

Biotechnology

ALNEV-FR - NXT

November 19, 2015

PA

Closing Price 11/18/2015

€0.69

Rating:	Buy
12-Month Target Price:	€4.00
52-Week Range:	€0.66 - €3.82
Market Cap (M):	22
Shares O/S (M):	32.1
Float:	74.8%
Avg. Daily Volume (000):	374
Dividend:	€0.00
Dividend Yield:	0.00%
Risk Profile:	Speculative
Fiscal Year End:	December

Total Revenues ('000)

	2015E	2016E	2017E
H1	€94A	€2,603	€5,114
H2	€150	€2,603	€5,114
FY	€244	€5,207	€10,227

Pretax Income ('000)

	2015E	2016E	2017E
H1	(€5,825)A	(€4,897)	(€4,886)
H2	(€6,050)	(€4,897)	(€4,886)
FY	(€11,875)	(€9,793)	(€9,773)

GAAP Net Income (loss) ('000)

	2015E	2016E	2017E
H1	(€4,870)A	(€4,897)	(€4,886)
H2	(€6,050)	(€4,897)	(€4,886)
FY	(€11,875)	(€9,793)	(€9,773)



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Neovacs S.A.

Buy

MedImmune MAb Is Paving the Way for Neovacs' Vaccine in Lupus

Summary

- The American College of Rheumatology (ACR) held its annual meeting in San Francisco (November 7-11), and interferon alpha (INFA) targeting approaches for halting systemic lupus erythematosus (SLE) were on display from both MedImmune (AstraZeneca [AZN-\$33.69-NR]) and Neovacs.
- As a reminder, SLE may be driven by the cytokine INFA turning on dozens of inflammatory genes that cause the flares and damage, thus SLE has a 'gene signature' we can quantify. Shutting down INFA signaling should then shut down the other genes (reversing the gene signature) and stop the inflammation (i.e flares). This may be the key to halting SLE.
- Neovacs' INFA-kinoid vaccine is the shotgun approach that knocks out all of the 13 INFA subtypes, effectively shutting down the INFA gene signature and thus SLE. INFA-K-treated patients (N=5/6) remained flare-free and gene signature-negative for more than four years (and are still going!). A global phase IIb study (N=166) is underway, with data expected in 1Q17.
- What should be exciting for Neovacs and its investors is what MedImmune presented: Phase II data (N=305) of its monoclonal antibody (MAb), anifrolumab, which does not target the INFA cytokine, but the INFA receptor (meaning it is the same pathway, knocking out the INFA driver of SLE). Anifrolumab shuts down the INFA gene signature, resulting in improved SLE disease severity scores ([abstract link](#)). In our opinion, this further validates Neovacs' INFA-K vaccine. However, like Humira and other MABs, anifrolumab will likely cost \$30K+ every year. Neovacs could treat SLE with INFA-K for just one year at a fraction of the cost, and, so far, the data look positive. Big Pharma should be watching Neovacs.

Details

Kinoid technology: Active immunotherapy. Cytokines are like mediators of the immune system, and can be overexpressed or abnormally released in autoimmune diseases, cancer, and allergies. Blockbuster anti-cytokine MABs targeting cytokines (like Humira, Remicade, and Avastin) are given as passive immunotherapy and have shown efficacy, but they have limits, specifically, the development of resistance. Kinoids avoid this problem by fusing inactivated cytokines with the immunogenic protein, KLH (keyhole limpet hemocyanin). Kinoids (like INFA-K) are injected into the patient as an active immunotherapy, inducing a polyclonal antibody immune response against the endogenous cytokine driving the disease.

INFA-K in SLE: A gene signature gives visibility. Where is POC in SLE? What is the target? What is the endpoint? It's a challenging indication. We now know that SLE is driven by INFA, the master regulator of inflammatory genes being turned on and causing tissue damage in SLE. In other words, INFA and, thus, SLE, have a "gene signature" and can be measured. The INFA-K phase I/II study showed that polyclonal MABs neutralize all subtypes of INFA, and the gene signature goes negative; it shuts off. Neovacs now has a target (INFA), a population (mild-mod SLE, INFA-gene-signature positive), and endpoints (immunogenicity, biomarkers, and improved SLE activity score). Most importantly, the company has visibility in the gene signature that may be a predictor of disease activity. MedImmune's anifrolumab phase II POC data show that blocking the INFA receptor has a similar effect to INFA-K in SLE (taking out INFA signaling). Thus, it stands to reason that MedImmune's progress with a MAB could be a predictor of the INFA-K phase IIb outcome. However, a cheaper vaccine, as opposed to a MAB, is more attractive from a commercial perspective. Combined, we believe that Neovacs' probability of success is significantly increased in the ongoing and upcoming phase II trials. Data expected in 1Q17...stay tuned.

DISCLOSURES

Neovacs S.A. Rating History as of 11/18/2015

powered by: BlueMatrix



Maxim Group LLC Ratings Distribution

As of: 11/18/15

		% of Coverage Universe with Rating	% of Rating for which Firm Provided Banking Services in the Last 12 months
Buy	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to outperform its relevant index over the next 12 months.	87%	47%
Hold	Fundamental metrics are currently at, or approaching, industry averages. Therefore, we expect this stock to neither significantly outperform nor underperform its relevant index over the next 12 months.	12%	20%
Sell	Fundamental metrics and/or identifiable catalysts exist such that we expect the stock to underperform its relevant index over the next 12 months.	1%	0%

**See valuation section for company specific relevant indices*

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Maxim Group makes a market in Neovacs S.A.

Maxim Group managed/co-managed/acted as placement agent for an offering of the securities for Neovacs S.A. in the past 12 months.

Maxim Group received compensation for investment banking services from Neovacs S.A. in the past 12 months.

Maxim Group expects to receive or intends to seek compensation for investment banking services from Neovacs S.A. in the next 3 months.

ALNEV-FR: For Neovacs, we use the BTK (Biotechnology Index) as the relevant index.

Valuation Methods

ALNEV-FR: Our therapeutic model assumes that INF α -K could be approved and launch for SLE in the U.S., Europe, and China in 2020. INF α -K approval for dermatomyositis follows in 2021 in the U.S. and Europe. We assume a high risk rate due to the early stage of development and the risk associated with any drug in development for SLE. Our model assumes that Neovacs will seek a partner for sales outside of Europe and receive a royalty stream. A 30% discount rate is applied to our free cash flow, discounted EPS, and sum-of-the-parts models, which are equally weighted to derive our price target.

Price Target and Investment Risks

ALNEV-FR: Aside from general market and other economic risks, risks particular to our price target and rating for Neovacs, Neovacs faces multiple risks including: (1) development – the products are in the early stages of development and may not be successful in current and/or future clinical studies; (2) regulatory – the FDA or EMA may not approve Neovacs' products.; the company's ongoing and future studies may not be sufficient to gain approval; (3) commercial – the company lacks the commercial infrastructure to support a product launch, if approved; and (4) financial – the company is not yet profitable and may need to raise additional capital to fund product development.

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Risk ratings take into account both fundamental criteria and price volatility.

Speculative – Fundamental Criteria: This is a risk rating assigned to early-stage companies with minimal to no revenues, lack of earnings, balance sheet concerns, and/or a short operating history. Accordingly, fundamental risk is expected to be significantly above the industry. **Price Volatility:** Because of the inherent fundamental criteria of the companies falling within this risk category, the price volatility is expected to be significant with the possibility that the investment could eventually be worthless. Speculative stocks may not be suitable for a significant class of individual investors.

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