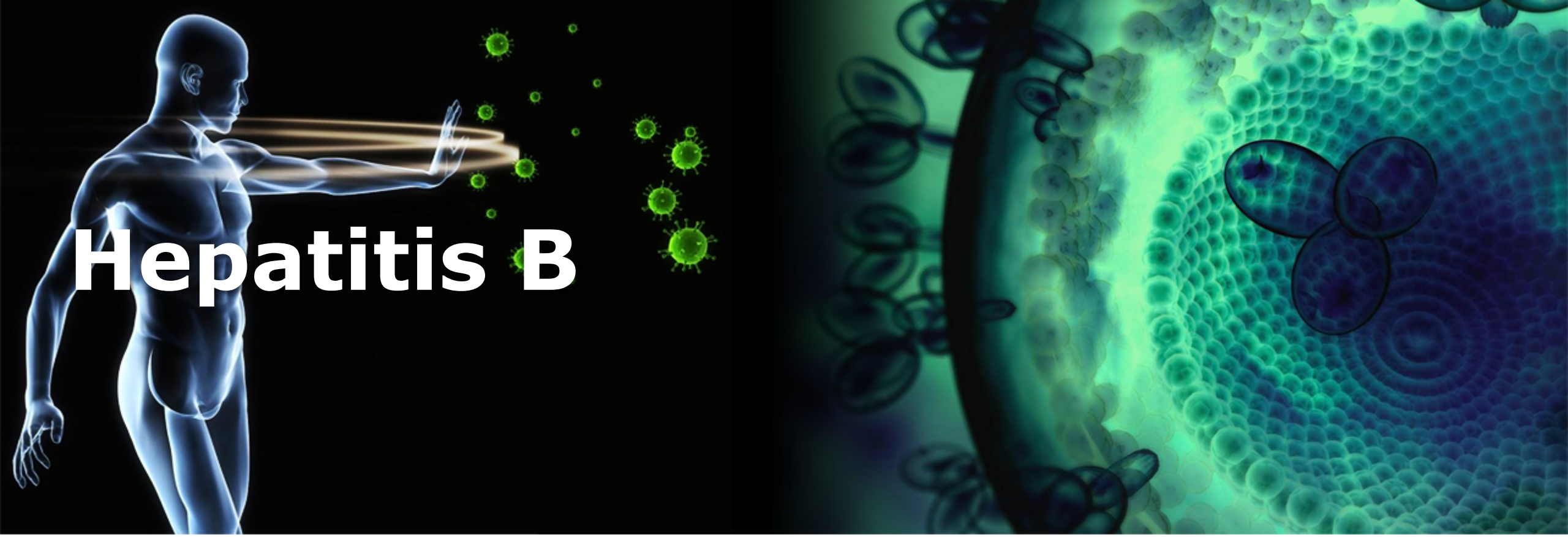

Hepatitis B

HBV Cure: Insights for the Biotechnology and the Research Analyst Community

November 11, 2016

Lalo Flores, PhD
Global Head HBV R&D

janssen | PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Janssen's Vision for Hepatitis B

HEPATITIS B VISION

Transform treatment by significantly reducing duration and increasing rates of functional cure

PRIMARY GOALS

Build a robust portfolio of diverse mechanism of action agents and establish clinical proof of concept

Evaluate licensing and acquisition opportunities to accelerate and fill gaps in the internal portfolio

Launch transformational regimens in sequential waves increasing rates of functional cure

Janssen HBV Strategy

Combined investment in antiviral & immune-based interventions

Disease Hypothesis	Approach
Replication not fully suppressed leading to new infections & maintenance of a stable pool of infected hepatocytes	**Intensify Antiviral Treatment** Combination of ≥2 potent antivirals to block virion production below threshold needed for new infections
Tolerance and exhaustion of HBV-specific T-cell responses prevents clearance of chronic HBV infection	**Modulate Host Immunity** Up the balance in favor of cytolytic and/or non-cytolytic clearance of infected hepatocytes by inducing HBV-specific T-cell responses

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Janssen HBV Strategy

Build portfolio of drugs with diverse mechanism of action that enable additive efficacy

