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Arena CEO: Our drug curbs hunger, obesity

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Arena Pharmaceuticals, a US-based biopharmaceutical company focused at discovering, developing and commercializing novel drugs for weight management, cardiovascular disease, inflammation and other disorders, has made significant developments in the year 2012.

In June 2012, the US FDA approved the company's internally discovered drug Belviq (lorcaserin HCL), which is currently under review for marketing approval in the European Union and Switzerland. Belviq is believed to decrease food consumption and promote satiety by selectively activating serotonin 2C receptors in the brain. Activation of these receptors helps a person eat less and feel full after eating smaller amounts of food.

In November 2012, the company entered into a marketing and supply agreement with IIdong Pharmaceuticals for Belviq. Under the terms of the agreement, Arena granted Ildong exclusive rights to market and distribute Belviq in South Korea, subject to regulatory approval of the drug by the Korea Food and Drug Administration (KFFDA).

Mr Jack Lief, president and CEO, Arena Pharmaceuticals, speaks with BioSpectrum about the company's latest partnership with Ildong and how the company is going forward to introduce this drug in other markets.

Could you please tell us in detail about Belviq?
Belviq is a novel single agent discovered and developed by Arena that selectively targets specific receptors (5-HT2C) in the brain to decrease food intake in combination with a reduced calorie diet and exercise. The clinical trial program for Belviq was initiated in 2004, with Belviq achieving FDA approval in the US in June, 2012.

Patients on Belviq in pivotal phase III studies achieved clinically meaningful weight loss and improvements in important cardiovascular and metabolic parameters in a well-tolerated manner. Patients who completed one year of Belviq treatment lost an average of approximately eight percent of their weights.

What is the market size that you are planning to tap through Belviq?
Worldwide, there are more than 1.4 billion overweight and obese adults who may benefit from Belviq. We are focused on effectively commercializing Belviq around the world through strategic marketing and supply collaborations in order to provide physicians and patients with a new tool for successful chronic weight management.

What made you choose South Korea to launch this drug in Asia rather than other countries in the region?
In terms of the market opportunity for South Korea, the country is among the top 15 pharmaceutical markets in the world and has a significant overweight and obese population. Approximately one-third of the adult population in South Korea is classified as obese, which is locally defined as a BMI greater than or equal to 25.

In addition, we feel strongly that Ildong Pharmaceutical, one of the country's leading pharmaceutical companies, would be the right collaborator for Belviq. Though South Korea is the first agreement we've established in Asia, we are also pursuing commercial strategies in other countries.

What is the price at which Belviq will be available to patients in South Korea?
It is too early to speak about pricing in South Korea. At this point, Ildong is targeting a late 2014-to-early 2015 launch of Belviq.

Could you please share with us the highlights of you agreement with Ildong Pharmaceutical?
Under the agreement, we will receive an upfront payment of $5 million from Ildong and an additional $3 million upon the approval of Belviq by the Korean FDA. Ildong is responsible for the development, regulatory approval and, ultimately, marketing and distribution of Belviq in South Korea, including all related costs and expenses.

We will manufacture Belviq at our facility in Switzerland, and sell finished product to Ildong for a purchase price starting at 35 percent of Ildong's annual net sales. The purchase price will increase on a tiered basis up to 45 percent on the portion of annual net sales exceeding $15 million.

What is next from Arena Pharmaceuticals?
We are currently focused on working with our partner Eisai to launch Belviq in the US early in 2013. In addition, we are independently pursuing approval of Belviq in Europe.

Beyond Belviq, we are focused on the continued advancement of our pipeline of internally discovered drug candidates. We recently initiated dosing in a phase I multiple dose clinical trial of APD811, which is intended for the treatment of pulmonary arterial hypertension (PAH). Beyond APD811, other prioritized programs include APD334, our S1P1 receptor agonist for the treatment of autoimmune diseases, which we expect to evaluate in a phase I clinical trial in the first half of next year, and APD371 - our CB2 receptor agonist intended for the treatment of pain that is in the final stages of preclinical development.

How important is the Asia Pacific market for Arena? What are the strategies in place to tap the Asia Pacific market?
We see a great deal of potential for Belviq to address the unmet needs of the millions of overweight and obese individuals in Asia Pacific. We continue to evaluate and pursue strategic collaborations that support Belviq's development, approval and commercialization in territories worldwide, including Asia Pacific.