



***BIONOR*PHARMA**

Exploring the Path Towards a Functional Cure for HIV

Company Presentation

CEO Anker Lundemose MD PhD

February 27, 2014

Disclaimer

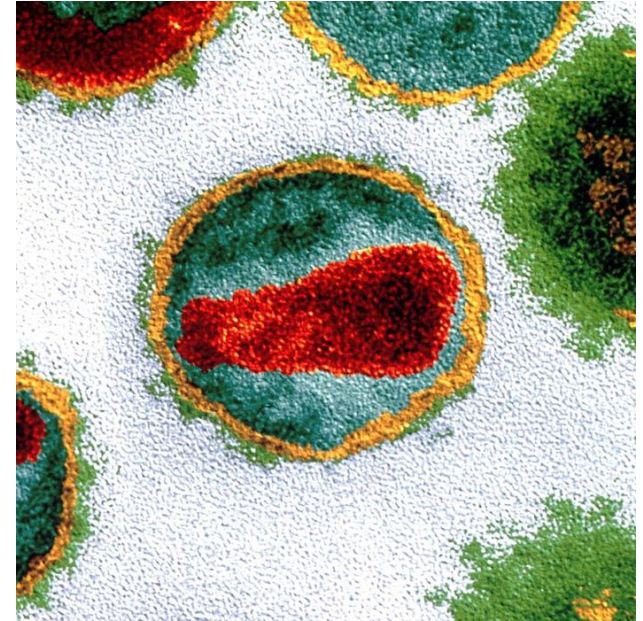
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Bionor Pharma

Exploring the Path Towards a Functional Cure for HIV

- Bionor Pharma is a biotechnology company focusing on the treatment of life threatening viral diseases, especially HIV
- Lead investigational product Vacc-4x
 - One of the furthest advanced therapeutic vaccines in the HIV space
 - Three clinical trials ongoing – next readout Q1 2014
- Second investigational product Vacc-C5
 - One of the first humoral therapeutic vaccines in the HIV area
 - Positive Phase I results reported Q1 2014



Board of Directors

Bionor Pharma ASA



Dr. Lars H. Høie, Chairman

- Chairman from 2011
- Co-founder of Nutri Pharma 1993
- Dr.Philos in protein- and lipid research
- Scientist and entrepreneur



Dr. Jerry Zeldis

- Joined the BoD 2012
- CMO Celgene Corporation
- CEO Celgene Global Health
- Board certified gastroenterologist



Øystein Soug

- Joined the BoD 2013
- CFO Algeta ASA
- Ex. Norwegian ind. group Orkla



Benedicte Fossum

- Joined BoD 2012
- Co-founder of Pharmaq AS
- Ex. Alparma



Marianne Kock

- Joined the BoD 2013
- Reg. Affairs Ferring Pharmaceuticals
- Ex. Novo Nordisk AS



Executive Management

Proven Track Record



Dr. Anker Lundemose, CEO

- Joined March 2013
- Ex. EVP Corp.& BD
OSI Pharmaceuticals Inc., US
- Ex. CEO Prosidion Ltd., UK
- Ex. Novo Nordisk A/S
- MD, PhD, DMSc in Medical
Microbiology



Synne H. Røine, CFO

- Joined May 2013
- Ex. CFO Pronova BioPharma



Current HIV Treatment - Unmet Need



HIV Pandemic

Global Health Care Problem at a Huge Cost

- Total of 35 million HIV patients W-W
- Treatment of HIV infection consists of combination antiretroviral therapy (cART)
- There are >20 approved cART drugs in six classes
- cART HIV sales in the US and five major EU markets estimated at \$15bn in 2014