Intensify Antiviral Treatment

Reduce cccDNA formation & Virus production

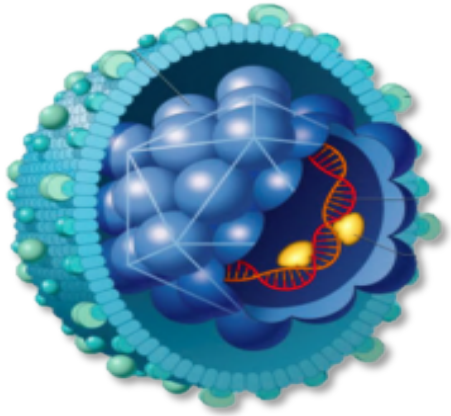
1

Capsid Assembly Modulators

Tx Oligos (siRNA)

Silence/Eliminate cccDNA

2



Boost Immune Response

1

Boost specific T-cell Responses

HBV therapeutic Vaccine

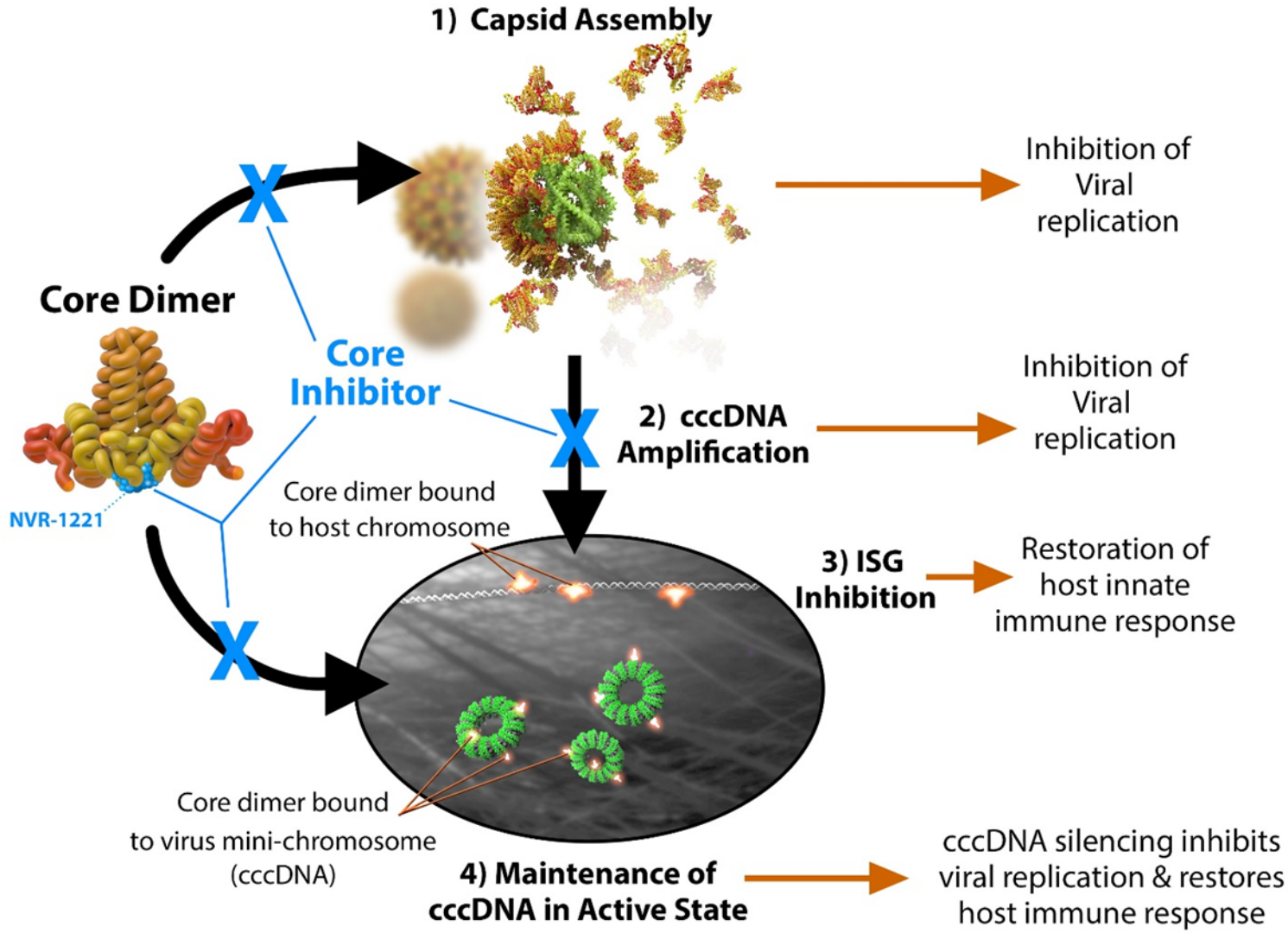
2

Boost Innate Immunity

TLR & PRR agonists

Capsid Assembly Modulators (CAMs)

