Treatment of Hepatitis C in Children and Adolescents

William F. Balistreri, M.D.

Cincinnati Children's
changing the outcome together

Disclosures*

1. Investigator:
   - Gilead (HCV & HBV antivirals)
   - Merck (HCV antivirals)
   - AbbVie (HCV antivirals)
2. Consultant:
   - Roche (HBV antivirals)
   - Vertex (HCV antivirals)

* since 2012

The Goal of Treatment of Chronic HCV Infection

Eradicate the virus

↓

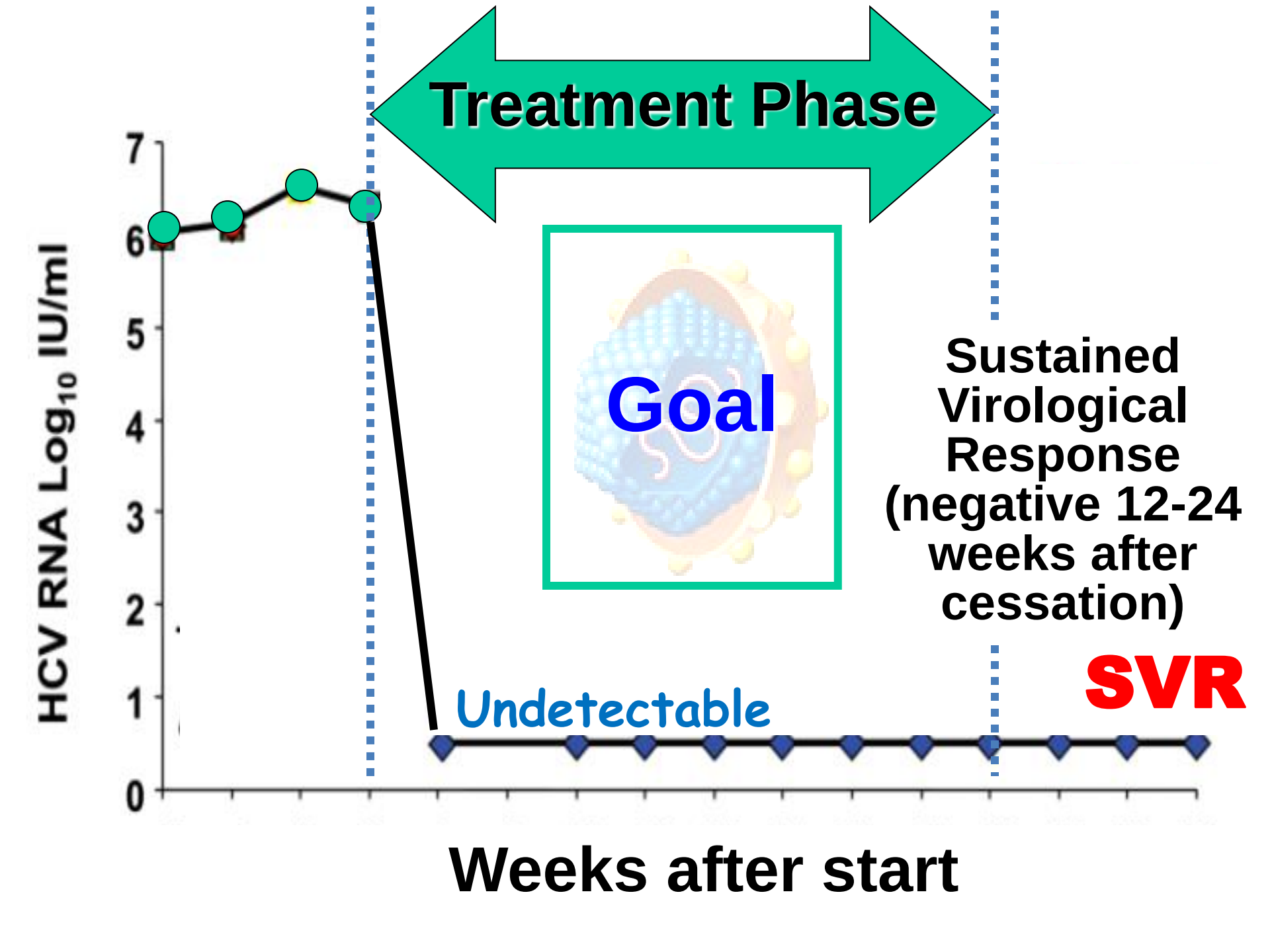
Induce a remission in liver injury

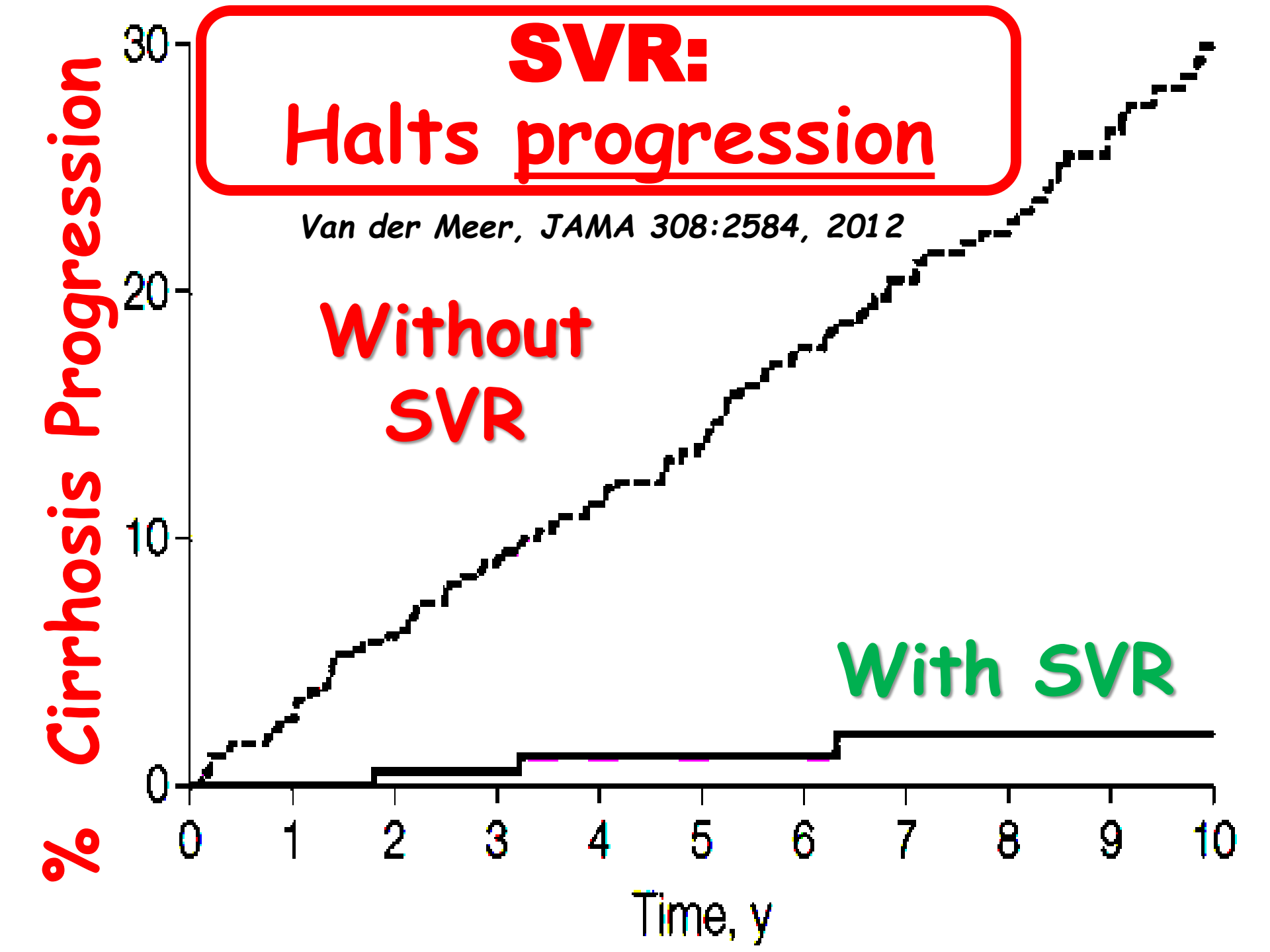
Prevent transmission

↓

Outcomes of chronic inflammation

Progression to end stage liver disease (fibrosis / cirrhosis)
Hepatocellular Carcinoma (HCC)


Treatment Phase
HCV RNA Log10 IU/ml
7
6
5
4
3
2
1
0
Goal
Sustained Virological Response (negative 12-24 weeks after cessation)
SVR
Undetectable
Weeks after start


SVR:
Halts progression
Van der Meer, JAMA 308:2584, 2012
Without SVR
With SVR
% Cirrhosis Progression
30
20
10
0
0
1
2
3
4
5
6
7
8
9
10
Time, y

DAA

Clinical Gastroenterology and Hepatology 2014;12:728–737

Direct-Acting Antiviral Agents and the Path to Interferon Independence

Warren N. Schmidt,[*,‡] David R. Nelson,[§] Jean–Michel Pawlotsky,[‖,¶] Kenneth E. Sherman,[#] David L. Thomas,[**] and Raymond T. Chung[‡‡]

*Department of Internal Medicine and Research Service, Veterans Affairs Medical Center, Iowa City, Iowa; [‡]Roy G. and Lucille A. Carver College of Medicine, University of Iowa, Iowa City, Iowa; [§]University of Florida, Section of Hepatobiliary Disease, Gainesville, Florida; [‖]National Reference Center for Viral Hepatitis B, C and Delta, Department of Virology, Henri Mondor Hospital, University of Paris-Est, Créteil, France; [¶]INSERM U955, Créteil, France; [#]University of Cincinnati College of Medicine, Division of ... Maryland; and [‡‡]GI D... etts