Adults and Children Estimated to be Living with HIV



Source: UNAIDS 2012

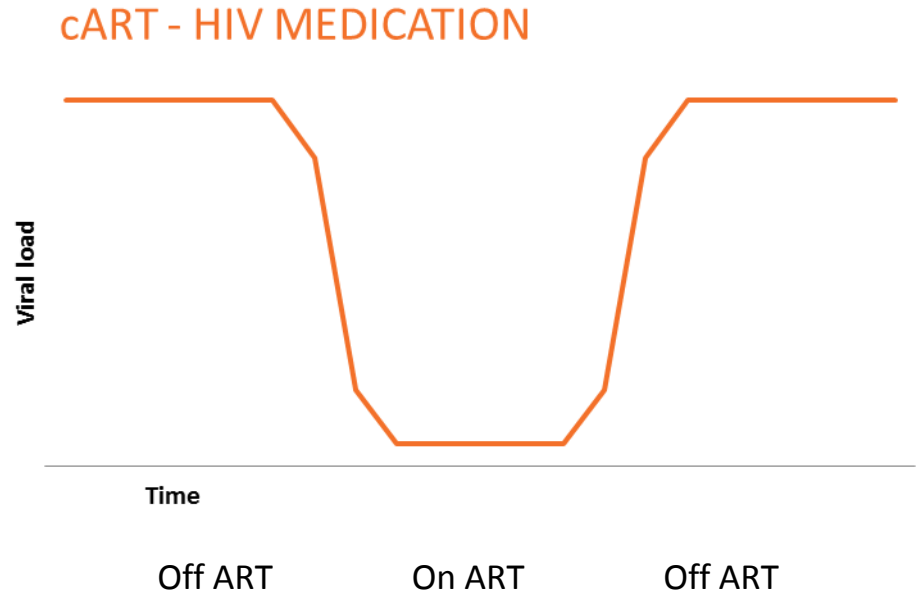
Source: CDC; Aidsfocus.ch and Nature Publications



The Conventional HIV Medication - cART

Existence of an Unmet Need - cART Does Not Cure HIV

- cART HIV Medication effectively reduces viral load, BUT:
 - 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)
- 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 social marginalization and stigma



Graphics for illustration purposes only



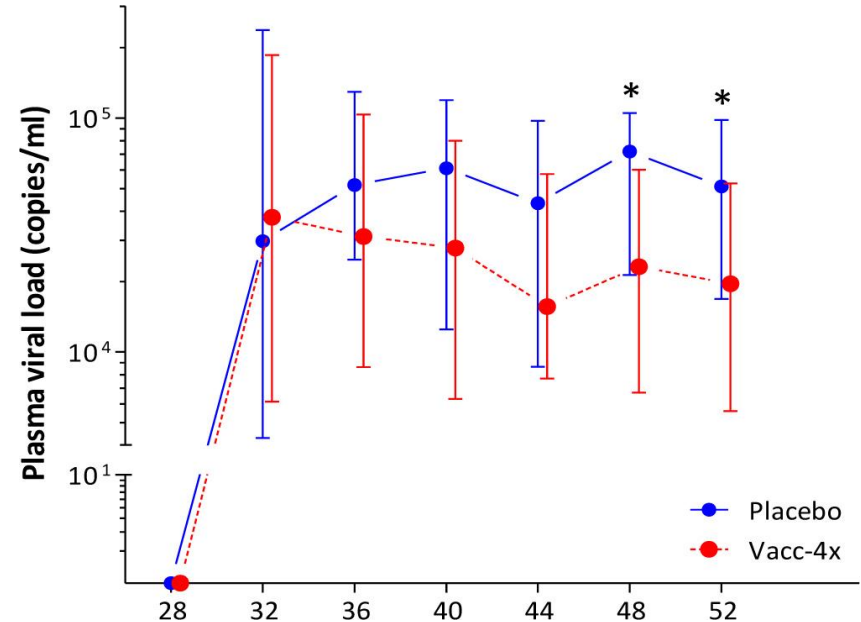
Vacc-4x
Lead Vaccine Candidate



Vacc-4x Lead Vaccine Candidate

Furthest advanced therapeutic vaccine

- Largest HIV therapeutic vaccine trial in the world to date – 135 patients in randomized, placebo controlled multicenter trial
- Vacc-4x has showed the ability to
 - Reduce viral load (HIV in the blood)
 - Increase proliferation responses in both CD4 & CD8 cells (Immune system)
- Goal for Vacc-4x is to improve previous demonstrated results
 - Combination with other treatment
 - In subset of HIV patients