Disrupt the function of HBV Core a multifunctional viral protein



Intensify Antiviral Treatment

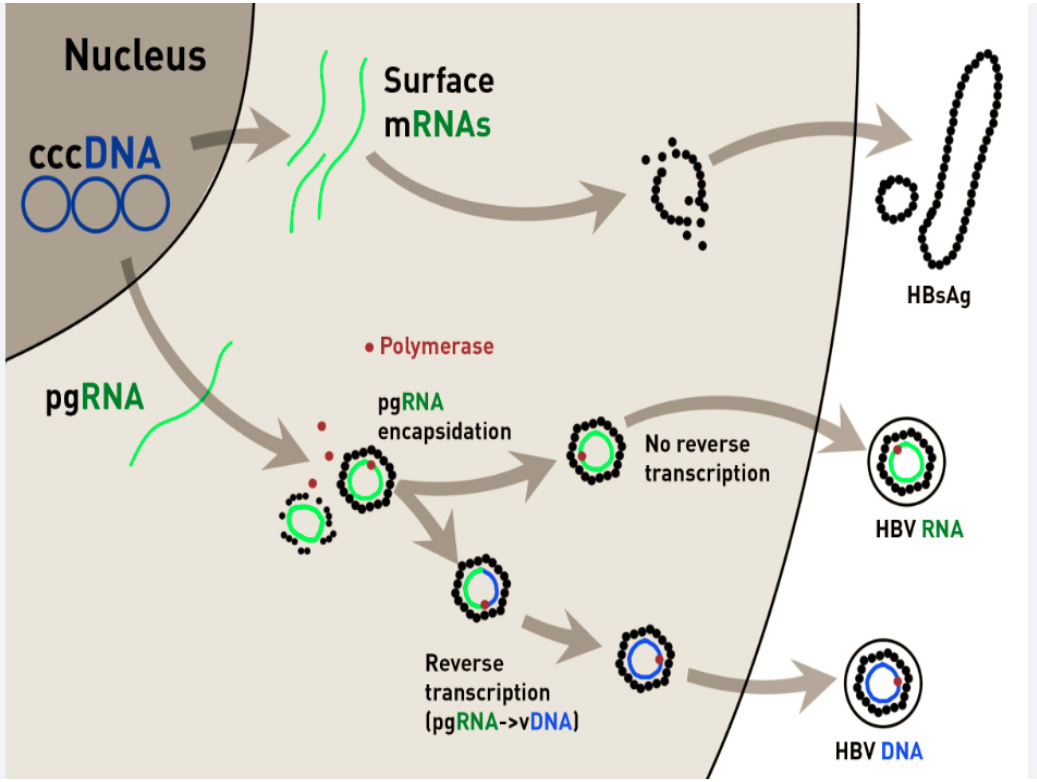
1

Capsid Assembly Modulators (CAMs)

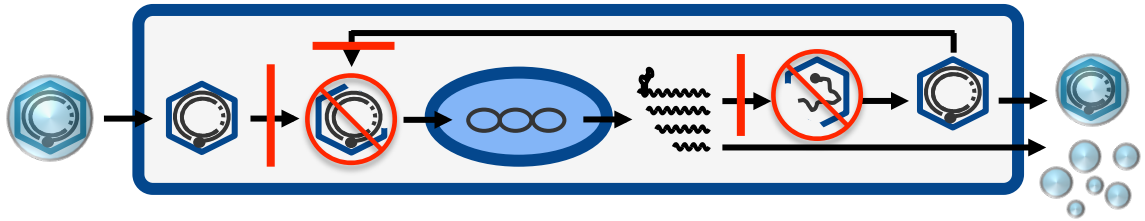
A promising new HBV antiviral drug class with strong differentiation from NAs