Chronic in... pectively) global hea... lRp), and million ch...

drugs specifically designed to inhibit enzymes HCV uses to replicate

Schmidt, Clinical Gastroent Hepatol 12:728, 2014

Direct Acting Inhibitors

Polymerase Inhib:

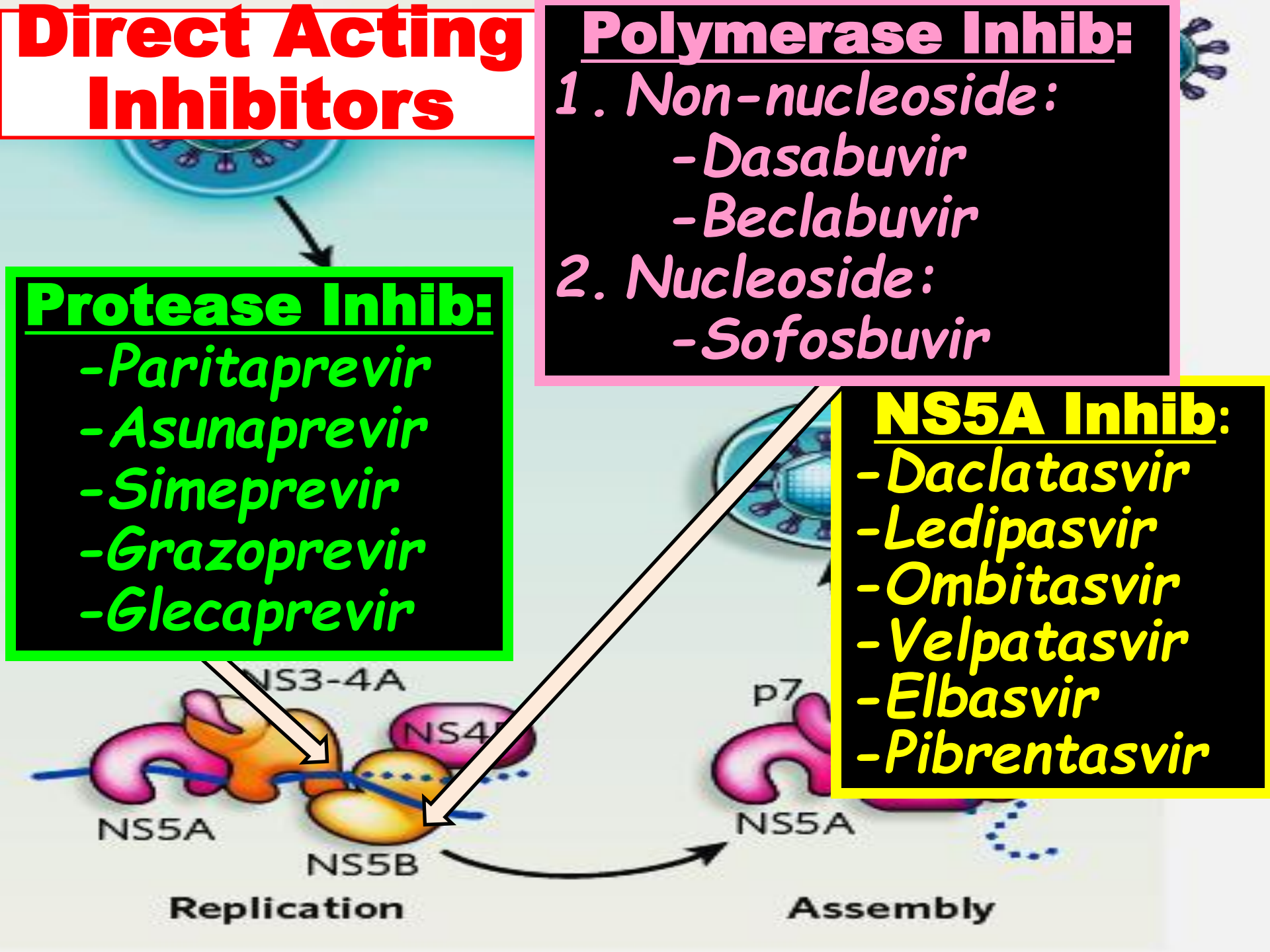
1. Non-nucleoside:
   - Dasabuvir
   - Beclabuvir
2. Nucleoside:
   - Sofosbuvir

Protease Inhib:

- Paritaprevir
- Asunaprevir
- Simeprevir
- Grazoprevir
- Glecaprevir

NS5A Inhib:

- Daclatasvir
- Ledipasvir
- Ombitasvir
- Velpatasvir
- Elbasvir
- Pibrentasvir



Open-Label, Multicenter, Multi-cohort, Single-Arm Phase 2 PEDIATRIC Trials

1. **Sofosbuvir + Ledipasvir** - *Genotype 1*

   NCT02249182 (GS 337-1116)

2. **Sofosbuvir + Ribavirin** - *Genotype 2/3*

   NCT02175758 (GS 334-1112)

3. **Glecaprevir + Pibrentasvir** - *All GTs*

   NCT03067129 (M16-123)

4. **Sofosbuvir + Velpatasvir** - *All GTs*

   NCT03022981 (GS 342-1143)

5. **Elbasvir + Grazoprevir** - *Genotype 1,4*

   NCT03379506 (MK5172-079)

Aims (Similar for All)

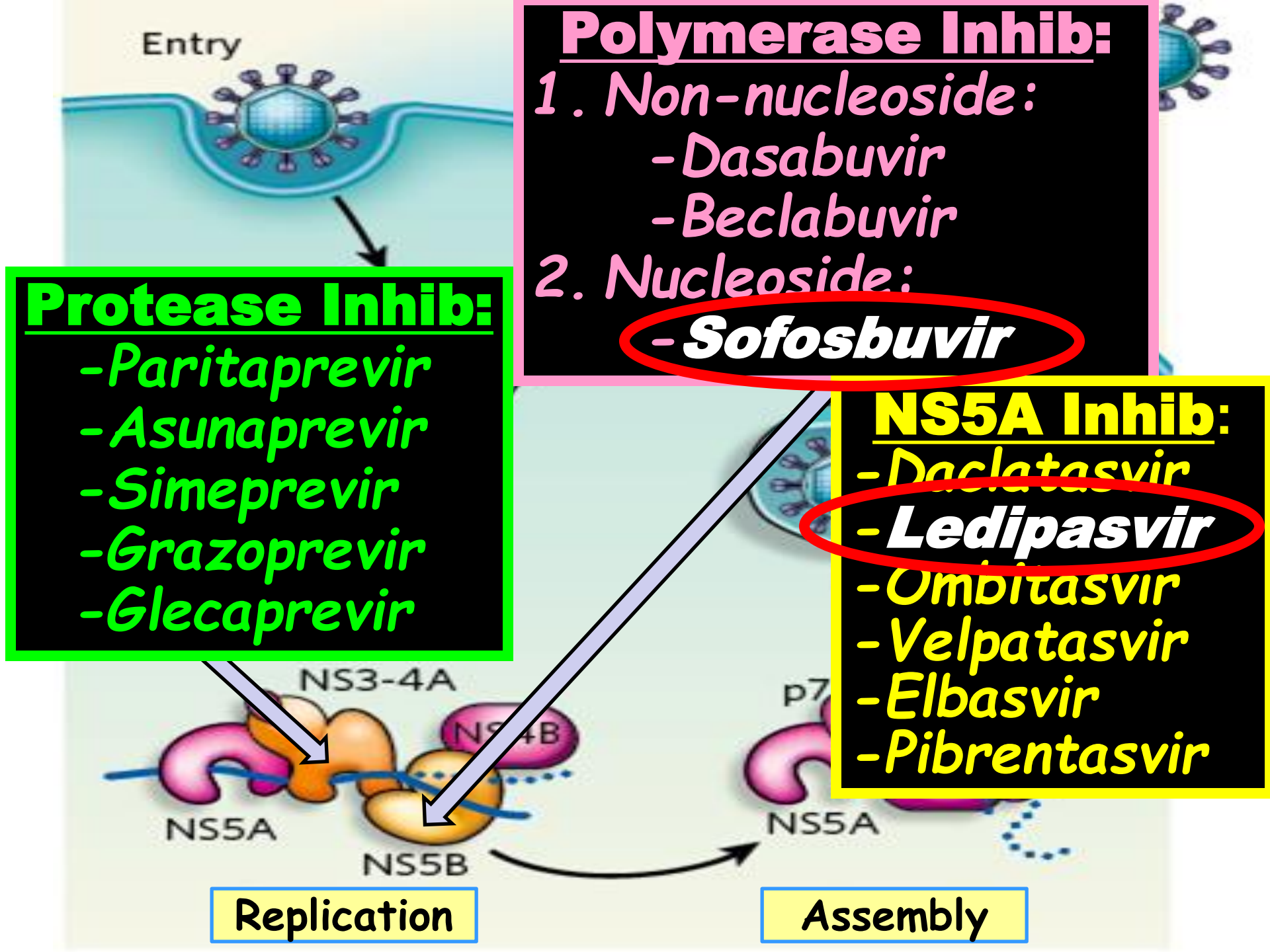
- **Primary objective:**
  - **Safety & tolerability (one/d x 8-12 wks)**
- **Secondary objectives:**
  - **Antiviral efficacy (SVR12)**
  - **Pharmacokinetics (PK) evaluation relative to adults (confirm dose)**
  - **Resistance?**
- **Age Groups:**