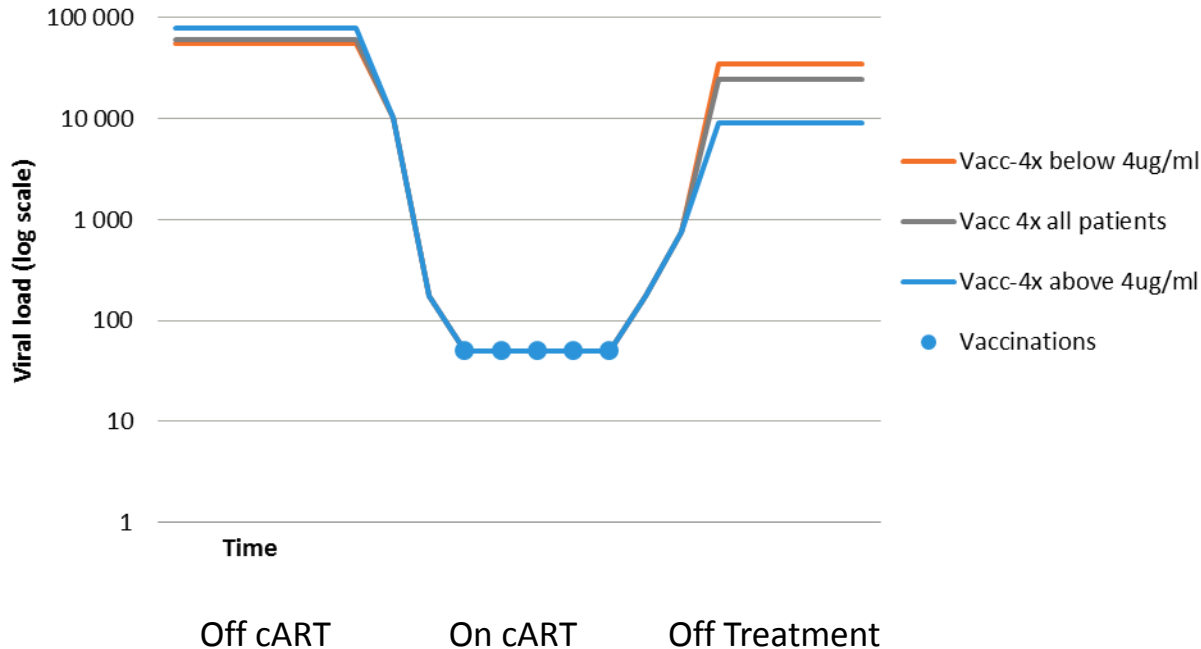
Week	28	32	36	40	44	48	52
Placebo: n=	38	38	34	32	27	25	24
Vacc-4x: n=	86	88	79	71	63	59	56



Effects of Anti-C5 Antibodies on Vacc-4x Vaccination

Identification of Potential Biomarker – 2010 Vacc-4x Phase II Study

Viral Load Reduction from pre-ART values



- Patients with anti-C5 antibodies below 4ug/ml had a viral load reduction of **log 0.2 or 37%** (p=0.019)
- Patients had a reduction a viral load of **log 0.4 or 60%** (p=0.0001)
- Subjects with anti-C5 antibodies above 4ug/ml had a reduction in viral load of **log 0.94 or 88%** (p=0.005)