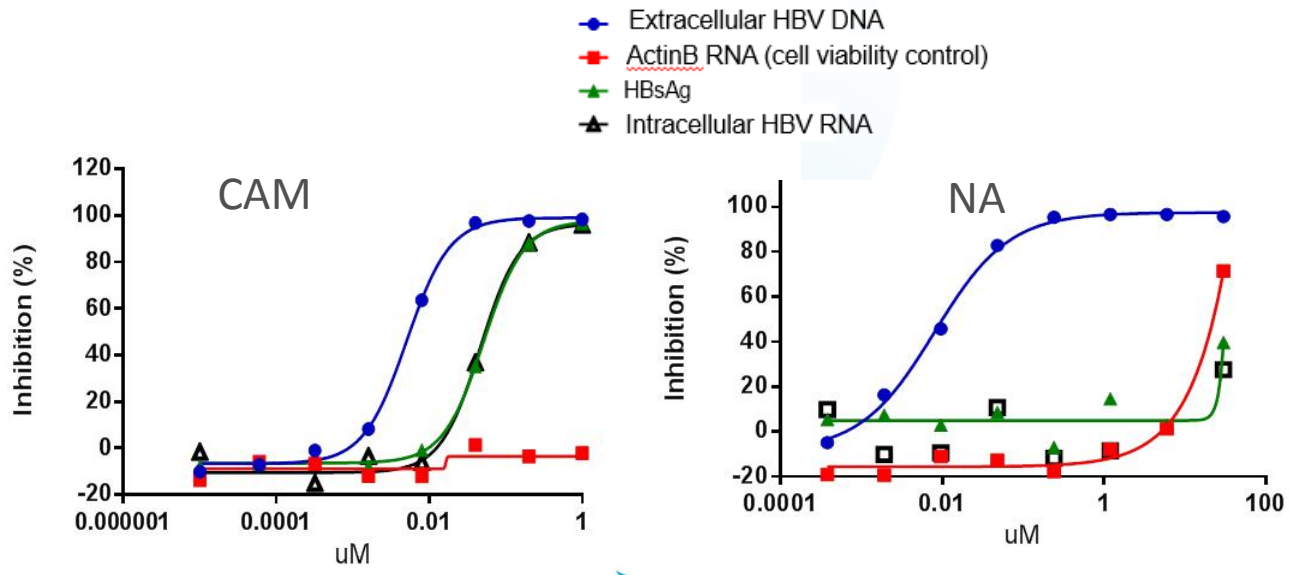
CAMs prevent pgRNA encapsidation and block both HBV DNA and HBV RNA particle secretion

