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Physician Views: Can Intarcia's Implantable GLP-1 Treatment Revolutionise the Diabetes Market?

https://marketpublishers.com/r/P31ADCF0010EN.html
Date: April 2015
Pages: 0
Price: US$ 695.00 (Single User License)
ID: P31ADCF0010EN

Abstracts

Intarcia has previously suggested that it is the highest-valued privately owned biotech company in history. This claim is heavily built around the potential success of ITCA 650; a matchstick-sized, subcutaneous osmotic mini-pump designed to secrete the GLP-1 agonist exenatide (the active ingredient in AstraZeneca's Bydureon) in patients with type 2 diabetes over a period of up to one year.

The company is not alone in its bullish assessment of ITCA 650, having last week raised financing worth $225 million from a group of investors who in return will receive a 1.5 percent royalty on future global net revenues of the product.

The financing package follows an ex-US licensing deal for ITCA 650 signed with Servier last year, through which Intarcia received a $171 million upfront payment, with a further $880 million folded into future development, regulatory and sales milestones.

Furthermore, data from two Phase III studies assessing ITCA 650 versus placebo were met with some encouragement from key opinion leaders (KOLs) interviewed by FirstWord's Therapy Trends team in November last year.

The FREEDOM-1 study demonstrated that ITCA 650 was significantly superior to placebo for both 40 mcg and 60 mcg doses and met all its clinical endpoints, while pre-specified sub-group analyses showed substantial improvement in hyperglycaemia across a wide spectrum of patients and background medications. The FREEDOM-1 HBL (High Baseline; patients with very high baseline HbA1c levels of between 10-12 percent) study showed a sustained reduction of 3.4 percent in HbA1c among these poorly controlled patients. The HBL study also showed ITCA 650 could bring 25 percent of these patients, many uncontrolled on multi-drug therapy, to their HbA1c goal of less

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than 7percent after 39 weeks.

One KOL told FirstWord 'these data look very good. The efficacy is there, the side effects are not bad, and it probably has a role in managing patients with diabetes who don't like to inject so often.' While GLP-1 agonists will continue to play a key role in the treatment of diabetes, however, the KOL suggested that a product such as ITCA 650 would likely find use in only a niche population.

The valuation that investors appear to have placed on ITCA 650 would suggest that the mini-pump is not viewed by everyone as only having niche potential; as another KOL noted, many physicians in the field are likely holding judgement on the opportunity that ITC 650 potentially represents until head-to-head Phase III data versus Merck & Co.'s DPP-4 inhibitor Januvia are announced later this year.

To better ascertain the potential commercial opportunity for ITC 650, and where it could be positioned within the GLP-1 agonist landscape, we are asking EU5 and US-based endocrinologists…

How impressive they consider the FREEDOM-1/FREEDOM-1 HBL data to be?

If ITCA 650 was to demonstrate superiority to Januvia in ongoing Phase III studies, and taking into account the nature of the mini-pump device, what role they would anticipate for the product when launched?

What level of growth they anticipate in GLP-1 usage over the next decade (based on currently available products and current treatment trends)?

Assuming that ITCA 650 reaches the market (supported by positive head-to-head data versus Januvia), what negative impact the subsequent launch of an oral GLP-1 agonist would have on usage of a subcutaneous mini-pump device such as ITCA 650?

How much it would increase their confidence in prescribing a subcutaneous mini-pump device for the treatment of type 2 diabetes if it was marketed/endorsed by one of the leading current diabetes manufacturers?

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