➔ *Potential biomarker identified*

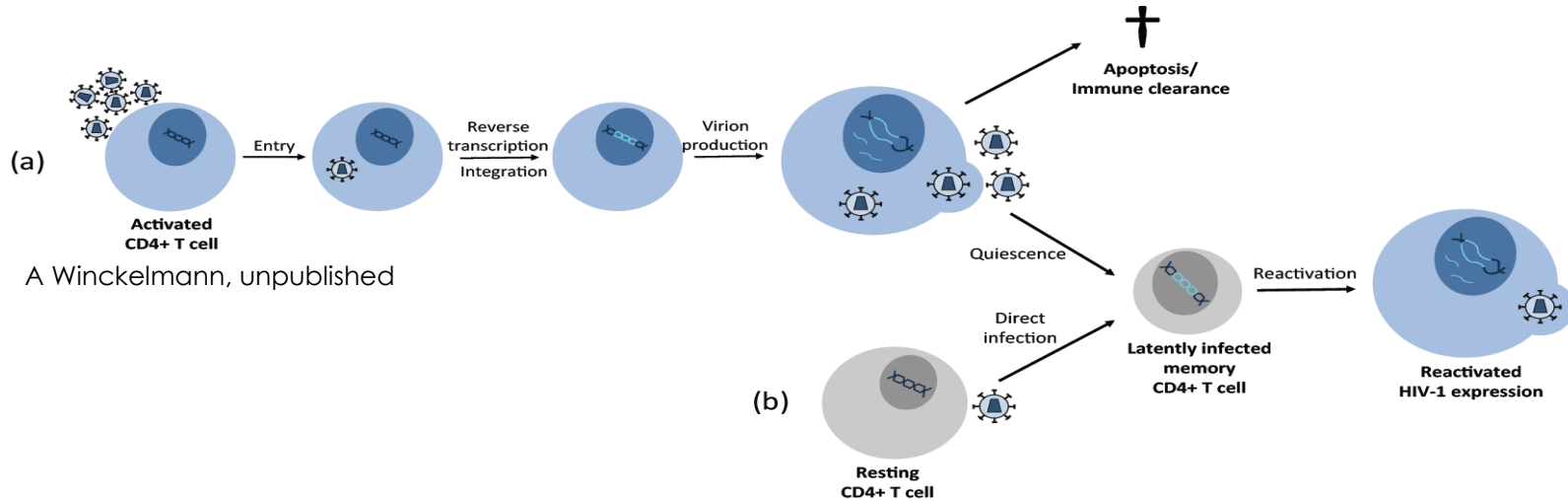


Kick, Kill & Boost –
Clinical Development
Strategy & Pipeline



The Latent HIV Reservoir

Unaffected by cART Medication and Invisible to the Immune System



- HIV patients have variable degrees of reservoir size
- Re-activation (“Kick”) of the latent virus reservoir likely prerequisite for immune eradication of infected cells
- Therapeutic vaccination (“Kill”) and potentially other forms of immune priming (“Boost”) prior to virus reactivation (“Kick”) may provide for virus eradication and a Functional Cure for HIV

