



Creation of “Hep B Patients for a Cure Committee”

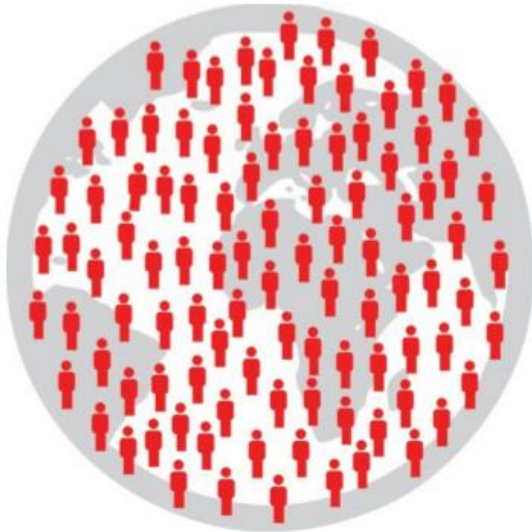


Henry E. Chang | Community Advocate

NYC Hep B Coalition Meeting

June 21, 2017

Status Quo | HBV Infection



CHRONICALLY INFECTED



DIAGNOSED



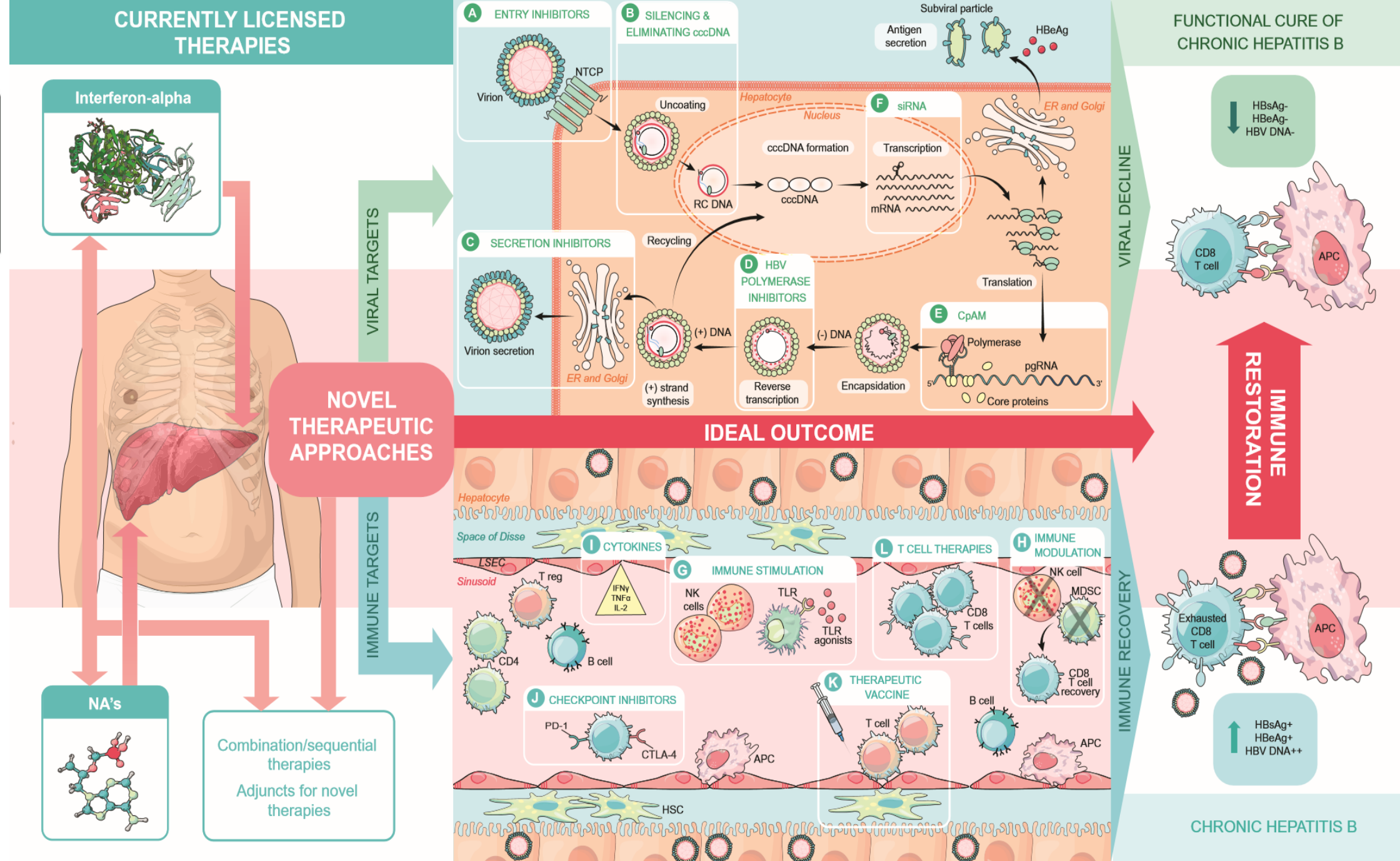
TREATED



Advances in HBV Research & Drug Development

- There is increasing research in the field of HBV infection
- The new goal of HBV therapy is to achieve “functional cure” with HBsAg loss/conversion and clearance of cccDNA.
- New agents are starting to emerge (*e.g.* HBV entry inhibitors, small interfering RNA, capsid inhibitors, CRISPR/Cas9) are promising, but are early in development.
- New drugs aimed to decrease or eliminate cccDNA and/or HBsAg are promising.

HEP FREE NYC





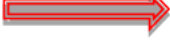







Investigational Agents for Chronic HBV Infection



Table 1

Therapeutics in development for the treatment of hepatitis B chronic infection

| Drug | Preclinical | Phase I | Phase II | Phase III | FDA Approved | Target/Type |
|---|--|---------|----------|-----------|--------------|-------------------------|
| Nonnucleoside antivirals: interfere with proteins involved in virus replication | | | | | | |
| Myrcludex B |  | | | | | Entry inhibitor |
| ARC-520 |  | | | | | RNAi gene silencer |
| ARB-1467 |  | | | | | RNAi gene silencer |
| ALN-HBV |  | | | | | RNAi gene silencer |
| Hepbarna |  | | | | | RNAi gene silencer |
| SB 9200 HBV |  | | | | | RIG 1 and NOD 2 agonist |
| Rep 2139-Ca |  | | | | | HBsAg release inhibitor |
| NVR 3-778 |  | | | | | Capsid inhibitor |
| Morphothiadinine mesilate (GLS4) |  | | | | | Capsid inhibitor |
| AIC 649 (Bay 41-4109) |  | | | | | Capsid inhibitor |

Investigational Agents for Chronic HBV Infection



| Drug | Preclinical | Phase I | Phase II | Phase III | FDA Approved | Target/Type |
|--|-------------|---------|----------|-----------|--------------|-----------------------|
| CpAMS | | | | | | HBV core protein |
| EYP001 | | | | | | FXR agonist |
