“The Therapeutic Vaccines Company For The Functional Cure of HIV”
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Why Bionor Pharma
“The Therapeutic Vaccines Company For The Functional Cure of HIV”

Current HIV medication does not cure HIV and patients need life-long medication at an enormous cost

All preventive vaccines have failed so far - the focus on therapeutic vaccines for the a Functional Cure for HIV has intensified

Bionor Pharma has been in the therapeutic vaccine area for more than 10 years and has the largest pipeline in the industry within the HIV space

Bionor Pharma strongly believes that with its advanced therapeutic vaccine position in the HIV space can spearhead the development of a functional cure for HIV

Bionor Pharma’s peptide vaccine platform are poised for addressing other unmet medical needs within serious viral diseases

Bionor Pharma believes that its advanced vaccine position in the HIV space and the general platform in infectious diseases may drive value creation, partnering and exit optionality going forward
Bionor Pharma Outline of Presentation
The Therapeutic Vaccines Company For The Functional Cure of HIV

Overview of the HIV unmet need
- Patient Population
- Current treatment options
- The unmet need

Bionor Pharma’s HIV Strategy
- Addressing the unmet clinical need
- Pipeline and ongoing clinical studies
- Planned clinical studies

Milestones and Deliverables
- Key data available in 2014 & 2015

Summary and Value Proposition

“A Functional Cure will enable people to live long-term with no disease progression nor viral transmission in the absence of ongoing antiretroviral therapy”
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Bionor Pharma’s Primary Focus Area - HIV
Definitions & Sales of cART

- **HIV Infection** Infection with Human Immunodeficiency Virus

- **AIDS** Acquired Immune Deficiency Syndrome is the final stage of the disease leading to severe immune dysfunction and development of associated opportunistic infections

- **CD4 counts** Number of CD4+ T helper lymphocytes per mm$^3$ blood – normally above 1000

- **Viral Load** Number of virus particles (RNA copies) per ml plasma - less than 50 copies per ml considered optimal treatment – less than 1000 copies patient do not transmit the virus

HIV sales ($bn) in the US and five major EU markets, 2011–21

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CAGR = Compound Annual Growth Rate

CAGR 2011-17 = 3.6%
HIV Market
Overview of the Problem

- Total of 34 million HIV patients

- Despite access to lifesaving HIV medication new HIV infections in 2011 rose to 2.5 million people and AIDS deaths to 1.7 million people

- Providing long-term HIV medication to millions of people worldwide through public and private aid efforts is unlikely to be sustainable

- For every two people who start HIV medication today, it is estimated that three more are newly infected. “We will not be able to treat ourselves out of the epidemic”
The Conventional HIV Medication - cART

Existence of an Unmet Need - cART Does Not Cure HIV

- Treatment of HIV infection consists of combination antiretroviral therapy (cART)
- There are >20 approved cART drugs in six classes
- cART HIV Medication:
  - Effectively reduces viral load
  - It does not cure HIV, and must be taken daily for the rest of the patients life
  - If cART is discontinued, virus load rebounds rapidly
  - It does not destroy virus producing cells (latent infected reservoirs)

Graphics for illustration purposes only
Huge Unmet Need for a Functional Cure of HIV

Current HIV Care

- Daily administration burden on patients & long-term adverse effects
- cART compliance requirements – barrier to penetration
- Risk of development of viral resistance
- Cost of life-long treatment in the US is estimated to approximately $400,000 per patient
- Emergence of co-morbidities related to chronic HIV infection (cardiovascular diseases, chronic liver disease, reduced renal function, premature aging and cancers)

“A Functional Cure will enable people to live long-term with no disease progression nor viral transmission in the absence of ongoing antiretroviral therapy”
Bionor Pharma Outline of Presentation
The Therapeutic Vaccines Company For The Functional Cure of HIV

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- Bionor Pharma’s HIV Strategy
  - Addressing the unmet clinical need
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“A Functional Cure will enable people to live long-term with no disease progression nor viral transmission in the absence of ongoing antiretroviral therapy”
Bionor Pharma Positioning for The Functional Cure

Therapeutic Vaccines in HIV

- cART medication *does not cure* HIV or prevent its comorbidities and patients need life-long medication at an enormous cost
- The field is now turning towards the focus on a Functional Cure for people already infected
- Therapeutic vaccines has the potential to become the cornerstone in providing the Functional Cure
- Bionor has the largest pipeline in the industry within the HIV Space
- Bionor strongly believes that with its advanced therapeutic vaccine position in the HIV space can spearhead the development of a functional cure for HIV