- NAs only block HBV DNA particle production



CAMs but not NAs prevent cccDNA formation when present at time of infection





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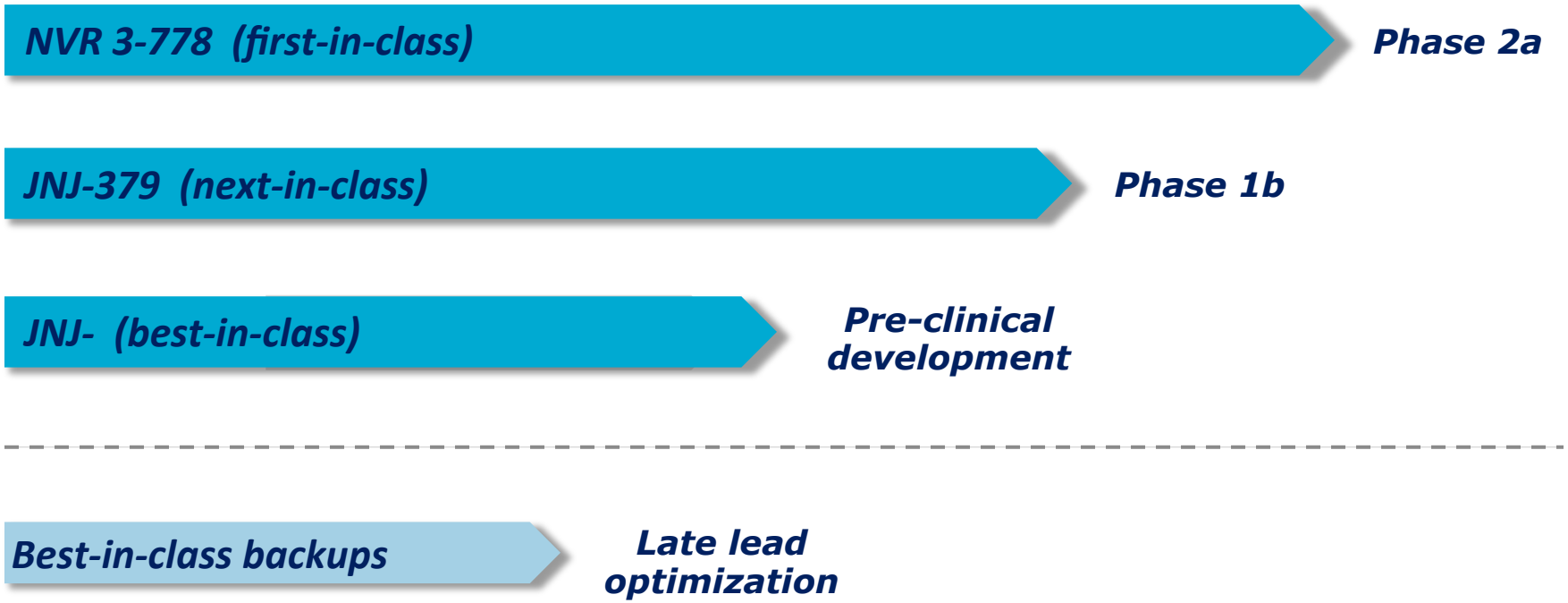
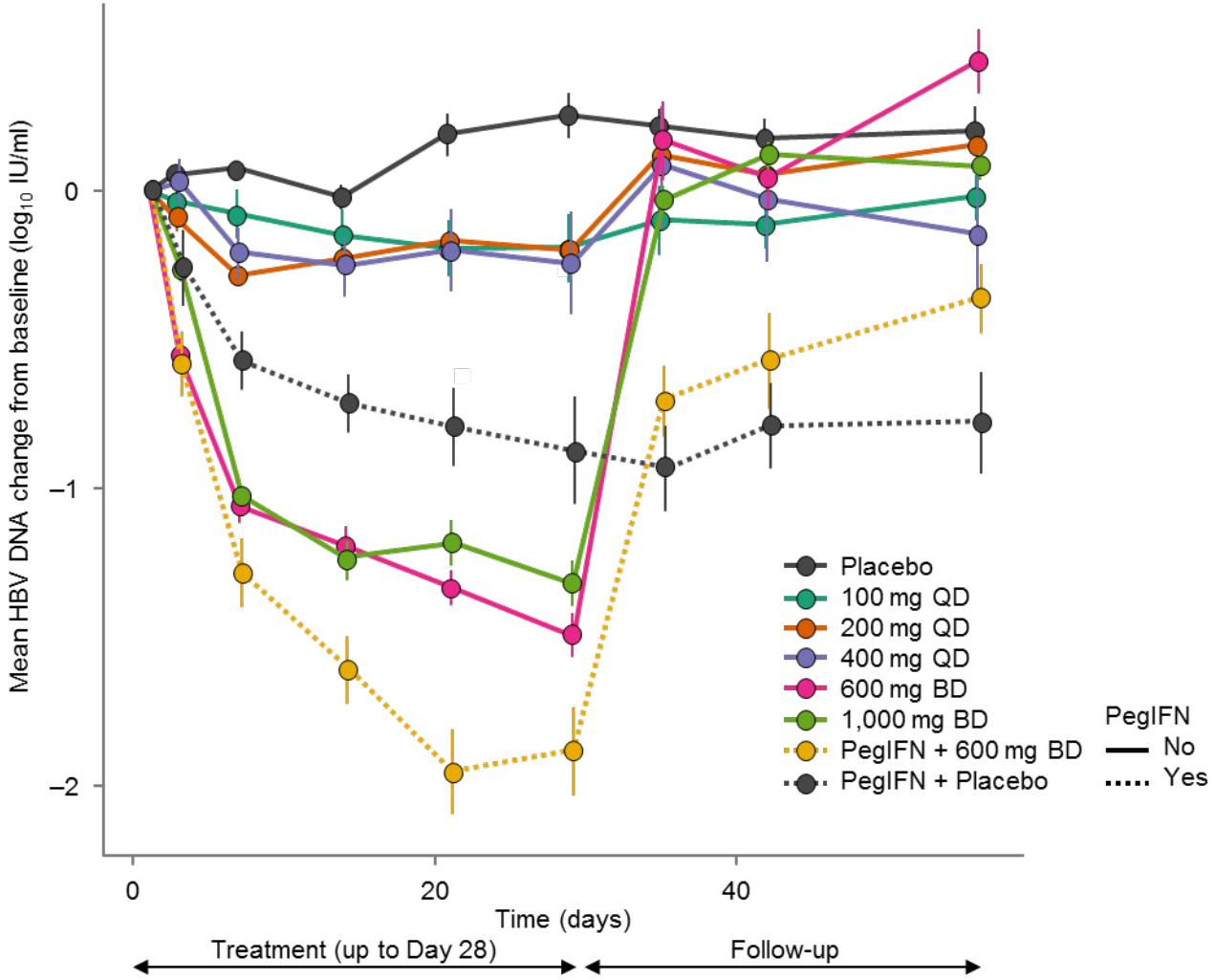
Janssen Capsid Assembly Modulator (CAM) Pipeline