| IONIS-HBVRx (ISIS-HBVRx) | | | | | | Antisense drug |
| IONIS-HBV-LRx (ISIS-GSK6-LRx) | | | | | | Antisense drug |
| CPI-431-32 | | | | | | Cyclophilin inhibitor |
| ARB-1740 | | | | | | Cyclophilin inhibitor |
| Noninterferon immune enhancers: boost T-cell infection-fighting immune cells and natural interferon production | | | | | | |
| RG7795 (formerly ANA773) | | | | | | TLR-7 agonist |
| GS-9620 | | | | | | TLR-7 agonist |
| ARB-1598 | | | | | | TLR-9 agonist |
| ABX 203 | | | | | | Therapeutic vaccine |
| GS-4774 | | | | | | Therapeutic vaccine |
| INO-1800 | | | | | | Therapeutic vaccine |
| NCT01641536 | | | | | | Therapeutic vaccine |
| CYT107 (interleukin-7) | | | | | | Immunomodulator |
| TG 1050 | | | | | | Immunotherapeutic |



Hep B Patients for a Cure Committee

GOAL

- Working towards a cure for HBV infection through collective action

PURPOSE

- The Committee will provide advice to drug/medical diagnostics developers on issues related to clinical development of investigational and marketed drugs/diagnostics and their use by patients with chronic HBV infection.

The Committee may consider topics such as:

- Patient-centric clinical trial design
- Patient preference study design
- Benefit-risk determinations
- Unmet medical needs
- Patient reported outcomes or health status issues
- Other patient related topics



Hep B Patients for a Cure Committee

PROPOSED NEXT STEPS

- Contact Henry if you are interested to join and serve on the Committee
- The Committee will convene its first meeting in July 2017
- Working with community partners, organize and host a citywide workshop on “Ending the Hep B Epidemic” with an official kick-off the Committee (4Q17)
- Invite HBV drug developers to review and provide patient-centric inputs on issues related to clinical trial strategies, protocols, and designs



Hep B Patients for a Cure Committee

“Nihil de nobis, sine nobis”

Nothing About Us Without Us!



Let's Get In Touch!



Henry E. Chang | Community Advocate



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