Methods:
3 Cohorts

1. 12 to <18 year old

2. 6 to <12 year old

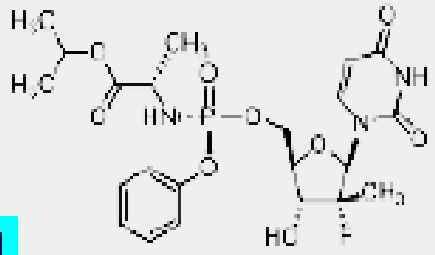
3. 3 to <6 year old


Entry
Polymerase Inhib:
1. Non-nucleoside:
-Dasabuvir
-Beclabuvir
2. Nucleoside:
-Sofosbuvir
Protease Inhib:
-Paritaprevir
-Asunaprevir
-Simeprevir
-Grazoprevir
-Glecaprevir
NS5A Inhib:
-Daclatasvir
-Ledipasvir
-Ombitasvir
-Velpatasvir
-Elbasvir
-Pibrentasvir
NS3-4A
NS4B
NS5A
NS5B
p7
NS5A
Replication
Assembly

Fixed-Dose Combination

Sofosbuvir

- Once-daily, oral, 400-mg NS5B inhibitor

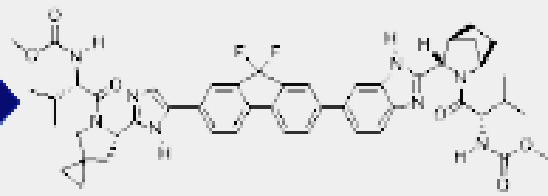


SOF
nucleotide
polymerase
inhibitor

Ledipasvir

- Once-daily, oral, 90-mg NS5A inhibitor

LDV
NS5A
inhibitor



12 weeks of treatment once daily

HEPATOLOGY, VOL. 66, NO. 2, 2017

Balistreri, Hepatology 66:371, 2017

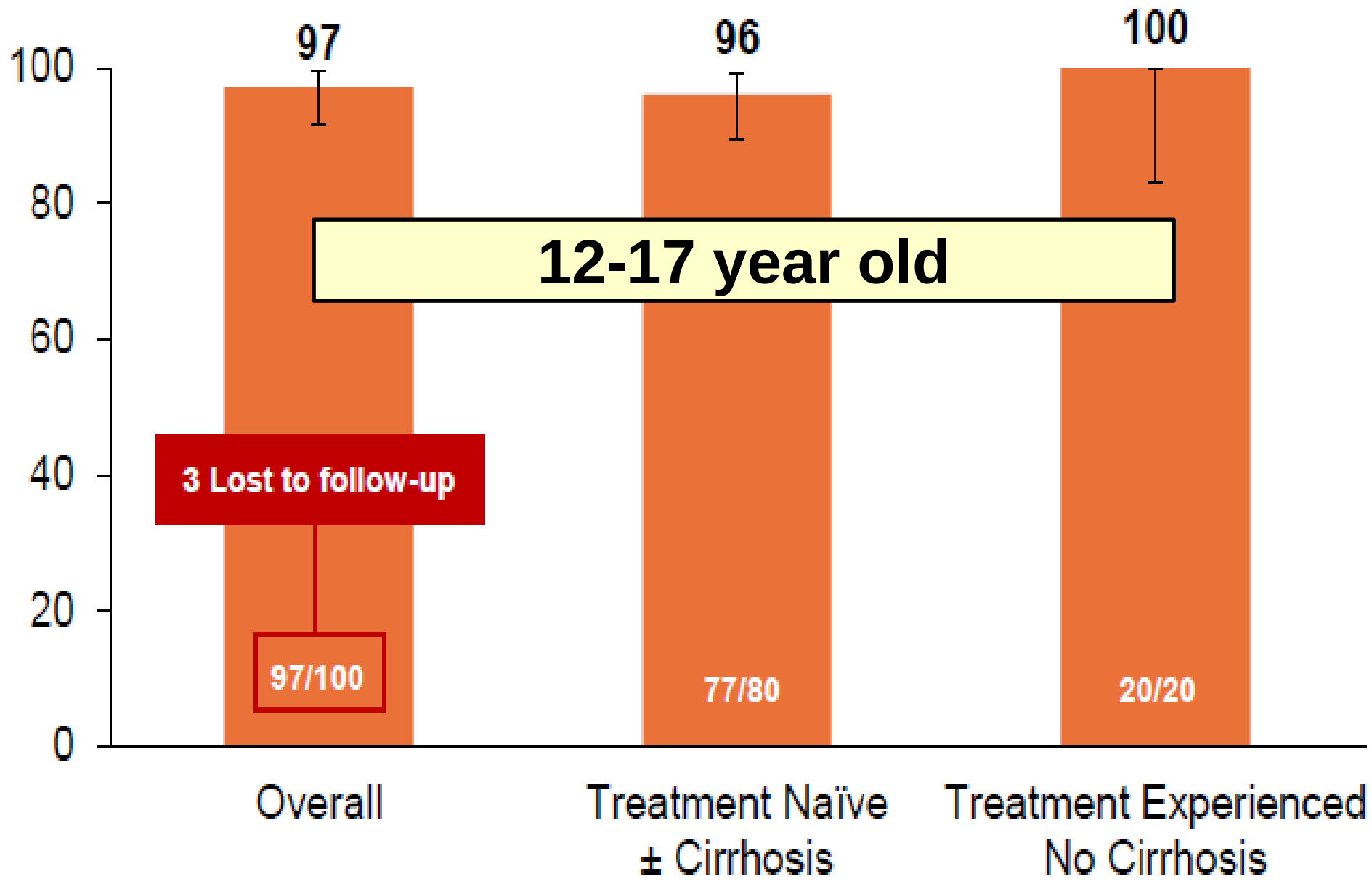
The Safety and Effectiveness of Ledipasvir–Sofosbuvir in Adolescents 12-17 Years Old With Hepatitis C Virus Genotype 1 Infection

(LDV/SOF)

William F. Balistreri,[1] Karen F. Murray,[2] Philip Rosenthal,[3] Sanjay Bansal,[4] Chuan-Hao Lin,[5] Kathryn Kersey,[6] Benedetta Massetto,[6] Yanni Zhu,[6] Bittoo Kanwar,[6] Polina German,[6] Evguenia Svarovskaia,[6] Diana M. Brainard,[6] Jessica Wen,[7] Regino P. Gonzalez-Peralta,[8] Maureen M. Jonas,[9] and Kathleen Schwarz[10]

No all-oral, direct-acting antiviral regimens have been approved for children with chronic hepatitis C virus (HCV) infection. We conducted a phase 2, multicenter, open-label study to evaluate the efficacy and safety of ledipasvir–sofosbuvir in adolescents with chronic HCV genotype 1 infection. One hundred patients aged 12-17 years received a combination tablet of 90 mg ledipasvir and 400 mg sofosbuvir once daily for 12 weeks. On the tenth day following initiation of dosing, 10 patients underwent an intensive pharmacokinetic evaluation of the concentrations of sofosbuvir, ledipasvir, and the sofosbuvir metabolite GS-331007. The primary efficacy endpoint was the percentage of patients with a sustained virologic response at 12 weeks posttreatment. Median age of patients was 15 years (range 12-17). A majority (80%) were HCV treatment-naive, and 84% were infected through perinatal transmission. One patient had cirrhosis, and 42 did not; in 57 patients the degree of fibrosis was unknown. Overall, 98% (98/100; 95% confidence interval 93%-100%) of patients reached sustained virologic response at 12 weeks. No patient had virologic failure. The 2 patients who did not achieve sustained virologic response at 12 weeks were lost to follow-up either during or after treatment. The three most commonly reported adverse events were headache (27% of patients), diarrhea (14%), and fatigue (13%). No serious adverse events were reported. Area under the concentration-time curve (tau) and maximum concentration values for sofosbuvir, ledipasvir, and GS-331007 were within the predefined pharmacokinetic equivalence boundaries of 50%-200% when compared with adults from phase 2 and 3 studies of ledipasvir and sofosbuvir. *Conclusion:* Ledipasvir–sofosbuvir was highly effective at treating adolescents with chronic HCV genotype 1 infection; the dose of ledipasvir–sofosbuvir currently used in adults was well tolerated in adolescents and had an appropriate pharmacokinetic profile. (HEPATOLOGY 2017;66:371-378).

Results: LDV/SOF - SVR 12 (%)



HEPATOLOGY

AASLD

HEPATOLOGY, VOL. 68, NO. 6, 2018

Safety and Efficacy of Ledipasvir–Sofosbuvir With or Without Ribavirin for Chronic Hepatitis C in Children Ages 6-11 GT-1