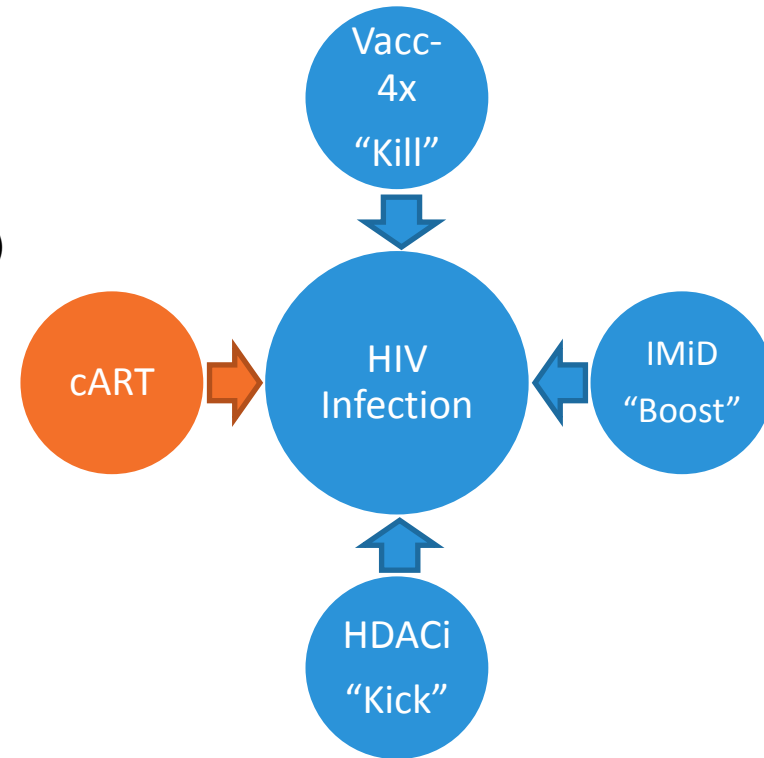


Bionor Pharma's "Kick, Kill and Boost" Strategy

Exploring the Path Towards a Functional Cure For HIV

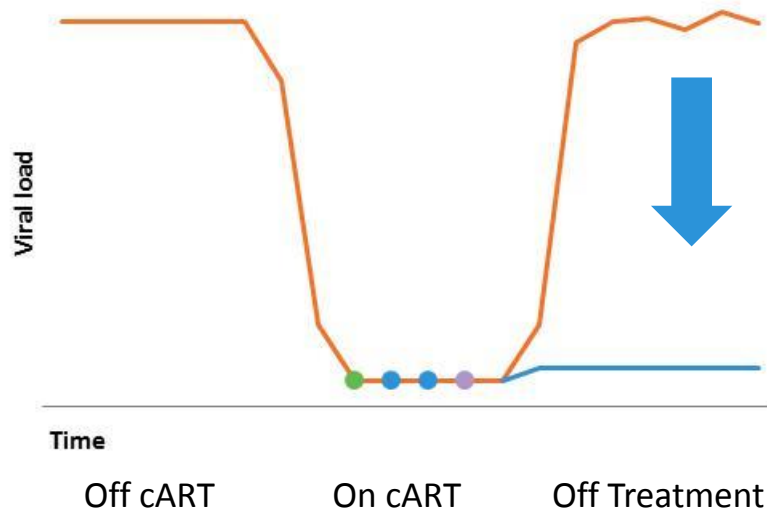
Bionor Pharma's strategy for the Functional Cure is based on the "Kick", the "Kill", and the "Boost"

- The "Kick" constitutes the HDACi (romidepsin) reactivation 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 (an IMiD) to enhance the effect of Vacc-4x.



The Functional Cure – “Kick, Kill and Boost”

