TiGenix NV (TIG.BR)

Company Update

August 27, 2015

TiGenix Reported Positive Pivotal Phase III data for Cx601 in Crohn's Disease; Achieved Primary Endpoint

Please click here for full report

On August 23rd, TiGenix (Euronext Brussels: TIG) reported topline data from the pivotal Phase III trial evaluating its lead product candidate Cx601, a cell therapy for the treatment of complex perianal fistulas in patients with Crohn's disease. The trial met its primary endpoint, as patients receiving a single dose of Cx601 achieved a significant increase in the rate of fistula closure at week 24 following treatment ($p<0.025$). Results from this trial will allow TiGenix to file a Marketing Authorization Application to the European Medicines Agency (EMA) in the first quarter of 2016, and an approval decision is expected in the second half of 2017. The Company is developing Cx601 for the US market and has received an SPA from the FDA for the Phase III trial that is expected to commence in the second half of 2016.

- **ADMIRE-CD Phase III Trial Meets Primary Endpoint.** TiGenix conducted a randomized, double-blind, placebo-controlled study of Cx601 in Crohn's disease patients with complex perianal fistulas.[1] 289 patients were recruited across 50 active sites in 7 European countries and Israel and were randomized 1:1 into treatment and control arms. Patients included in the trial were refractory to prior treatments for perianal fistulas such as antibiotics, immunosuppressant drugs, and anti-TNFα therapies. The primary endpoint was combined remission at 24 weeks following treatment, defined as closure of all treated external openings draining at baseline despite gentle finger compression. Closure of the fistula was confirmed using MRI. The intent-to-treat (ITT) population consisted of 212 subjects, equally split between treatment and placebo arms. Results indicate that 49.5% of Cx601-treated patients achieved a combined remission compared to 34.3% in placebo group ($p<0.025$). Treated patients were 44% more likely to achieve remission. Treatment-emergent adverse events and discontinuations due to adverse events were comparable between treatment and placebo groups. TiGenix is expected to present full efficacy and safety results at the 11th Congress of European Crohn's and Colitis Organization (ECCO) in March of 2016.

Analysts

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Market Data

Price	**$1.00**
Market Cap (M)	**$168**
EV (M)	**$142**
Shares Outstanding (M)	**168.2**
Avg Daily Vol	**976,249**
52-week Range:	**$0.55 - $1.07**
Cash (M)*	**$42.0**
Net Cash/Share	**$0.16**
Annualized Cash Burn (M)	**$15.0**
Years of Cash Left	**~2.5**
Debt (M)	**$15.6**

relevant values converted at 1.15 USD to 1 Euro
**pro forma*

Financials

FY Dec		2013A	2014A	2015A
EPS	H1	(0.12)A	(0.08)A	NA
	H2	NA	NA	NA
	FY	(0.21)A	(0.11)A	NA