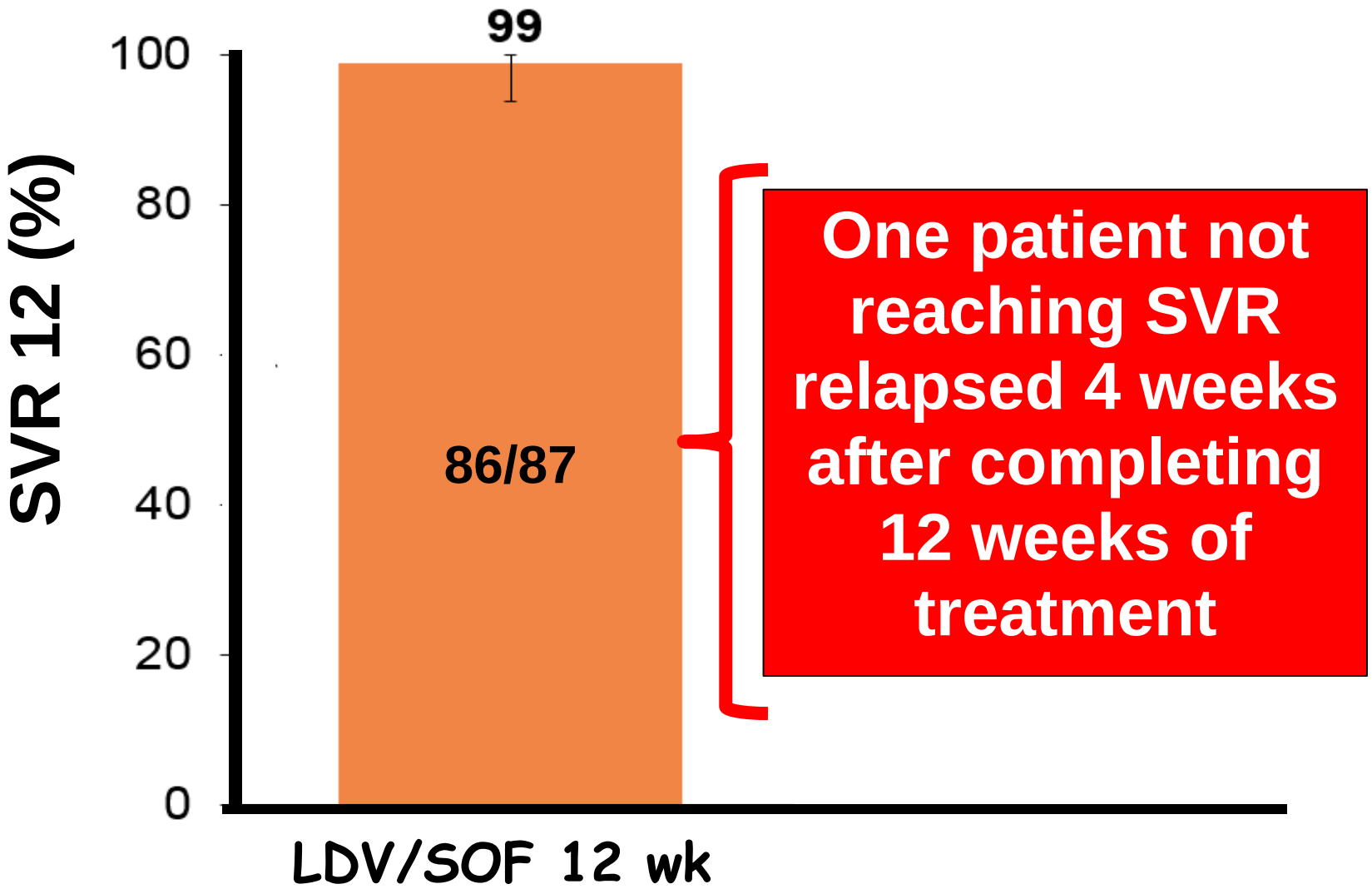
Karen F. Murray,[1] William F. Balistreri,[2] Sanjay Bansal,[3] Suzanne Whitworth,[4] Helen M. Evans,[5] Regino P. Gonzalez-Peralta,[6] Jessica Wen,[7] Benedetta Massetto,[8] Kathryn Kersey,[8] Jiang Shao,[8] Kimberly L. Garrison,[8] Bandita Parhy,[8] Diana M. Brainard,[8] Ronen Arnon,[9] Lynette A. Gillis,[10] Maureen M. Jonas,[11] Chuan-Hao Lin,[12] Michael R. Narkewicz,[13] Kathleen Schwarz,[14] and Phili

Murray, HEPATOLOGY 68:2158, 2018

- "Half-strength" FDC tablet
  - LDV/SOF – 45mg/200mg

Curren
than 12
HCV-i
45 mg–
for 12
virologi
to confi
type 1,
(97%) a
in 55 p
not rea
headache and pyrexia. One patient had three serious adverse events, which were considered to be not related to study treatment: tooth abscess, abdominal pain, and gastroenteritis. The area under the concentration–time curve and maximum concentration values for sofosbuvir, its primary metabolite GS-331007, and ledipasvir were within predefined pharmacokinetic equivalence boundaries (50%-200%) compared to values in adults in phase 2/3 of the ledipasvir and sofosbuvir studies. *Conclusion:* Ledipasvir–sofosbuvir was well tolerated and highly effective in children 6 to <12 years old with chronic HCV. (HEPATOLOGY 2018;68:2158-2166).

Results:
LDV/SOF in Children 6 to 11 years



HEPATOLOGY

AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

HEPATOLOGY, VOL. 0, NO. 0, 2019

Ledipasvir-Sofosbuvir for 12 Weeks in Children 3 to <6 Years Old With Chronic Hepatitis C

GT-1

Kathleen B. Schwarz,[1] Philip Rosenthal,[2] Karen F. Murray,[3] Jonathan R. Honegger ,[4] Winita Hardikar,[5] Rosie Hague,[6] Naveen Mittal,[7] Benedetta Massetto,[8] Diana M. Brainard,[8] Chia-Hsiang Hsueh,[8] Jiang Shao,[8] Bandita Parhy,[8] Michael R. Narkewicz,[9] Girish S. Rao,[10] Suzanne Whitworth,[11] Sanjay Bansal,[12] and William F. Balistreri[13]

Schwarz, Hepatology 71:422, 2020

For children under 12 years of age who have chronic hepatitis C virus (HCV) infection, there are currently no approved treatments with direct-acting antiviral agents. We therefore evaluated the safety and efficacy of ledipasvir-sofosbuvir in HCV-infected children aged 3 to <6 years. In an open-label study, patients 3 to <6 years old chronically

Ledipasvir-sofosbuvir was well tolerated and highly effective in children 3 to <6 years old with chronic HCV infection. (HEPATOLOGY 2019;0:1-9).

Weight-based doses (as pellets):

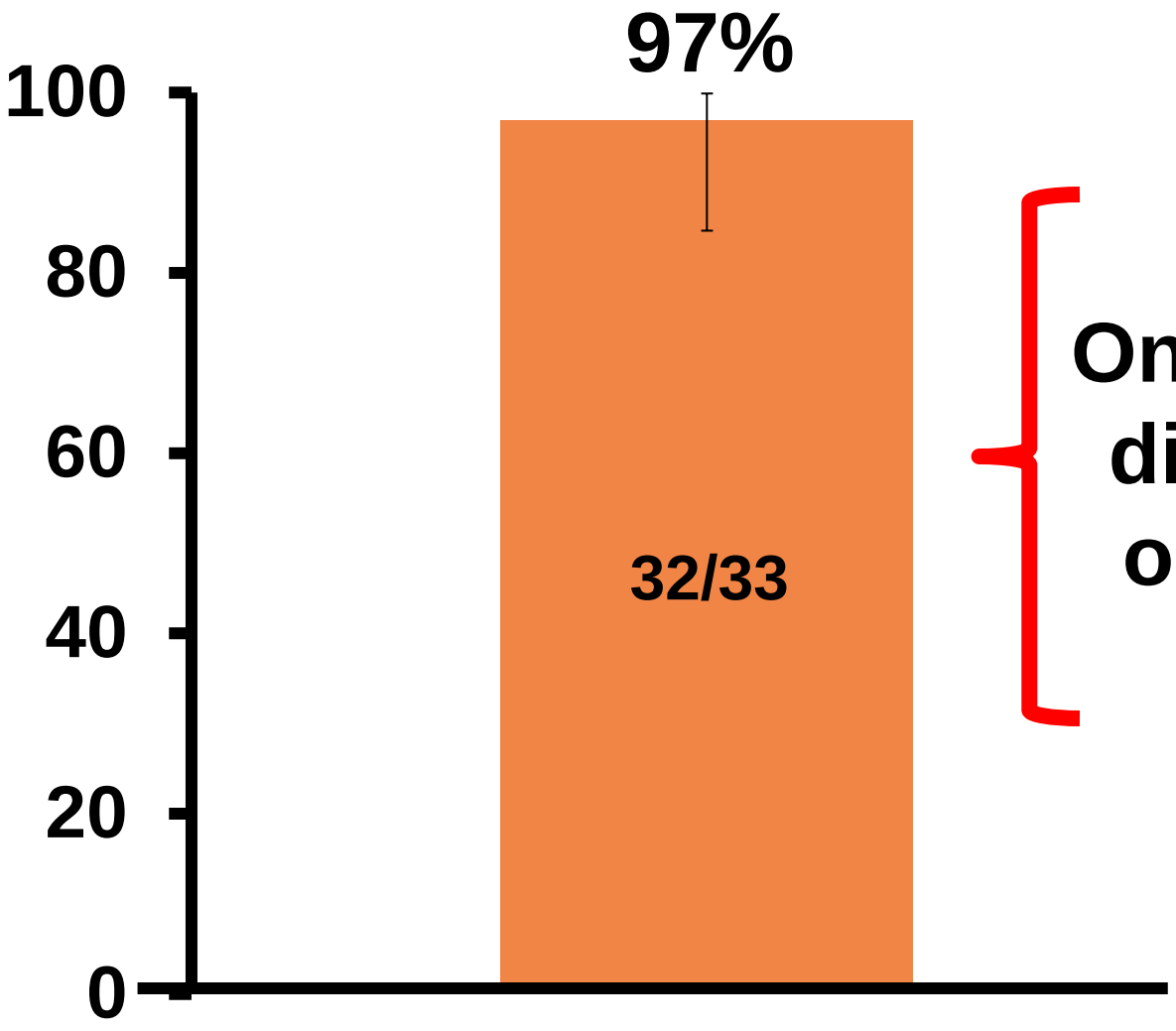
- **LDV 33.75mg/SOF 150 mg (wt <17 kg)**
- **LDV 45 mg/SOF 200 mg (wt ≥17 kg)**

Weight-based doses (as pellets):

