

Clock ticking for Lexicon to deliver licensing deal



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It was clear from the surge and swift pullback in Lexicon Pharmaceuticals' share price yesterday that the data the drug developer released were not what investors were waiting for. The trial of its lead product might have generated some encouraging signals in type I diabetes, but it is a deal that the company really needs to deliver.

LX4211 is a dual-acting SGLT1/2 inhibitor that Lexicon believes has advantages over other drugs in the class. The company's \$800m market cap is largely based on the assumption that a big partner will appreciate this potential, and hand over big bucks for commercial rights (see table below). But with the two-year anniversary of phase IIb data approaching, the apparent lack of interest in the product should be ringing loud alarm bells.

Empty promises

Lexicon yesterday announced data from a small study testing LX4211 in 33 patients with type I diabetes who rely on daily insulin injections. The four-week trial, which was double blind and placebo controlled, found a significant reduction in mealtime insulin use in patients who were given the drug compared with those in the control arm. Secondary measures were also successful: patients on LX4211 showed significantly improved glycaemic control without any increase in dangerous hypoglycaemic episodes.

For patients destined to take insulin for the rest of their lives, any drug that can reduce this burden while improving blood sugar control would be considered a big step forward. Lexicon executives said the results justify taking the product into late-stage phase III development, and no doubt feel they validate the company's desire to play a bigger role in type I diabetes under any partnership deal.

Leaving the much bigger type II subset to a richer interested party certainly sounds sensible. However the split of any partnership deal is moot until Lexicon can prove that the product has value in the eyes of a more powerful player. And aside from verbal reassurances, it has so far failed to do this.

Chief finance officer Jeff Wade told investors on a conference call yesterday that talks are continuing and that "we continue to feel that those are going well". He also added that the development programme for type I would be of a different scope to type II, and is "something that we feel like that we could do if we chose to do that". Considering the lack of options for these patients, the drug could be eligible for fast-track status from the FDA, the company also suggested.

Losing appeal

Because of the risks involved in pushing on alone - and the signal that this would send - neither the company nor its investors will be hoping that this comes to pass. So once again, investors must sit tight and wait. Which has essentially been the message since June 2012, when the company first unveiled data in type II diabetics ([Lexicon hopes data not words will win a partner, June 27, 2012](#)).

Since then, the class has largely overcome concerns that tolerability issues would prevent approvals and uptake, and the table below shows that products that have already made it to market are projected to become successful diabetes medicines. With LX4211 many years behind and the pipeline full, its commercial position has weakened.

As *EP Vantage* argued previously, there are big diabetes players out there without an SGLT2 inhibitor, like Sanofi, who might theoretically be interested ([Lexicon could define Sanofi as the ideal diabetes partner, March 5, 2013](#)). But the time and effort still needed to bring LX4211 to market, even if it does have advantages over other more specific candidates in the class, may make the practicalities of its development unattractive.

With \$129m in the bank at year end, enough to last well into 2015 if it does not pull the trigger on in-house phase III trials, Lexicon can afford to wait for now. But the longer the wait the less likely it is that a big partner will ever emerge.

SGLT inhibitors on the market and in development

Current WW Phase	Product	Pharma Class	Company	WW sales 2018e (\$m)
Marketed	Invokana (canagliflozin)	SGLT2 inhibitor	Johnson & Johnson	1,951
Marketed	Farxiga/Forxiga (dapagliflozin)	SGLT2 inhibitor	AstraZeneca/Ono Pharmaceutical	993
Filed	Empagliflozin	SGLT2 inhibitor	Boehringer Ingelheim/ Eli Lilly	753
Approved (Japan)	Suglat (ipragliflozin)	SGLT2 inhibitor	Astellas Pharma	149
Phase III	Ertugliflozin	SGLT2 inhibitor	Pfizer/Merck & Co	90
Filed (Japan)	Luseogliflozin	SGLT2 inhibitor	Taisho Pharmaceutical	89
Phase II	LX4211 (sotagliflozin)	SGLT1/2 inhibitor	Lexicon Pharmaceuticals	70
Approved (Japan)	CSG452 (tofogliflozin)	SGLT2 inhibitor	Chugai Pharmaceutical/Sanofi	-
Phase II (On-going status unclear)	LIK066	SGLT1/2 inhibitor	Novartis	-
			Total	4,095

Source: EvaluatePharma

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