“A Functional Cure will enable people to live long-term with no disease progression nor viral transmission in the absence of ongoing antiretroviral therapy”
The Effects of Vacc-4x - “The Kill”
The Furthest Advanced Therapeutic Vaccine in the HIV Space

- Vacc-4x educates the cellular immune system to kill virus producing cells

- Vacc-4x has undergone successful testing in several Phase II studies including a randomized, blinded and placebo controlled Phase II study in 135 patients where it exhibited a 64% statistically significant reduction in viral load in the treated group compared to placebo

- Benign safety profile

- Vacc-4x has the potential to become the backbone in a future Functional Cure for HIV

Vacc-4x - VIRAL LOAD REDUCTION

In phase II study: 64% statistically significant reduction of viral load after vaccination with Vacc-4x (logarithmic scale) Blue circles indicate vaccination

Graphics for illustration purposes only
Clinical Development Strategy
“The Therapeutic Vaccine Company for HIV”

- Primary focus of the development of therapeutic vaccines for HIV is the development of a Functional Cure for all HIV patients
  - Bionor Pharma launched its “Kick”, “Kill”, and “Boost” Strategy for providing for the Functional Cure of HIV at CMD in June 2013
  - Bionor Pharma is currently planning on combining our Vaccine Vacc-4x with an HDAC inhibitor as “The Kill” and “Kick” part of this strategy

- Development program also addresses:
  - Specific re-immunization focus with regards to monotherapy with therapeutic vaccine for HIV (Phase II Reboost Study with Vacc-4x)
  - Specific focus on improving outcome for late presenters/discordant patients (Lenalidomide & Vacc-4x Phase II Program)
  - Specific focus on HIV patients with HyperImmune Activation (Vacc-C5 Phase I/II Program)

Graphics for illustration purposes only. 50% of HIV patients estimated to be late presenters. 25% of HIV patients estimated to have persistent Immune Activation.
Bionor Pharma’s Kick, Kill and Boost Strategy

Bionor is “The Therapeutic Vaccine Company for HIV”

Bionor Pharma’s strategy for the Functional Cure is based on the “Kick”, the “Kill”, and the “Boost”

- The "Kick" constitutes the HDACi reactivations of the virus in latent infected cells
- The "Kill" is our Vacc-4x's training the cellular immune system leading to killing of virus infected cells
- The "Boost" is the stimulation of the immune system by lenalidomide to enhance the effect of Vacc-4x.
The Functional Cure – The Kick, Kill and Boost

ART + IMiD + Vacc-4x + HDACi

- **cART** Virus replication kept at minimum
- **IMiD – “Boost”** Boosting immune system
- **Vacc-4x - “Kill”** Efficient killing of virus producing cells
- **HDACi – “Kick”** Activation of latent reservoirs
- *Functional Cure potentially achieved*
The Largest Therapeutic Vaccine Pipeline in the HIV Space

Current R&D Pipeline – HIV Products Being Developed for the Functional Cure

Drug discovery Pre-clinical development Phase I Phase II Phase III Registration

Vacc-4x (HIV) Mono Therapy Reboost

Vacc-4x (HIV) combined with the IMiD - Lenalidomide (Revlimid®)

Vacc-4x (HIV) combined with Latent HIV virus Activator HDACi

Vacc-C5 (HIV)

Vacc-HIV (combined C5 & 4x)

Vacc-Flu (influenza)

Candidate Drug Selection

IND = Investigational New Drug
CTA = Clinical Trial Application

BLA = Biologics License Application
MAA = Marketing Authorization Approval

Ongoing HIV Studies
Planned Studies
Vacc-4x Reboost Mono Therapy Study
Revaccination of Patient Population from the Previous Phase II Study

- Boosting with Vacc-4x in patients from the previous Phase II Vacc-4x study to explore a further reduction in viral load
- The Vacc-4x Reboost study will guide boosting strategies for the Functional Cure

The primary endpoints: changes in viral load compared to the previous study, and immune responses to the vaccine

Data expected in Q1 2014

The aim of reboost with Vacc-4x is a stepwise viral load reduction as a result of vaccination while on ART, following periods without ART. Open blue circles indicate vaccination. Graphics for illustrative purposes only.
Vacc-4x + Lenalidomide (Revlimid®)
Vacc-4x in Combination with Celgene’s Immune Modulator Revlimid®

- This study aims to show a potential enhancing effect of lenalidomide on Vacc-4x’s ability to stimulate and boost the immune system.
- Study tests the effect of lenalidomide and Vacc-4x in combination – If study is positive it opens up the possibility of “Boosting” the effect of Vacc-4x in HIV patients in the efforts towards achieving a Functional Cure for HIV.
- Data expected in Q2 2014.