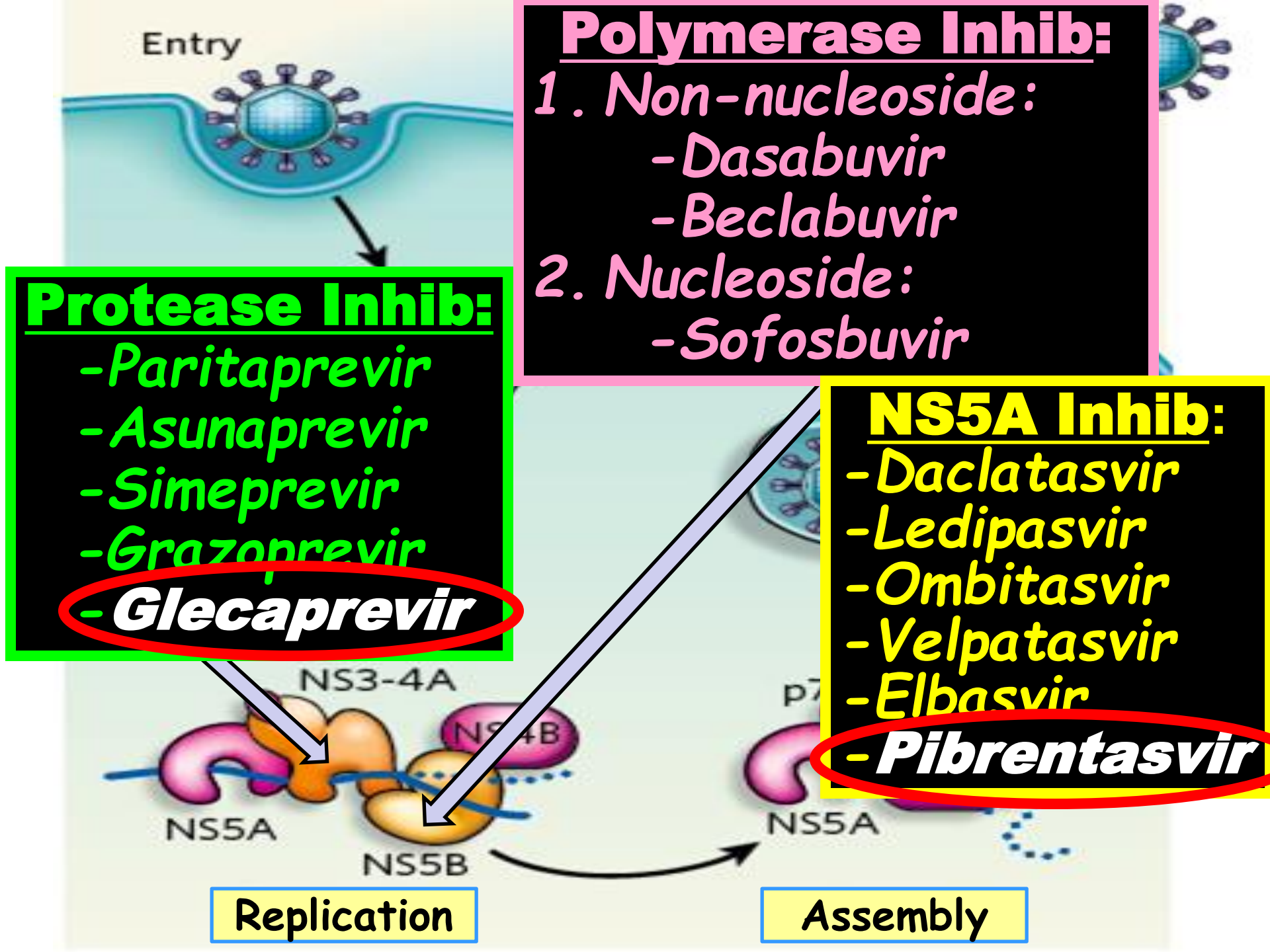
- LDV 33.75mg/SOF 150 mg (wt <17 kg)
- LDV 45 mg/SOF 200 mg (wt ≥17 kg)

Results: SVR12

LDV/SOF Children 3 to <6 yrs old



One subject (3 yo) discontinued Rx on Day 4 due to drug taste


Entry
Polymerase Inhib:
1. Non-nucleoside:
-Dasabuvir
-Beclabuvir
2. Nucleoside:
-Sofosbuvir
Protease Inhib:
-Paritaprevir
-Asunaprevir
-Simeprevir
-Grazoprevir
-Glecaprevir
NS5A Inhib:
-Daclatasvir
-Ledipasvir
-Ombitasvir
-Velpatasvir
-Elbasvir
-Pibrentasvir
NS3-4A
NS4B
NS5A
NS5B
p7
NS5A
Replication
Assembly

Pharmacokinetics, Safety, and Efficacy of Glecaprevir/Pibrentasvir in Adolescents With Chronic Hepatitis C Virus: Part 1 of the DORA Study

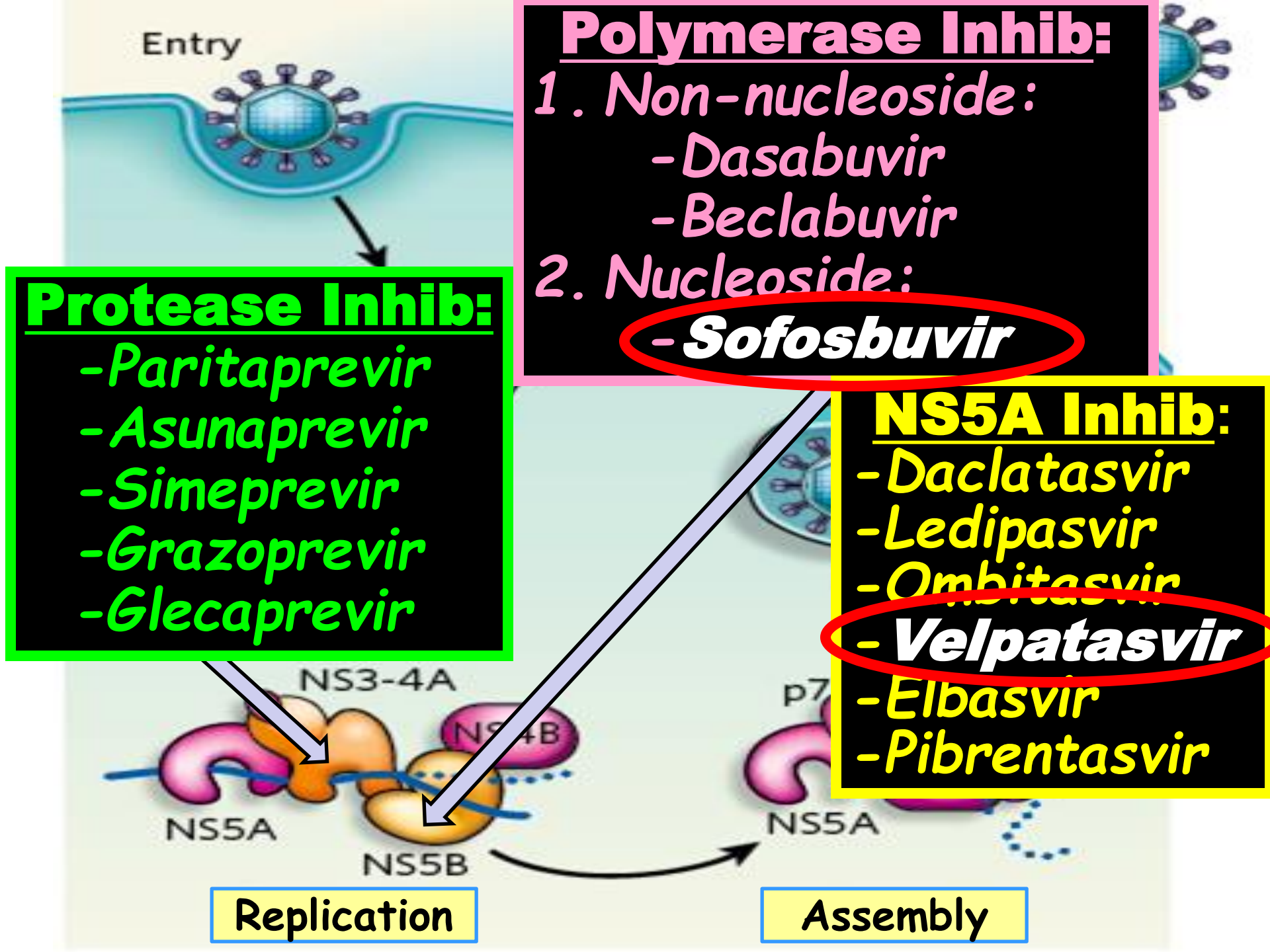
Maureen M. Jonas,[1,2] Robert H. Squires,[3,4] Susan M. Rhee,[5] Chih-Wei Lin,[6] Kazuhiko Bessho,[7] Cornelia Feiterna-Sperling,[8] Loreto Hierro,[9] Deirdre Kelly,[10] Simon C. Ling,[11] Tatiana Strokova,[12] Antonio del Valle-Segarra,[13] Sandra Lovell,[5] Wei Liu,[5]

Jonas, Hepatology 71:456, 2020

The pangenotypic regimen of glecaprevir and pibrentasvir (G/P) is approved to treat adults with chronic hepatitis

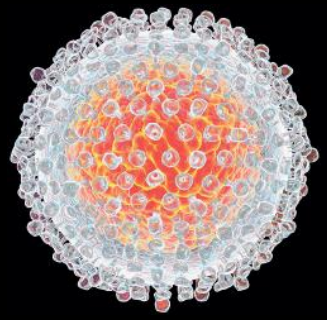
- **Adult formulation of GLE/PIB:**
  - **300 mg/120 mg**
- **Dosed once daily (8-16 weeks)**
- **47 patients (100%) SVR12**
- **No virologic failures**

typic regimen demonstrated 100% efficacy within the adolescent population in as little as 8 weeks of treatment. (Hepatology 2020;71:456-462).