ART + IMiD + Vacc-4x + HDACi

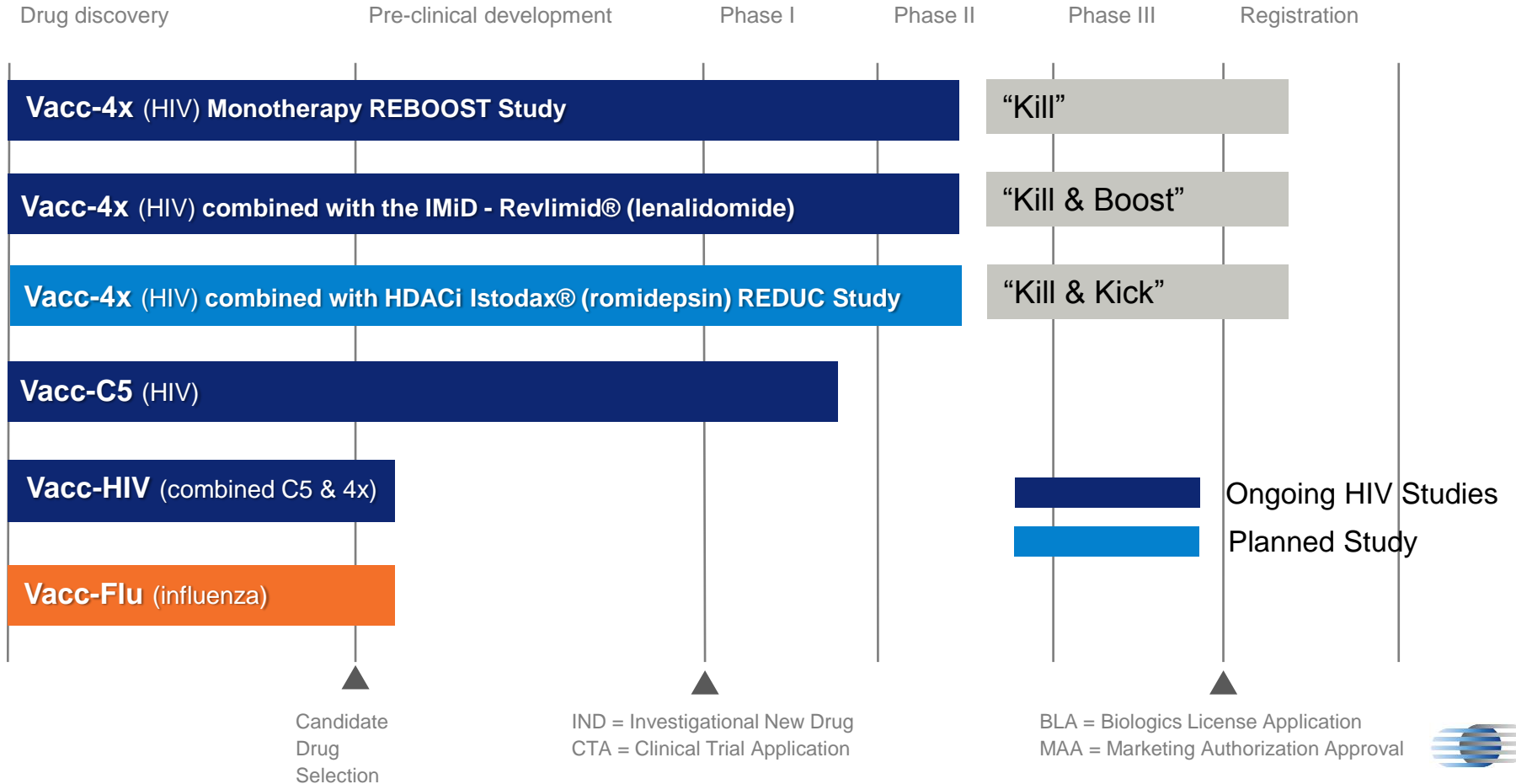


- **cART** Virus replication kept at minimum
 - **IMiD – Lenalidomide “Boost”**
Boosting immune system
 - **Vacc-4x – “Kill”** Efficient killing of virus producing cells
 - **HDACi – Romidepsin “Kick”**
Activation of latent reservoirs
- ➔ *Functional Cure potentially achieved*



The Largest Therapeutic Vaccine Pipeline in the HIV Space

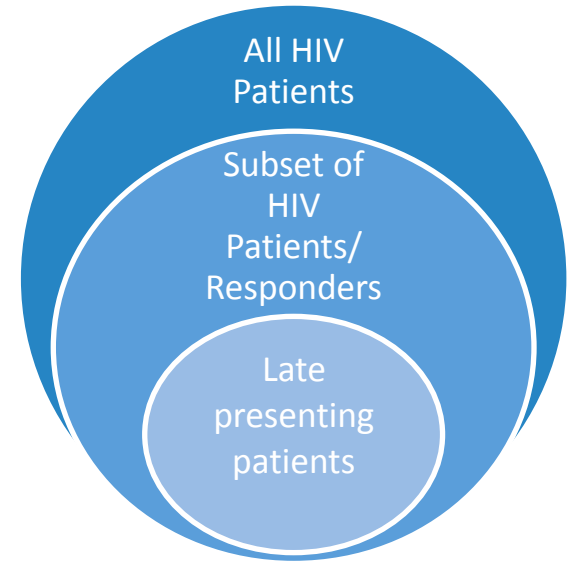
Current R&D Pipeline – HIV Products Being Developed for the Functional Cure



Bionor Pharma Positioning for The Functional Cure

First Mover in Therapeutic Vaccines for HIV

- Bionor has the largest pipeline in the industry and the furthest advanced therapeutic vaccine within the HIV space
- Bionor has the potential to spearhead the development of a Functional Cure for HIV
- Development strategy centered around the exploration of vaccine monotherapy as well as combinations of vaccine(s) with other treatment modalities for
 - The Functional Cure in all patients or in subsets of patients
 - Add-on to cART in specific patient populations



