PharmaRoth Looks Abroad With Type 2 Diabetes Product After NDI Notification Decision

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FDA's decision that **PharmaRoth Labs. Inc.**'s *Sucanon* "oral treatment" for type 2 diabetes is not a dietary ingredient steers the firm to prioritize selling the product outside the U.S.

PharmaRoth on March 17 announced that in response to the firm's new dietary ingredient notification for Sucanon as a nutraceutical, FDA said the substance is not a dietary ingredient and is not appropriate for use in nutritional supplements marketed in the U.S.

Instead, PharmaRoth would have to go through the rigorous investigational new drug application process before distributing Sucanon in the U.S. Diabetes drugs in particular must be supported by extensive evidence of safety - including large trials ruling out cardiovascular risk (*"Will CV Verdicts For* Onglyza, Nesina *Cause FDA To Change Its Tune On Antidiabetic Safety?" – "The Pink Sheet," Sep. 9, 2013*).

FDA's decision was "a very positive thing for the product going forward." As a drug designation for Sucanon has "large beneficial implications on an international level." – PharmaRoth

PharmaRoth filed an NDI for Sucanon in March 2013, when it also changed its name from **Fero Industries** and moved its headquarters from Calgary, Alberta, to Las Vegas. **Biotech Holdings Ltd.**, of Vancouver, British Columbia, originally developed Sucanon as an insulin sensitizer and sold the ingredient to Fero in 2010.

According to its release, PharmaRoth holds the intellectual property and exclusive worldwide rights for the production, marketing and distribution of Sucanon, which the firm says is "an oral treatment for Type-II diabetes" and a member of a class of diabetic medications called insulin sensitizers.

According to Biotech Holdings, insulin sensitizers lower blood sugar by increasing muscle fat and the liver's sensitivity to insulin. The product is a mix of tricosanthis, a natural dried root ingredient, and a synthetic kamagra jelly derived from the light metal molybdenum.

Since acquiring the product, PharmaRoth has sold Sucanon in Mexico at retail. The firm's website says U.S. consumers can obtain the product and have it delivered from Mexico under FDA's personal importation guidelines.

Following FDA's decision that Sucanon is not a dietary ingredient, bringing the product over the border no longer is permissible, said Michael Irving, who handles investor relations for PharmaRoth as an executive VP at Lake Mary, Fla.-based business-management consultancy Paramount Advisors LLC.

However, a website unaffiliated with PharmaRoth continued through March 19 to make available for sale a product branded as Sucanon and claiming to help treat type 2 diabetes. The site includes a statement that consumers in the U.S. and Canada can buy up to three-month supplies.

Can Only Go Up From Here

PharmaRoth said following FDA's decision it will focus on international development, particularly in Latin American markets, noting that U.S. expansion was not a major part of its business plan.

Sucanon was approved as a pharmaceutical in China and Peru and for over-the-counter sale in Mexico under Biotech Holdings' backing, and PharmaRoth has submitted the product for review in two other countries, the firm said.

PharmaRoth shares were trading at 2 cents the day the firm announced the FDA decision before reaching zero on March 18, and the firm currently is worth about $3 million. However, PharmaRoth expects to be well-positioned for a buyout after sales ramp up and valuation increases.

"We've worked way too hard to sell out at this valuation," Irving said in an interview.

Therapeutic Space Holds Promise

In a statement, PharmaRoth said FDA's decision was "a very positive thing for the product going forward" because it means Sucanon is powerful enough to be considered a drug. A "drug designation" has "large beneficial implications on an international level," the firm said.

In submitting an NDI notification for the product in the U.S., the firm said that it expected to sell Sucanon as a consumer health supplement via infomercials with no claims, "a revenue stream that every small company would appreciate," said Irving.

FDA's decision, while eliminating the consumer health market for the product, provides some validation that could help PharmaRoth gain traction in the therapeutic space, Irving said. Nutraceuticals are sometimes viewed with skepticism, and FDA's decision "removes that stigma permanently" for Sucanon, Irving said.

Food and drug lawyer Rick Collins, a partner at Collins, McDonald & Gann P.C. in Mineola, N.Y., noted that being denied in the NDI notification process still leaves PharmaRoth an attractive though more costly option for growing its business in the U.S.

"On the one hand you could see it as making lemonade out of lemons, but on the other hand what we're talking about could be a treatment for type 2 diabetes, which from a pharmaceutical perspective could be huge money," Collins said in an interview.

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"The investment would be much higher, but the potential return would be much higher," he added.

PharmaRoth believes the ingredient has a competitive edge for type 2 diabetes patients, despite many available approved pharmaceuticals from multiple drug classes, and that it will focus on the large market of people with pre-diabetes.

Other insulin sensitizers are members of the glitazone class, notably **GlaxoSmithKline PLCGlaxoSmithKline PLC**'s *Avandia* (rosiglitazone) and **Takeda Pharmaceutical Co. Ltd.**'s *Actos* (pioglitazone). Avandia has been associated with heart failure while Actos has been linked to bladder cancer ("Avandia *Panel Wants Another Trial: Pipe Dream Or Post-market Benchmark?*" – *"The Pink Sheet," Jun. 17, 2013*). Collectively, diabetes classes have been associated with risk for CV risk, pancreatitis, liver toxicity, cancer and urinary tract infection, among other adverse events (*"AstraZeneca's* Farxiga *Label Includes, But Downplays, Bladder Cancer Risk" – "The Pink Sheet," Jan. 13, 2014*).

Irving said pharma insulin sensitizers "work too, they just have side effects. We don't."

However, PharmaRoth acknowledges information about Sucanon's profile is limited and the clinical trials dataset available for the product is much smaller than pharmaceuticals' datasets.

The most recent data for Sucanon were presented at the 2013 meeting of the European Association of the Study of Liver Disease in September in Vienna. In a 12-week, single-arm study of Hispanic obese, pre-diabetic patients, Sucanon reduced hemoglobin A1c from 6.2 to 5.6.

From baseline HbA1c ranging between 5.7 and 6.4, 81% of participants reached the clinical target of 5.7 after 12 weeks of treatment. Also, body mass index dropped from 32.3 to 30.4, a numerical though not statistically significant result. Investigators reported no changes in liver tests and no edema. No other adverse events were reported in the abstract.

PharmaRoth's website also cites a 370-patient double-blind randomized type 2 diabetes trial against the sulfonylurea gilbenclamide in China. Sucanon was effective for blood-sugar lowering in that trial, and no adverse events from the study were reported.

A section on toxicity on the clinical studies section of Fero's website cites animal studies. No carcinogenicity, mutagenicity or teratogenicity was reported in mice studies. And in dog and rat studies, "chronic dosing at 2,000 times the therapeutic dose was free of toxicity."

"We think the status of safety feature will put us front and center as the first product prescribed," Irving said.

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