Three assets in active development



NVR 3-778 Phase 1b Study

Viral load reduction (mean HBV **DNA** change from baseline)

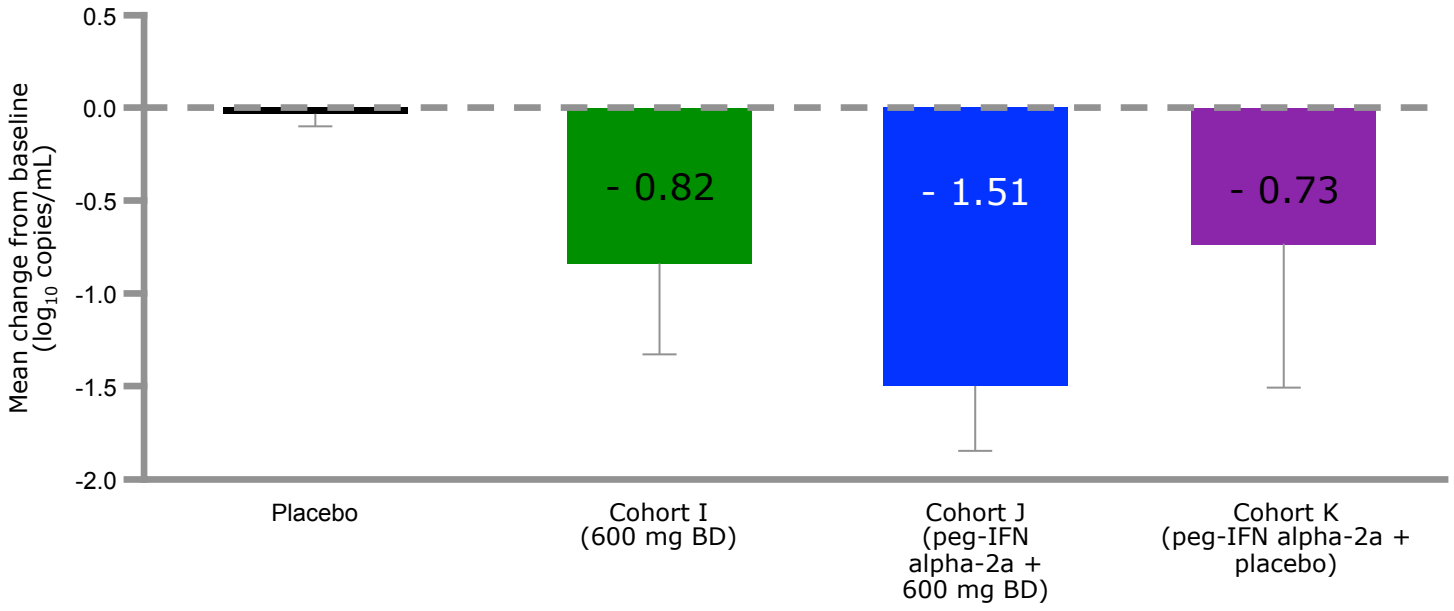


- Monotherapy in treatment naïve HBV patients
  - 5 multiple ascending dose cohorts
  - Robust 1.7 log viral load reduction efficacy with 600 mg dose
- peg-IFN alpha-2a + NVR 3-778 combination in treatment-naïve HBV patients
  - Combination showed greater HBV DNA reduction efficacy (-2 log) than either pegIFN (-1 log) or NVR 3-778 (-1.7 log) monotherapy

NVR 3-778 Phase 1b Study

Antiviral efficacy (day 29 mean HBV **RNA** change from baseline)