Clinical Development Program

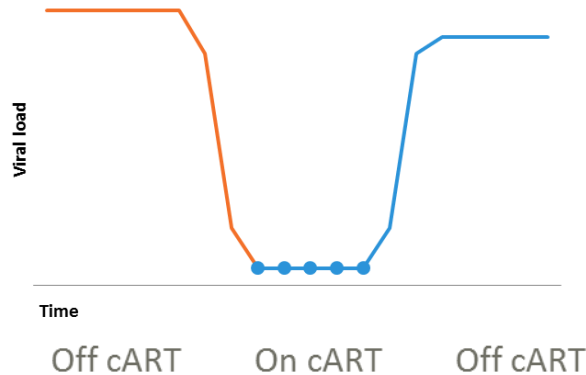


Vacc-4x Reboost Mono Therapy Study

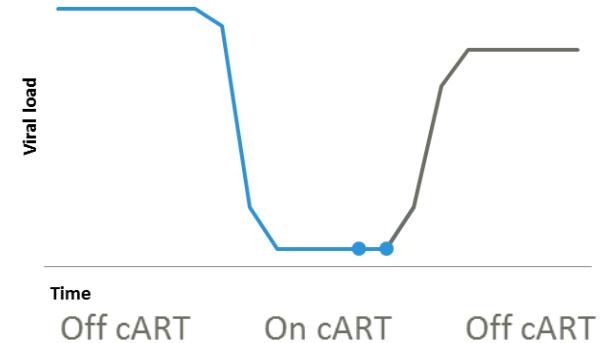
Revaccination of Patient Population from the Previous Phase II Study

- Revaccination 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 explores the monotherapy option 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 late Q1 2014