One of the primary endpoint: Changes in the number and quality of CD4 helper cells.
Planning of the HDACi «Kick» and Vacc-4x «Kill» Combination Study
Bionor Pharma in collaboration with Professor Lars Østergaard’s Group

We continue our discussions with the world’s leading experts at University of Aarhus, Denmark on the combination of Vacc-4X with an HDACi

- The clinical synopsis for the combination of an HDACi and Vacc-4X has been outlined and operational planning continues

- We expect to be able to submit the study protocol to local Danish regulators in Q4 2013
Summary of Bionor Pharma’s Combination Strategy

**Kick, Kill and Boost for the Functional Cure Strategy**

- Vacc-4x is one of the most extensively studied and furthest advanced therapeutic vaccines in the HIV area.

- As such, Vacc-4x provides Bionor with a First Mover advantage.

- Combination of the furthest advanced therapeutic vaccine, Vacc-4x, with other treatment modalities including HDACi and lenalidomide, provides Bionor with a unique First Mover potential for a step in the direction of a Functional Cure.

“A Functional Cure will enable people to live long-term with no disease progression nor viral transmission in the absence of ongoing antiretroviral therapy.”
Vacc-C5 Therapeutic Vaccine
Antibodies to C5 may Interfere with Hyperimmune Activation

- Hyperactivation of the immune system and chronic inflammation is observed in HIV patients
- The C5 region of HIV shares homology with the human HLA system and C5 likely confuses the immune system
- C5 antibodies to HIV may block with the harmful effects of C5
- Current “First time in man” study is ongoing exploring three different dose levels of Vacc-C5 – Key endpoint is the ability of patient to generate antibodies to C5
- Vacc-C5 has the potential to help/contribute to a Functional Cure
- Data expected in Q1 2014 at the latest

An important aim of this vaccine is to reduce immune hyperactivation potentially triggered by the C5 region of HIV
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Strong News Flow over the next 6 to 18 months

*Milestones & Deliverables 2014 & 2015*

- Vacc-4x (The “Kill”) & Lenalidomide (The “Boost”) combination Proof of Concept Phase II Data in H1 2014
- Vacc-4x (The “Kill”) reboost monotherapy Phase II Data Q1 2014
- Vacc-C5 Phase I/II data Q1 2014
- Vacc-4x (The “Kill”) & HDAC (“The Kick”) combination Proof of Concept Phase II Data - Precise timing subject to planning & execution

- Proof of Concept data will be a key value driver and will promote partnering and exit optionality going forward
- The Company with its ongoing activities is currently financed into Q3 2014
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Summary of Bionor Pharma’s Value Proposition
Combination of Bionor Vaccines with other drug modalities may provide for a Functional Cure for HIV

In the interest of both shareholders and patients Bionor Pharma will execute on its First Mover potential for exploring initially Vacc-4x in combination with HDAC inhibitors (HDACi) and subsequent to data also potentially add Immunomodulators like IMiDs/Lenalidomide and potentially even Vacc-C5 for providing for the Functional Cure for HIV.
Execution of Bionor’s New Kick & Kill Strategy
Planning and Funding of Future Pipeline Including new HDACi & Vacc-4x Initiatives

- Bionor strongly believes that with its advanced therapeutic vaccine position in the HIV space can spearhead the development of a functional cure for HIV
- In recent years therapeutic vaccines (i.e. immunotherapy) in the cancer area has been very successful
- To execute Bionor’s new HDACi & Vacc-4x combination strategy, the Company is currently evaluating various strategic and financial opportunities
- Bionor will keep the market appraised of any updates and outcome of this process in H2 2013
- Bionor strongly believes that the First Mover potential in the HIV space and the general platform in infectious diseases will drive value creation, partnering and exit optionality

May 29th 2013; GlaxoSmithKline has acquired upstart vaccine developer Okairos for $325 million. The deal delivers the Swiss biotech's genetic vaccine development platform, which uses viral vectors to spur a T-cell attack on a range of diseases such as hepatitis C, HIV, malaria, tuberculosis and human respiratory syncytial virus (RSV).

Statement from Okairos’ CEO Riccardo Cortese:
“We believe that, during the next decade, a new generation of T-cell based vaccines will become the major medical contribution in the fight against infectious disease.”
Q&A