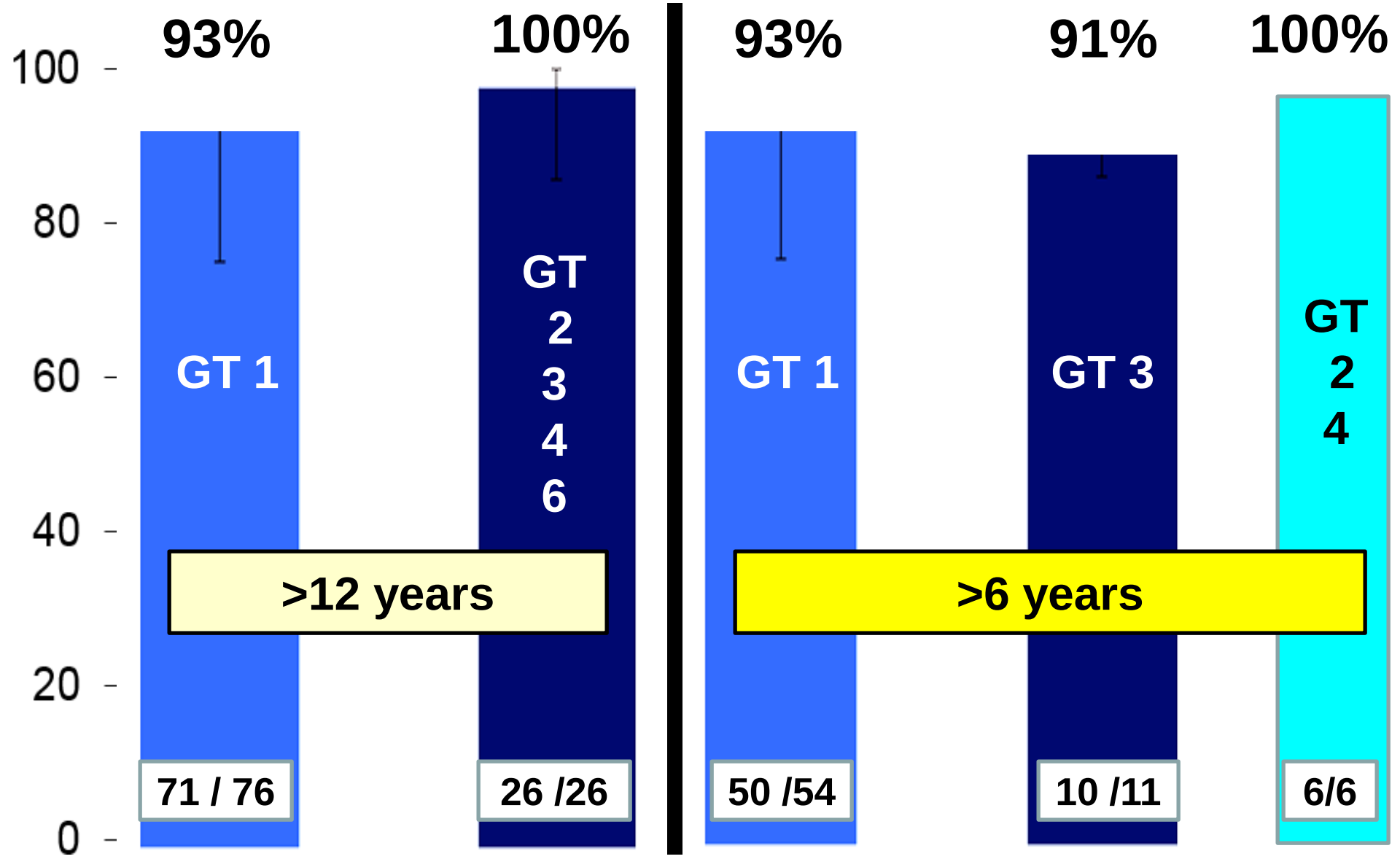

Entry
Polymerase Inhib:
1. Non-nucleoside:
-Dasabuvir
-Beclabuvir
2. Nucleoside:
-Sofosbuvir
Protease Inhib:
-Paritaprevir
-Asunaprevir
-Simeprevir
-Grazoprevir
-Glecaprevir
NS5A Inhib:
-Daclatasvir
-Ledipasvir
-Ombitasvir
-Velpatasvir
-Elbasvir
-Pibrentasvir
NS3-4A
NS4B
NS5A
NS5B
p7
NS5A
Replication
Assembly

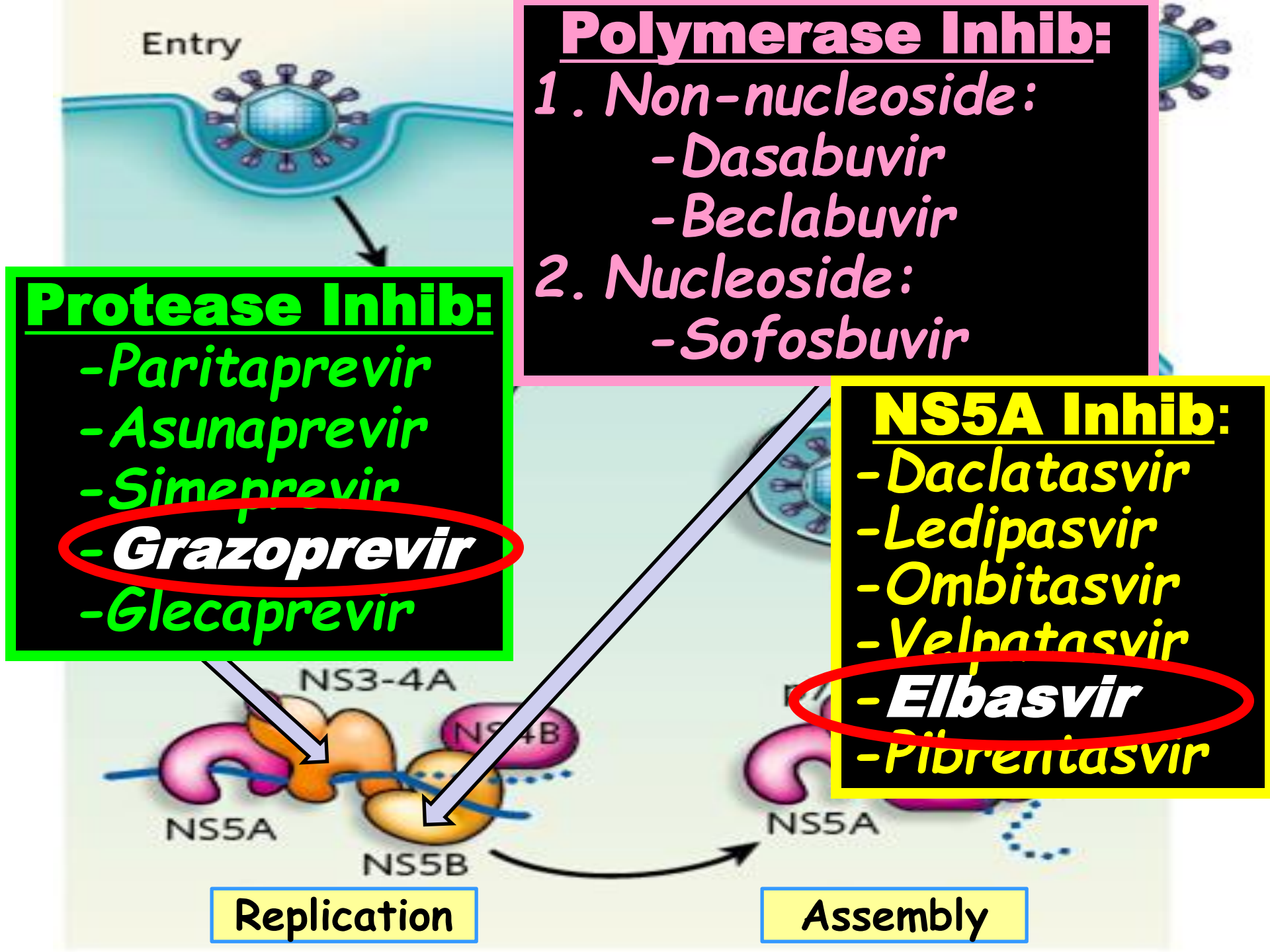
Sofosbuvir/Velpatasvir Patients 6 to < 18 years old

- Any genotype; fixed dose combo
- ≥12 to <18 yo: SOF/VEL400mg/100mg
- ≥6 to <12 yo: SOF/VEL 200 mg/50 mg
  - Pellets Or Tablet
- Once/d x 12 weeks



Results: SOF-VEL (% SVR12)

