits-all" blockbusters towards drugs for smaller, more targeted patient populations. It holds great promise for patients and our industry, but it is making our mission more complicated.

Regulatory environments are more challenging. Government agencies such as Health Canada and the FDA are taking longer to approve new drugs. They are also asking for more extensive proof of efficacy and safety. We are definitely in favour of efficacy and safety! But sometimes these demands can create a disconnect. For example: agencies asking for larger clinical trials involving more patients, when at the same time medical research is focusing on more personalized treatments for smaller populations.

The reimbursement environment is difficult. Cash-strapped governments are slow to cover the cost of new drugs and want to see ever more solid demonstration of value.

But their perception of "value" often remains narrowly focused on price alone and does not take into account the savings that innovative medicines can offer in other areas of the healthcare system. For example, a cardiology drug can save tens of thousands of dollars in hospital costs by preventing a single stroke.

Pharmaceutical R&D is evolving to meet these challenges. Let me tell you about some of the things Sanofi is doing.

1. In 2009 we completed a rigorous overhaul of the products in our development pipeline, keeping only the most promising targets.

2. We also consolidated research sites and restructured to focus on patient needs, entrepreneurship and autonomy.

3. We have begun to partner extensively with external companies.
We recognize that as R&D grows more complex, no one company can be an expert in everything. Since the beginning of 2009, Sanofi has signed more than 60 agreements with external parties. These agreements give us access to new technologies or strengthen our existing capacities in fields like diabetes, oncology and vaccines.

Our partners include leading biopharmaceutical companies, such as Regeneron (New York) and Zealand Pharma (Denmark). They include major universities such as Harvard and MIT. And here in Canada, about a year ago, we announced a partnership with Toronto's Sunnybrook Health Sciences Centre to develop a treatment for diabetic foot ulcers.

We now have a 70-30 ratio of internal to external research, and our global CEO recently said he'd like to get this to 50-50.

4. We are also trying to strike these partnerships earlier in the drug discovery process. Traditionally a smaller biotech company might have to spend 7 or 8 years on a new drug before they could find a major pharmaceutical partner willing to invest and help bring it to market.

In a partnership like this, a big part of the expertise provided by a company like Sanofi is what we call validation: evaluating drug candidates and predicting their future success. We're saying: let's bring our validation expertise onboard earlier. Find the promising candidates before 7 or 8 years have elapsed so we can work together to make the whole R&D process more efficient.

5. We are shifting our focus from the disease to the patient.
Traditionally, our R&D would target a disease, trying to understand it, then identifying a drug to manage or cure it. We did not take into account the patient's experience as a whole.

We're doing things differently now: taking patients' needs as a starting point, and coming up with solutions based on those needs.

Let me give you an example. Sanofi has been providing insulin to treat diabetes for 90 years. Over the decades we developed many new and improved types of insulin: making it easier to tolerate, longer-lasting, fast-acting.... These improvements made a great impact in people's lives but addressed only one aspect of diabetes management.

Today our expanded diabetes offering includes insulin injection pens, blood glucose monitors and, soon, a web-based platform to help people manage their blood sugar levels. The program includes free sessions with a health and wellness coach who will help patients make changes in their daily routine to be successful with their health-related goals.

This approach goes well beyond insulin by empowering people to take charge of their disease. And taking charge of diabetes is critical: to protect patients against cardiovascular disease, blindness and amputation, and to spare the healthcare system the high cost of treating these devastating complications.

6. We will start talking to decision-makers and stakeholders about new products earlier in the process. This is another way to ensure our R&D has relevance and delivers tangible healthcare solutions. Whether it's clinical trial design or the management of potential side effects, we need to create a broader understanding and coordinated approach to the challenges we share. We will invest more effort in proving the value of our offerings in Canada, not just on traditional R&D end points of safety and efficacy.

I was asked to talk about what these changes mean for British Columbia. From our industry's point of view, I'd say that B.C. is well poised to play a role in today's R&D environment.

1. B.C. is home to many innovative organizations like Genome BC, the Centre for Drug Research and Development, the Michael Smith Foundation, and the Genetic Pathology Evaluation Centre – an organization to which Sanofi has contributed over $2 million in recent years.

2. Some of Canada's brightest and best-trained scientists and universities are located here – and they are excellent ambassadors for B.C. at international research events and with companies like Sanofi.

3. Your healthcare system has generated robust and comprehensive databases that could prove invaluable in studying the full impact of drugs once they are launched on the market, or in recruiting appropriate patients for clinical trials.

4. This would be a great area for collaboration between BC's medical researchers and its very strong local IT experts.

5. And finally, we sense a willingness to work with the research-based pharma industry to help British Columbians by improving their access to new medicines and by attracting further research investments – something that's good for healthcare, jobs and the economy.

All in all, I think that B.C. is very well positioned to play a role in the shifting R&D landscape.