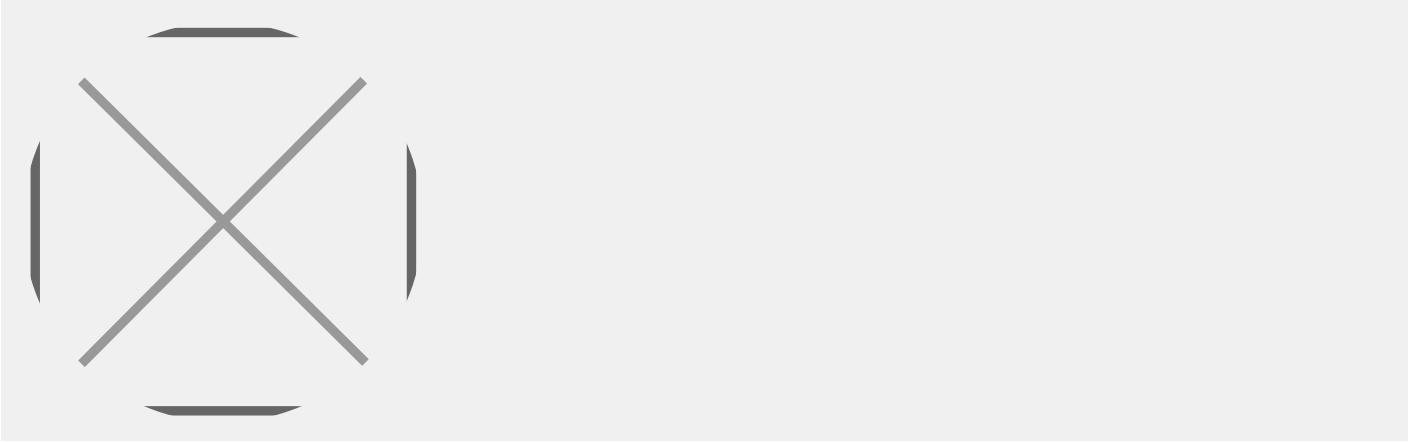
Interview: Kevin Leshuk, Vice President & General Manager, Celgene Inc.



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Kevin Leshuk, Vice-President and General Manager of Celgene in Canada, offers his critique of the Canadian reimbursement and approval process as well as the advantages his affiliate enjoys in specialty pharma using Canada's strong clinical base.

What do Canadian biopharmaceutical companies offer as a competitive edge?

I believe we have two standout strengths. Our operating environment with centers of academic and clinical excellence allows us the ability to leverage clinical trial activity to generate significant numbers of patients and to positively contribute to global patient access. In addition, Canada has a well-trained, experienced and resourceful pool of talent that effectively supports Canada's public support of biotechnology.

How does the lack of an orphan drug act in Canada impact Celgene's operations in terms of getting products into the marketplace?

The lack of a formalized orphan drug designation in Canada highlights us as a laggard country compared to other countries where most if not all have some form of recognized orphan disease policy. This needs to change. Companies, including Celgene, looking to invest in Canada see this as a significant barrier to new and future research. In addition, though there have been advances in the formalization of a policy, in the end it must be in tandem with formal funded access in order for it to truly benefit patients. If Canada only improves the front end through R&D incentives or tax

credits without focusing on the intellectual property and reimbursement components then we are not truly improving the future for patients living with rare diseases.

Should Canada focus on innovation or imitation?

You need investment in innovation both at the clinical level and in gaining appropriate public access for innovative therapies. Medical innovations have created worldwide improvements in the general health state, which explains shifts in overall survival and quality of life for millions of patients suffering from many diseases. The industry and governments at large must continue to find ways to collaborate and actively support new innovation efforts. Focus on the generic environment should capitalize on the monies saved from off-patent products, which can be reinvested back into the innovative system. This is one very tangible way of creating a sustainable, virtuous cycle of research investment and access to medication while still being fiscally responsible.

Celgene operates 300 clinical trials worldwide. What portion of that is represented in Canada?

Canada has consistently represented around 10 percent in terms of Celgene's patient contribution in active clinical trials. The Canadian affiliate therefore consistently punches above its weight. This focus has resulted in locally active clinical trials for multiple myeloma, MDS, AML, CLL, breast and pancreatic cancer along with other solid tumors. These will continue along with studies in immune inflammatory diseases including psoriasis and psoriatic arthritis.

To what extent does Celgene Canada participate in consumer education?

Our approach is to work closely with patient education organizations to provide them with what they feel is in the best interest of their communities. Groups like Myeloma Canada or the Arthritis Society educate and create awareness among their patient populations, which is the best way as "direct to consumer" is not appropriate nor allowed in Canada.

To what extent do partnerships or licensing agreements play a role in Celgene Canada?

Celgene's Corporate has a very active business development team that ensures we are identifying partners or making acquisitions of new molecules that will satisfy global disease and patient needs. Canada's fundamental role is to ensure that any drug ultimately becomes publicly available through the regulatory and reimbursement processes. Upfront, Celgene's business development team is aware that Canada is a core country and this ensures we have the opportunity to participate early in drug development and commercialization activities.

What is the strategic importance of Celgene Canada to the entire organization?

The Canadian environment is very representative of the European market, yet has strong social and business ties with the United States so we are in a unique strategic position. As a result, Canada has been a major contributor to many of the most significant Celgene clinical programs. Canada is recognized internally as a core country so we have the very real opportunity to contribute meaningfully to the organization as it advances clinical and commercial programs worldwide.

Could Celgene Canada, given its importance, act as a role model for other affiliates in Europe?

Yes, that is our operational attitude. I think we are able to bring an important perspective because we have a very complex yet manageable regulatory and reimbursement environment that includes a strict regulator along with risk-adverse public and private payers. How we behave and lead in these diverse areas can inform other markets on how best to advance important value discussions.

Celgene's tagline is "committed to improving the lives of patients worldwide". How is that demonstrated here?

"Focus on the patient" is one of Celgene's hallmark values. From our very first day, every decision we have made has internalized and addressed the impact on the patient. Celgene Canada supports one of the most extensive compassionate programs within the country to ensure that the right patient gets the right drug hopefully at the right time.

In addition, we have been successful in supporting the Canadian academic and clinical community such that the data from locally implemented trials have been used effectively worldwide for regulatory and reimbursement approvals.

What does Canada need to do to make itself more attractive?

We are politically and economically an attractive market with huge upside opportunities available; however, we need to modernize and improve our Intellectual Property policies. We need policies that value and reward enhanced investment in Canada which are supported by progressive provincial and private reimbursement practices.

What attracted you to Celgene and what were the initial challenges in founding a new affiliate?

Celgene’s unique blend of science, core values and focus on the needs of patients was very appealing to me. These traits, along with .the opportunity to build the Canadian organization from the ground up, were something I could not ignore.

There were many challenges, but the few that stand out were overcoming the early regulatory hurdles, particularly in the area of pricing and reimbursement; and recruiting top employee talent. Canadians are relatively risk-averse so without an established product portfolio many individuals were concerned with the risks associated with moving from an existing organization to a biopharma startup.

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