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-Paritaprevir
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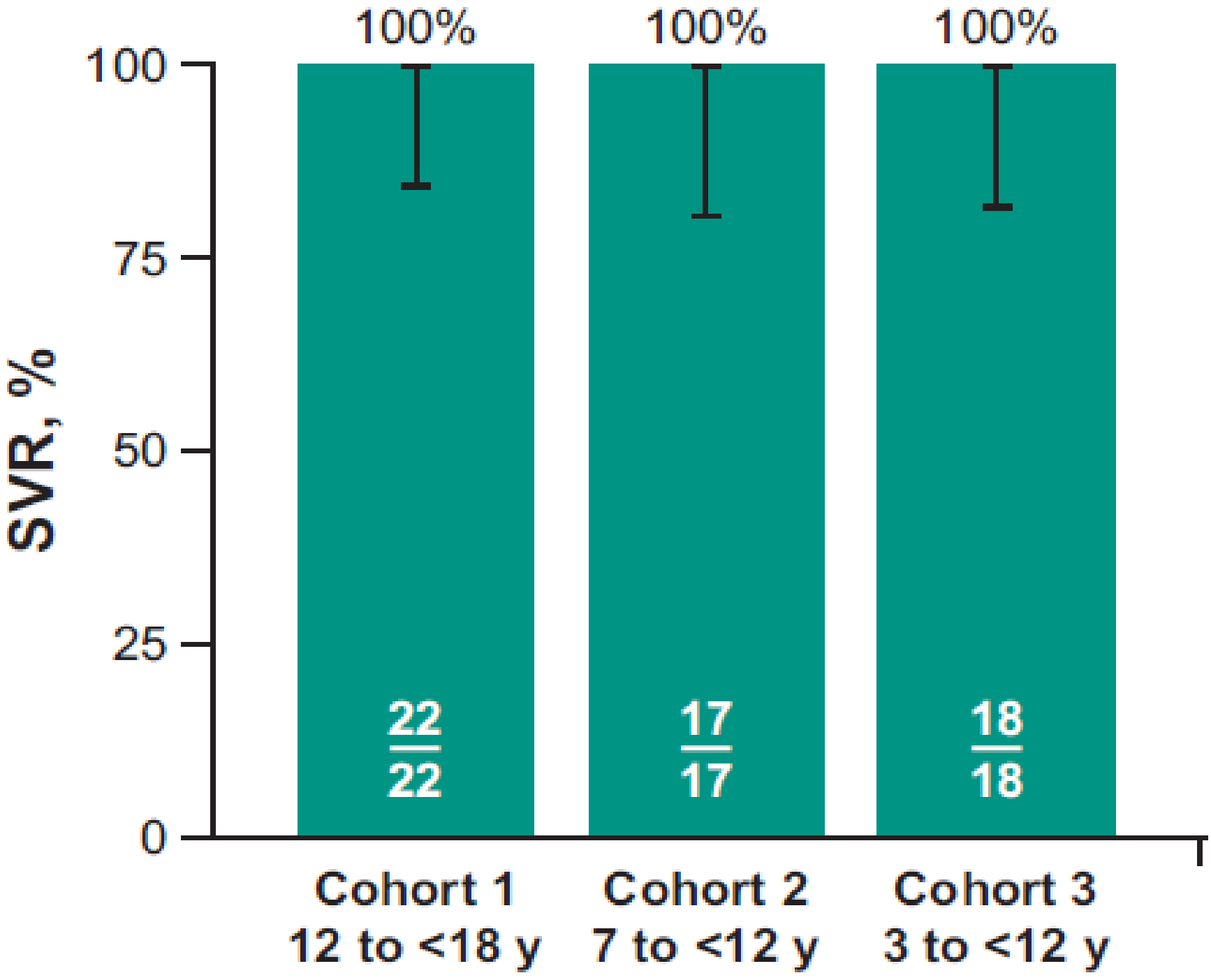
-Simeprevir
-Grazoprevir
-Glecaprevir
NS5A Inhib:
-Daclatasvir
-Ledipasvir
-Ombitasvir
-Velpatasvir
-Elbasvir
-Pibrentasvir
NS3-4A
NS4B
NS5A
NS5B
NS5A
Replication
Assembly


100%
100%
100%
100
75
50
25
0
SVR, %
22/22
17/17
18/18
Cohort 1
12 to <18 y
Cohort 2
7 to <12 y
Cohort 3
3 to <12 y

Quality of Life

Substantial improvements in social functioning and school performance domains following attainment of SVR

Younossi, JPGN 66:112, 2018

Younossi, J Viral Hepat 25:354, 2018

Notes re: DAAs

- Most common adverse reactions observed in clinical trials:
  - fatigue and headache
- Be aware:
  - Drug-Drug interactions
  - Boxed warning:
    - HBV reactivation (test all before)

MEDICAL PROGRESS
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Journal of Pediatrics 221:12, June 2020

Treatment of Hepatitis C: A New Paradigm toward Viral Eradication

James E. Squires, MD, MS[1], and William F. Balistreri, MD[2]

18 Published studies; Subjects = 758 (all genotypes)

Direct-Acting Antivirals

"This unprecedented efficacy has led to speculation that HCV infection might be eradicated even in the absence of a vaccine, but there are many impediments to global eradication including ascertainment of silent carriers, access to medication, and high drug cost". - Harvey J. Alter[1].

In the late 1970s and early 1980s, an epidemic of silent, post-transfusion hepatitis directly led to the discovery of a novel, hepatotropic agent of the flavivirus family aptly named the hepatitis C virus (HCV, formerly known as the non-A, non-B hepatitis virus). Less than 30 years later, through advancements in viral sequencing and 3-dimensional determination of the nonstructural proteins that direct RNA polymerases required for HCV replication, a new class of medications, known as direct-acting antivirals (DAAs), were introduced to treat HCV. DAAs have demon-

Importantly, these newly developed antiviral agents will expand and decentralize the delivery of HCV care from the domain of hepatologists and infectious disease specialists to community stakeholders/midlevel providers in real-world settings.

The New Treatment Strategies

The modern era of DAA therapy has enabled dramatic changes in the medical treatment of HCV in children with recently published guidance suggesting that the regimen of pegylated-interferon (PEG-IFN) and ribavirin (RBV) should not be utilized[3] (Figure 1). To appreciate the degree of superiority of DAA therapy over previous older HCV regimens, a review of

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Journal of Pediatrics 221:12, June 2020

Treatment of Hepatitis C: A New Paradigm toward Viral Eradication

James E. Squires, MD, MS[1], and William F. Balistreri, MD[2]

18 Published studies; Subjects = 758 (all genotypes)

Table I. Published studies of DAA regimens in children and adolescents

Authors	Year	Participant age in y (n)	HCV genotype	Therapy (duration)	SVR12 (%)
Balistreri et al[31]	2016	12-17 (100)	1	Ledipasvir 90 mg + sofosbuvir 400 mg (12 wk)	98
Wirth et al[32]	2017	12-17 (52)	2 or 3	Sofosbuvir 400 mg + ribavirin (variable)	98
Hashmi et al[33]	2017	5-18 (35)	1 or 3	Sofosbuvir 400 mg + ribavirin (variable)	97
Murray et al[34]	2018	6-11 (90)	1	Ledipasvir 45 mg + sofosbuvir 200 mg (12 wk)	98
El-Karaksy et al[35]	2018	12-18 (40)	4	Ledipasvir 90 mg + sofosbuvir 400 mg (12 wk)	100
Leung et al[36]	2018	12-17 (38)	1 or 4	Ombitasvir/paritaprevir/ritonavir + dasabuvir ± ribavirin (variable	100
Alkaaby et al[37]	2018	7-18 (22)		Ledipasvir + so	91
Tucci et al[38]	2018	0.5 (1)	4	Ledipasvir 22.5	100
El-Shabrawi et al[39]	2018	6-12 (20)	4	Ledipasvir 45 n	95
Quintero et al[40]	2019	6-18 (9)	1 or 4	Ledipasvir + so	100
Ghaffar et al[41]	2019	8-18 (40)	4	Sofosbuvir + da	97.5
Fouad et al[42]	2019	11-17.5 (51)	4	Ledipasvir 90 n	100
Ohya et al[43]	2019	10-13 (3)	1b	Ombitasvir + paritaprevir + ritonavir (12 wk) Or glecaprevir + pibrenastavir (8 wk)	100
Kamal et al[44]	2020	3-6 (22)	4	Ledipasvir 45 mg + sofosbuvir 200 mg (8 or 12 wk)	100
El-Araby et al[45]	2020	9-12 (100)	4	Ledipasvir 90 mg + sofosbuvir 400 mg (12 wk)	100
Rosenthal et al[46]	2020	3-11 (54)	1 or 4	Sofosbuvir 400 mg + ribavirin (variable)	98
Schwarz et al[47]	2020	3-<6 (34)	1 or 4	Ledipasvir + sofosbuvir (variable)	97
Jonas et al[48]	2020	12-17 (47)	1, 2, 3, or 4	Glecaprevir 300 mg + pibrentasvir 120 mg (8-16 wk)	100

SVR: 91-100%

What about “Real World” data?

Efficacy of Sofosbuvir/Ledipasvir in Adolescents With Chronic Hepatitis C Genotypes 1, 3, and 4: A Real-world Study

Serranti, JPGN 72:95, 2021

*Daniele Serranti, †Gabriella Nebbia, ‡Mara Cananzi, §Emanuele Nicastro, ||Fabiola Di Dato, ¶Federica Nuti, #Silvia Garazzino, #Erika Silvestro, **Vania Giacomet, **Federica Forlanini, ††Michele Pinon, ††Pier Luigi Calvo, ‡‡Silvia Riva, §§Icilio Dodi,

- **Open-label study involving (12 Italian centers)**
  "The Ciao-C study"
- **Overall, SVR12 was 98.7%**

(at least 3 years of age) with chronic hepatitis C (CHC) genotype 1, 3, and 4 infection. The aim of this study was to evaluate the efficacy and safety of SOF/LDV in adolescents (12 to <18 years old) with CHC in the real-world setting.

THE JOURNAL OF PEDIATRICS • www.jpeds.com ORIGINAL ARTICLES

Mogahed, Journ of Pediatrics, 233:126, 2021

Improvement in Liver Stiffness in Pediatric Patients with Hepatitis C Virus after Treatment with Direct Acting Antivirals

Engy A. Mogahed, MD[1], Hanaa El-Karaksy, MD[1], Hala Abdullatif, MD[1], Noha A. Yasin, MD[1], Ahmed Nagy, MD[2], Shereen Abdel Alem, MD[2], Hadeel Gamal Eldeen, MD[2], and Mona S. El-Raziky, MD[1]

Objectives To assess th… r stiffness using transient elastography in Egyptian children infected with hepatitis C… year after achievement of sustained virologic response (SVR) with direct

…luded children infected with HCV who received treatment with sofosbu-… and 1 year after achievement of SVR, the extent of hepatic fibrosis was …tography using FibroScan to measure liver stiffness, in addition to noninvasive markers …partate

Results The study… …es ranged between 10 and 18 years. At … …s had F3; 2 had F3-F4; and 2 patients w… …nt improvement in liver stiffness, APRI… …, the liver stiffness improved; in 7 patients, it was stationary, and the remaining 3 patients showed mild increase in liver stiffness that was, however, associated with improvement in APRI and FIB-4 index. Comorbid conditions and previous treatment with interferon were not associated with increased liver stiffness 1 year after SVR.