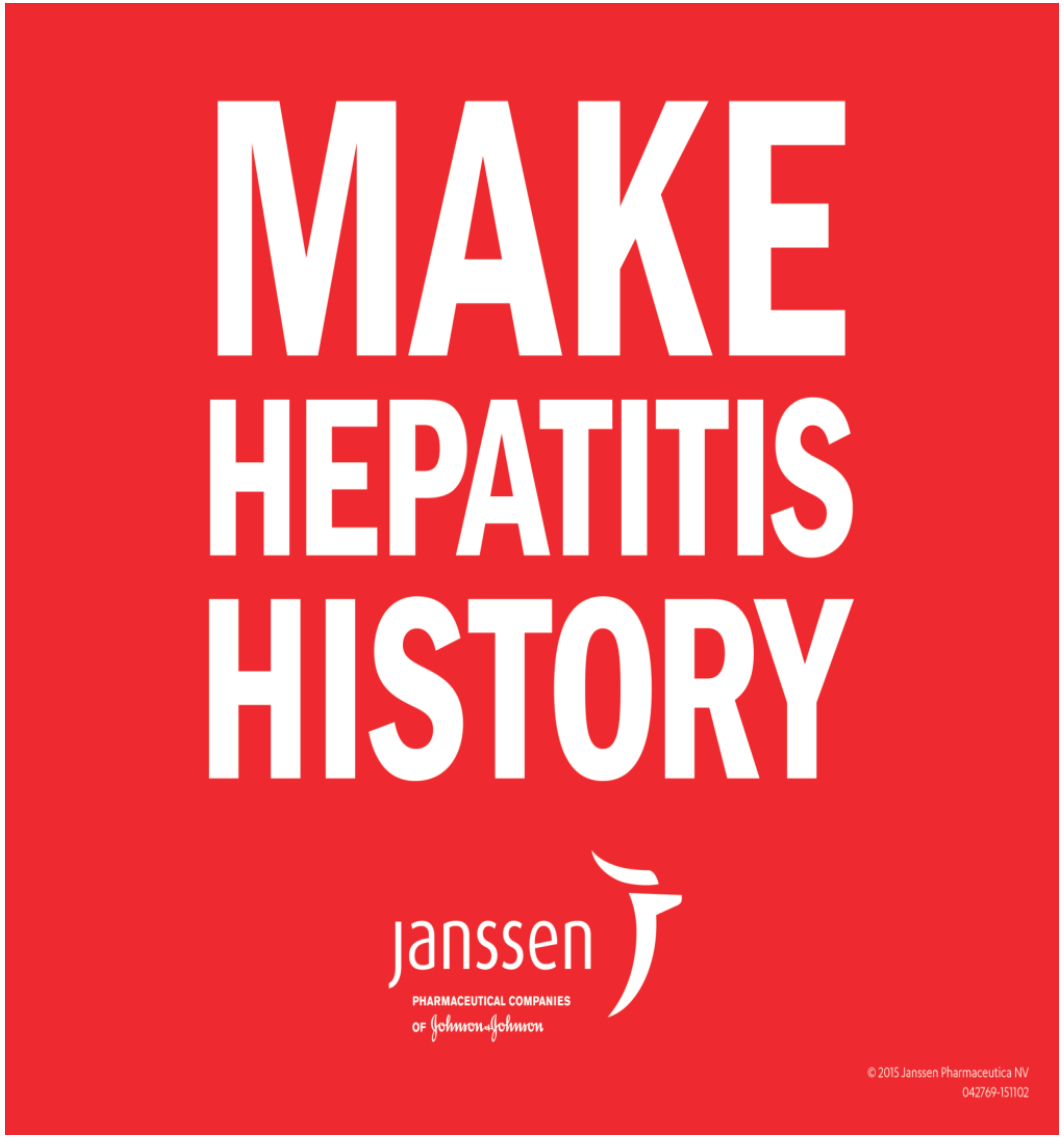
- **Effective reduction of serum HBV RNA by NVR 3-778**
- **Highest HBV RNA reduction with NVR 3-778 + peg-IFN alpha combination**



Summary

- **Janssen is pursuing R&D efforts and collaborations in multiple mechanisms of action to enable combination regimens that:**
  - **Intensify suppression of virus replication**
  - **Boost antiviral host immune response**

- **Building leading pipeline of Capsid Assembly Modulators (CAMs)**
  - **First-in-class NVR 3-778 progressing to Phase 2a**
  - **Next-in-class JNJ-379 progressing to Phase 1b**
  - **Best-in-class lead advancing to pre-clinical development**
- **Also investing in Tx oligonucleotides and immunological approaches that can boost host immunity**
  - **Several pipeline products positioned to enter clinic in 2017**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