Genticel SA (GTCL.PA)

Company Update

December 22, 2016

Genticel Announces Merger Agreement with Genkyotex

Please click here for full report

On December 22nd, Genticel (Euronext Paris: GTCL.PA) and Genkyotex (private) announced plans to merge. The combined Company will focus on developing Genkyotex's pipeline of NOX inhibitors, including lead candidate GKT831 for the treatment of fibrotic diseases and GKT771 for inflammatory conditions, and expects to launch a Phase II trial for GKT831 in primary biliary cholangitis (PBC) in the first half of 2017. The Company also plans to launch a Phase I study for GKT771 in healthy volunteers in the second half of 2017 and then pursue inflammatory pain as a lead indication for this molecule.

- **Merger Expected to Close in First Quarter of 2017**. Genticel has chosen to merge with a privately-held Swiss company, Genkyotex, in order to maximize shareholder value in the wake of a negative data readout for their lead candidate in a Phase IIb study. Under the terms of the deal, Genkyotex shareholders would receive 11.8355 new shares in Genticel for each share of Genkyotex contributed. Following the closing of this transaction, shareholders of Genkyotex would own 80% of the merged company. The merger is subject to the approval of Genticel shareholders, which will hold a general meeting in the first quarter of 2017.

- **Well-Capitalized to Fund Operations through Major Data Readouts**. Genticel and Genkyotex have stated that the combined company would have sufficient capital to complete a Phase II study for GKT831 in primary biliary cholangitis (PBC) and a Phase I trial for GKT771 in healthy volunteers. Final data from the Phase II study are expected in the second half of 2018, suggesting that the Company is well-capitalized through 2018.

- **Merged Company Plans to Develop Portfolio of NOX Inhibitors for Fibrotic and Inflammatory Diseases**. Genkyotex is a leader in NADPH oxidase (NOX) biology and is developing a portfolio of NOX inhibitors to treat fibrotic and inflammatory diseases. NOX enzymes are an interesting therapeutic target in light of their modulatory role on signaling pathways associated with a wide range of disease states. The expected pipeline following the merger is shown in **Figure 1**.

Analysts

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Market Data

Price	**$2.58**
Market Cap (M)	**$40**
EV (M)	**$30**
Shares Outstanding (M)	**15.6**
Avg Daily Vol	**403,440**
52-week Range:	**$1.34 - $7.14**
Cash (M)	**$12.8**
Net Cash/Share	**$0.66**
Annualized Cash Burn (M)	
Years of Cash Left*	**~2.0**
Debt (M)	**$2.5**

Currency values converted at 1 EUR to 1.04 USD

**Reflects expected years of cash left for merged company*

Financials

FY Dec		2014A	2015A	2016A
EPS	H1	(0.48)A	(0.41)A	(0.34)A
	H2	NA	NA	NA
	FY	(1.02)A	(0.80)A	NA

Figure 1. Development Pipeline for Fibrotic and Inflammatory Diseases

Drug	Mechanism	Stage	Lead Indication	Next Milestone
GKT831	NOX1/4 inhibitor	Phase II ready	Primary biliary cholangitis (PBC)	Launch of Phase II study in H1 2017
GKT771	NOX1 inhibitor	Preclinical	Inflammatory pain	Launch of Phase I study in H2 2017

Source: LifeSci Capital

The lead candidate, GKT831, is a NOX1/4 inhibitor in development for fibrotic diseases like PBC and non-alcoholic steatohepatitis (NASH). The merged Company expects to launch a Phase II study for GKT831 in PBC, an orphan liver disease, in the first half of 2017. Demonstrating proof-of-concept in PBC and then moving into NASH and/or other fibrotic diseases would follow the development strategy of many of the companies in this space. An interim data readout from this Phase II trial is expected in the first half of 2018, which will provide a preliminary look at the safety and efficacy of GKT831. The merged Company also plans to move GKT771 into Phase I development in the second half of 2017. GKT771 is a highly-selective NOX1 inhibitor with potential applications in treating a broad range of inflammatory conditions. The Company also has a portfolio of preclinical NOX inhibitors that are being evaluated for central nervous system (CNS), hearing loss, and oncology indications.

Expected Upcoming Milestones

- H1 2017 – Launch Phase II trial evaluating GKT831 in PBC.
- H2 2017 – Initiation of Phase I study for GKT771.
- H1 2018 – Interim results from Phase II trial in PBC.
- Q2 2018 – Final results from Phase I study for GKT771.
- H2 2018 – Final results from Phase II study evaluating GKT831 in PBC.
- Q4 2018 – Launch of Phase II study for GKT771.

Risk to Investment

We consider an investment in Genticel to be a high-risk investment. Genticel is a clinical-stage company with no history of commercializing a product. There is also risk that the planned merger will not be completed. Early indications of efficacy do not necessarily translate into positive clinical results. The Company may need to raise funds to support its programs, which could be dilutive to current shareholders. There are also regulatory risks, and the Company may not receive FDA approval for its candidates despite significant time and financial investments. Even if Genticel secures regulatory approvals, there is no guarantee that expectations of market penetration and sales will come to fruition.

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