Vacc-4x - VIRAL LOAD REDUCTION



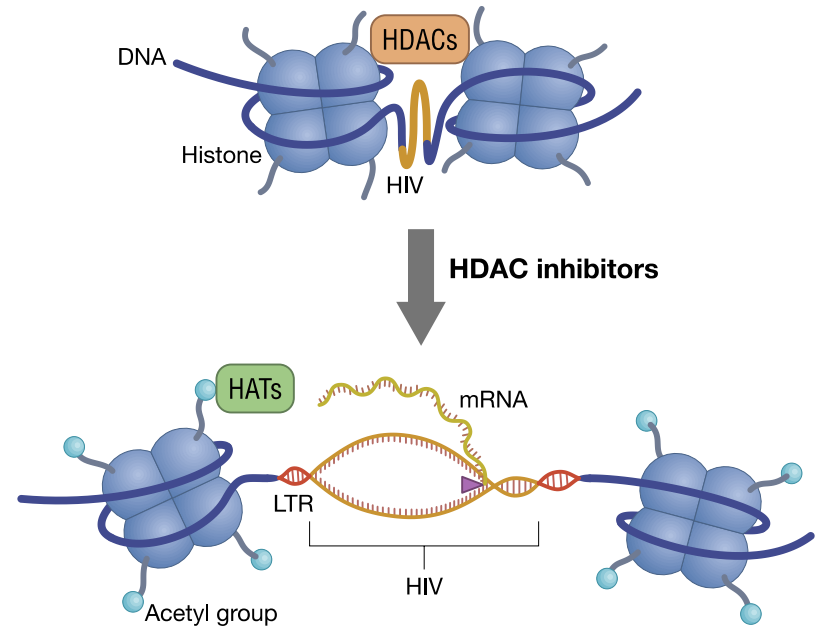
Vacc-4x - REBOOST HYPOTHESIS



HDACi “Kick” and Vacc-4x “Kill” Combination Study

REDUC Study

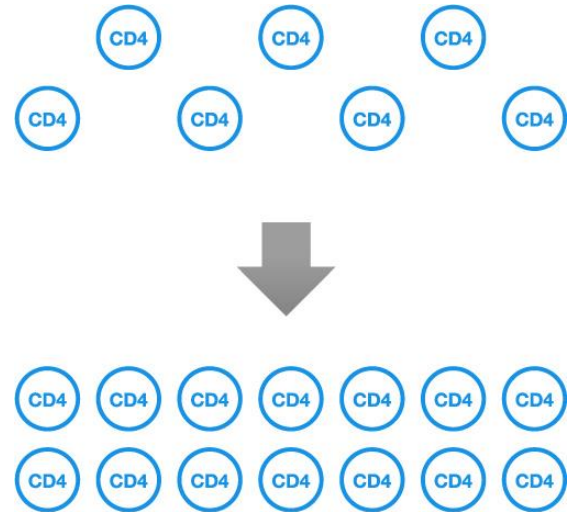
- The Company will execute the Kick & Kill study together with University Hospital of Aarhus led by Professor Lars Østergaard
- Study protocol submitted to Danish Regulators and Ethical Committee
- Subject to study approval, we expect to initiate enrollment of patients in Q2 2014
- Romidepsin has been selected as the preferred HDACi - Romidepsin is the most potent known activator of HIV reactivation in cell systems



Vacc-4x + Revlimid[®] (lenalidomide)

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
- Current study is a late HIV presenters as an add-on to cART
- Top line results expected in Q4 2014



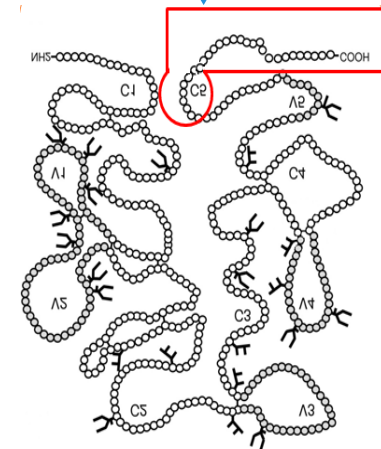
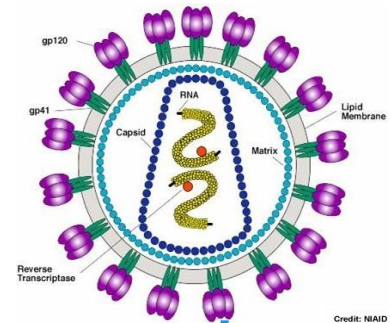
One of the primary endpoints: Changes in the number and quality of CD4 helper cells



Vacc-C5 Therapeutic Vaccine

Antibodies to C5 may Interfere with C5 Influence on Hyperimmune Activation

- Patients with high levels of antibodies to the C5 region of the HIV virus exhibits slower disease progression
- Vacc-C5 Phase I study reported positive results Q1 2014
 - Generation of C5 antibodies with effect of boosting, particularly in the top dose group and
 - Antibody generation against C5 observed primarily in patients with relative low preexisting levels of antibodies against C5
- Vacc-C5 vaccination in a subset of patients with low preexisting C5 antibodies may provide for improved response to our other lead vaccine candidate Vacc-4x



Future Strategy and Directions



Path to Market

Driven by Data & Discussion/Feedback From Regulators

- Bionor at the forefront of the cure agenda
 - Regulatory requirements being discussed directly with regulators (EMA and FDA)
- Dialogue with regulators driven by science, assessment of unmet needs and data
- Steps to commercialization/Exit
 - Data (Proof of Concept)
 - Dialogue with the FDA and EMA
 - Agreement with regulators on precise requirements for approval & market authorization
 - Data, discussion/agreement with regulators will drive value creation, partnering and exit optionality



Positioned for Execution - Outlook

Milestones & Deliverables 2014 & 2015

- Vacc-4x (The “Kill”) & HDACi romidepsin (“The Kick”) combination study – Study protocol submitted to regulators – Patient enrollment initiation is planned for Q2 2014 with top line results expected by H2 2015
- Vacc-4x (The “Kill”) reboost monotherapy Phase II top line results expected late Q1 2014
- Vacc-4x (The “Kill”) & Lenalidomide (The “Boost”) combination Proof of Concept Phase II - Top line results expected Q4 2014
- Readouts of the ongoing clinical trials in 2014 are major milestones for Bionor Pharma and catalysts for further development of the Company



Execution of Bionor Pharma's HIV Strategy

Towards a Potential Functional Cure for HIV

- 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
- In recent years therapeutic vaccines (i.e. immunotherapy) in the cancer area has been very successful
- Bionor Pharma 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."





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Thank You for Your Attention