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ASIA EDITION

Jeffery Bacha: DelMar targets orphan cancer drugs

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DelMar Pharmaceuticals was founded in 2010 to rapidly develop and commercialize proven cancer therapies in new indications where patients have developed resistance to the currently available therapies. The company is developing new drug candidates targeting orphan cancer indications. VAL-083 is the first product of the company that benefits from the investment of more than $50 million by the National Cancer Institute (NCI) in the US. VAL-083 is approved as a cancer chemotherapeutic in China for the treatment of chronic myelogenous leukemia and solid tumors, including lung cancer.

On October 29, 2012, DelMar collaborated with China-based Guangxi Wuzhou Pharmaceutical for the development of VAL-083 which is also known as "DAG for injection". Guangxi Wuzhou is licensed by the Chinese State Food and Drug Administration (SFDA) to manufacture and sell VAL-083 in China. BioSpectrum talks to Mr Jeffery Bacha, president and CEO, DelMar Pharmaceuticals, about this latest development and company's expansion in China.

Please tell us about your collaboration with Guangxi Wuzhou and how both will contribute towards this partnership?
The strategic collaboration between DelMar Pharma and Guangxi Wuzhou Pharmaceutical will benefit both partners. We will use new data being developed through DelMar's clinical programs to expand the market in China where VAL-083 is currently approved as a cancer chemotherapy for the treatment of chronic myelogenous leukemia (CML) and lung cancer.

We will work together to seek regulatory approval for the drug in multiple indications on a global basis, including new

indications such as brain cancer and other solid tumors. DelMar gains an exclusive supply, development and commercialization arrangement with the only current manufacture of VAL-083 drug product in the world. We will work together to ensure that the product is manufactured, and meets product specifications to the highest global standard, including compliance with cGMP regulations of the US FDA, EMEA in Europe and SFDA in China.

The collaboration also provides DelMar with the opportunity to benefit patients, and capture near-term revenue through commercial activities in the Chinese market. We will also use this initial collaboration as the basis upon which to explore further opportunities to work together outside of China for VAL-083 and potentially other products.

What role does DAG play towards cancer treatment?
VAL-083 is a novel alkylating agent. It works against cancer cells by interrupting DNA replication causing the tumor cells to die. Research on the drug was originally conducted at the National Cancer Institutes (NCI) in the US during the 'original war on Cancer' in the late 1970s and 1980s. There are more than 40 clinical publications from this original US-based work, supporting activity against multiple tumor types including leukemia, solid tumors such as lung cancer and central nervous system tumors such as glioblastoma multiforme (GBM), which the most common and aggressive form of brain cancer.

Are you planning to take VAL-43 outside China to other markets? If yes, then which markets are you targeting?
Yes we are planning to take VAL-43 outside China. Based on the activity from the previous NCI work, we have initiated new human clinical trials with VAL-083 as a potential treatment for refractory GBM. GBM is the aggressive form of brain cancer that claimed the lives of former Senator Ted Kennedy and former NY Mets star Gary Carter.

New research conducted by DelMar Pharmaceuticals demonstrates that VAL-083 maintains its activity in spite of drug-resistance mechanisms that cause many patients tumors to become resistant to the leading chemotherapy against GBM. We began treating patients whose tumors are resistant to other therapies with VAL-083 under an investigational new drug (IND) application filed with the US FDA. We initiated the study in 2011 and will present initial clinical findings at the Society of NeuroOncology meeting in Washington DC on November 16-17, 2012.

We eventually plan to initiate additional clinical trials in North America, Europe and Asia to evaluate the potential VAL-083 as a treatment against a number of cancers. In China, we will initially be focusing our initial commercial activities on CML and lung cancer, which are the two types of cancer for which VAL-083 is approved in China. We also plan to work toward expanding the approval to include other cancers such as GBM.

What made you choose Guangxi Wuzhou Pharmaceutical as a partner?
Guangxi Wuzhou Pharmaceuticals is the sole license holder from the Chinese State Food and Drug Administration (SFDA) to manufacture VAL-083 for the treatment of lung cancer and leukemia. They have also been the supplier of the drug product for DelMar's clinical trials in the US.

Over the past two years, we have been working closely with Guangxi Wuzhou Pharmaceutical on an informal basis as our drug supplier. This collaboration formalizes the relationship between our companies to work together to maximize the global potential for VAL-083 to benefit cancer patients and create shareholder value.

How important is this collaboration to DelMar?
The collaboration with Guangxi Wuzhou Pharmaceutical is important to DelMar Pharma for several reasons. It provides us with a near-term opportunity to benefit patients, and generate revenue, from our North American-based research in the Chinese market where the drug is already approved as a cancer chemotherapy for CML and lung cancer.

The partnership also provides us with funding from our partner to support future clinical research that we may conduct in China. It provides us with an exclusive relationship with the only manufacturer of the VAL-083 drug product in the world.

What is your take on the market in the Asia Pacific region and how are you planning to tap this market?
The Asia Pacific region represents a rapidly growing market for cancer therapies based on increasing incidence of major cancer types such as lung cancer; improved diagnostics and access-to-care; and a growing middle class with the financial resources to support the entry of modern drugs into the region. For example, in 2011, the Chinese pharmaceutical market grew by more than 25 percent as compared to six-to-seven percent in the US and Europe, and the dragon nation is set to become the second largest pharmaceutical market behind the US by 2020.

In general, our strategy for tapping the Asia Pacific market is based on the following general concepts. Firstly, we use VAL-083's unique mechanism. DelMar's data suggests that VAL-083 has the potential to benefit CML and lung cancer patients that are failing main-stay drugs in those indications known as tyrosine kinase inhibitors (TKIs).

TKIs such as Gleevec in CML and Tarceva in Lung Cancer benefit millions of patients world-wide every year, but recent research shows that the resistance to TKIs in patients of East Asian decent is higher than in Europe or North America due to unique mechanisms of resistance that are highly prevalent in these populations. DelMar is developing new data demonstrating that VAL-083 will benefit these patients, which will allow physicians to prescribe the medication in a new way and rapidly expand the current market.

Secondly, we are looking to leverage activity against resistant tumors to expand beyond China. Based on success in China, we will seek regulatory approval in additional Asia Pacific countries where similar mechanisms of TKI resistance are prevalent.

Importantly, we are seeking additional collaborations with a marketing partner with an existing oncology sales infrastructure in China in order to most efficiently and rapidly use DelMar's new data to tap the China market opportunity. Ideally, this partner will also have regulatory expertise and marketing infrastructure throughout the Asia Pacific region too.

What are the future goals of the company?
Overall, our goal is to benefit patients and build shareholder value by rapidly developing and commercializing proven chemotherapies in new cancer indications. We will invest in therapies where the mechanism of action suggests the potential to benefit patients who are failing other treatments. We have initially focused on VAL-083, but over time, we will seek to expand our pipeline in order to include new drug candidates that meet these criteria.