"Real World" data

Eradication of HCV - associated with regression of liver fibrosis

Currently approved DAAs (PED)

http://www.fda.gov

- **Sovaldi® -** (sofosbuvir)
- **Harvoni® -** (sofosbuvir & ledipasvir)
- **Epclusa® -** (sofosbuvir & velpatasvir)
- **Vosevi® -** (sofosbuvir, velpatasvir, voxilaprevir)
- **Zepatier ® -** (elbasvir & grazoprevir)
- **Mavyret® -** (glecaprevir & pibrentasvir)

One note: before treatment:

"Disease severity assessment via routine laboratory testing and physical examination, as well as use of evolving noninvasive modalities (i.e., elastography, imaging, or serum fibrosis markers) is recommended for all children with chronic HCV infection"

AASLD-IDSA guidance

Currently approved DAA

http://www.fda

Focus on Pangenotypic Agents

- **S** (…avir)
- **Ha…n®** - (sofosbuvir & ledipasvir)
- **Epclusa®** - (sofosbuvir & velpatasvir)
- **Vosevi®** - (sofosbuvir, velpatasvir, voxilaprevir)
- **Zepatier ®** - (elbasvir & grazoprevir)
- **Mavyret®** - (glecaprevir & pibrentasvir)

FDA approved Epclusa®
(sofosbuvir / velpatasvir); June 11, 2021

- Patients at least 3 years of age
- Oral pellets:
  - 200/50 mg
  - 150/37.5 mg
- Treatment of HCV genotypes 1-6

FDA approved Epclusa®
(sofosbuvir / velpatasvir); June 11, 2021

- Dosage = weight based:
  - < 17 kg: one 150mg/37.5 mg packet of oral pellets once daily
  - 17 to < 30 kgs: one 200 mg/50 mg packet of oral pellets once daily… OR
    - One 200/50 mg tablet once daily
  - ≥30 kgs: two 200 mg/50 mg packets of oral pellets once daily… OR
    - one 400 mg/50 mg tablet once daily

FDA approved Mavyret®
(glecaprevir / pibrentasvir); June 11, 2021

- Treatment of patients 3 to <12 years
- Oral pellets (100mg/40mg)
- HCV genotype 1-6 without cirrhosis or with compensated cirrhosis

FDA approved Mavyret®
(glecaprevir / pibrentasvir); June 11, 2021

- Dosage = weight-based:
  - <20 kg: three 50mg/20 mg packets of oral pellets once daily
  - 20 kg to <30 kg: 4 - 50 mg/20 mg packets of oral pellets once daily
  - 30 kg to <45 kg: 5 - 50 mg/20 mg packets of oral pellets once daily
  - >45 kg & >12 yrs: 3 - 100 g/40 mg tablets once daily

Administration of Pellets

- Taken with food, once daily
- Sprinkle pellets on spoonful of non-acidic soft food (room temp)
- Swallow entire mixture (food / pellets) within 15 min of preparation
- Do not crush or chew

AASLD
AMERICAN ASSOCIATION FOR THE STUDY OF LIVER DISEASES

Recommendations for Testing, Managing, and Treating Hepatitis C

IDSA
Infectious Diseases Society of America

Home | Test, Evaluate, Monitor | Treatment-Naive | Treatment-Experienced | Unique & Key Populations | About

New and updated:

HCV and People Who Inject Drugs
Injection drug use is the most common risk factor for HCV infection in the US and Europe, with an HCV seroprevalence of 10% to 70%, depending on geographic location and duration of exposure to injection drug use.

Start Here: Choose a patient profile from the menu above. ×

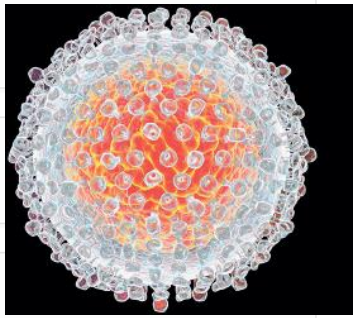
Welcome to HCVGuidelines.org

The AASLD and IDSA in partnership with the panel have created an updated web experience to facilitate easier and faster access to this important resource. Please select a patient profile from the menu above, click on a guidance section below, or use the search box to begin.

+ **Contents and Introduction** - *Select a Page*

+ **Testing, Evaluation, and Monitoring of Hepatitis C** - *Browse Topics*

+ **Initial Treatment of HCV Infection** - *Choose Patient Genotype*



http://www.hcvguidelines.org

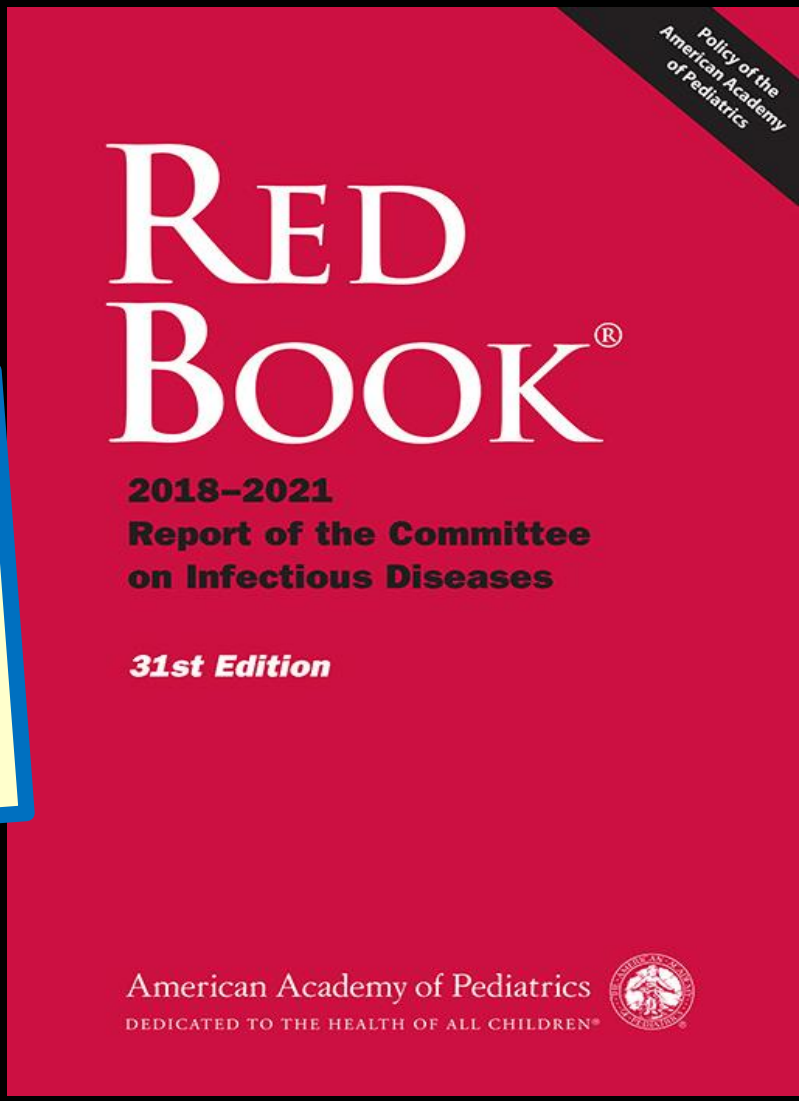
Management of Unique & Key Populations With HCV Infection

- Patients With Renal Impairment
- Kidney Transplant Patients
- Management of Acute HCV Infection
- HCV in Pregnancy
- HCV in Children

"DAA treatment is recommended for all HCV-infected children >3 years as they will benefit from antiviral therapy, independent of disease severity"

32nd Edition

"All HCV-infected children ≥3 years should be treated with FDA age-approved antiviral medications"



THE JOURNAL OF PEDIATRICS • www.jpeds.com ORIGINAL ARTICLES

Greenaway, Journal of Pediatrics 230:38, 2021

Treatment of Chronic Hepatitis C in Young Children Reduces Adverse Outcomes and Is Cost-Effective Compared with Deferring Treatment to

Emma Greenaway, MBBS, DM[1,3], Alexander Haines, MSc[2], Simon C. Ling, MBCh[1,3], and Murray Krahn, MD, MSc[2,4]

Objective To evaluate the cost-effectiveness of treating young children with chronic hepatitis C virus (HCV) with

"Delaying treatment to age 18 years results in increased lifetime risk of liver complications"

"Early treatment in young children is cost effective"

utilities.

Conclusions Delaying treatment until age 18 years results in an increased lifetime risk of late-stage liver complications. Early treatment in children is cost effective. Our work supports clinical and health policies that broaden HCV treatment access to young children. *(J Pediatr 2020; ■:1-8)*.

Conclusions

- Treatment of HCV-infected children with DAAs:
  - –Safe & Effective
  - –Several public health benefits:
    1. Reduce disease progression
    2. Reduce disease transmission
    3. Improve quality of life

HCV Vaccine?

"History has taught us that if you want to effectively control an infectious disease, you have to develop a vaccine" Houghton

- Another level of prevention
- DAAs do not prevent **re-infection**

Our children won't have to be afraid of these "bugs"