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HCV Treatment

TAG
Treatment Action Group

Waiting for Generics

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Since the adoption of the World Health Organization (WHO) health sector strategy to eliminate viral hepatitis as a public health threat, civil society has demanded care for all those living with chronic hepatitis C virus (HCV) infection. Sofosbuvir was approved in the United States as the first interferon-free curative treatment for HCV in December 2013. Yet in the years since, only 5.5 million of the 71 million people worldwide living with chronic HCV have been treated. And while Egypt and a handful of high-income countries make slow progress toward the WHO interim 2020 goals, global 2030 targets continue to recede over the horizon, with significant progress requiring more cures each year than new infections. This is an almost insurmountable challenge when drug use remains criminalized, and extrajudicial violence and social exclusion are the norm for people who inject and use criminalized substances.

Despite overwhelming evidence of the efficacy of pangenotypic direct-acting antivirals (DAAs) across patient subgroups and among people actively injecting and using criminalized substances, barriers to universal treatment access remain stubbornly in place. Too often, national health ministries require in-country clinical trials to prove efficacy, and payers and providers require sobriety in order prescribe. Originator companies continue to ignore middle-income country markets or delay registration for generic manufacture under voluntary licenses. Multinational trade agreements, in particular as pursued by the United States Trade Representative, seek to strengthen patent monopolies and threaten the sovereignty of governments that put their people over corporate profits. Regional procurement mechanisms are weak or non-existent, further disadvantaging smaller, poorer nations with limited resources to invest in treatment scale-up. Nevertheless, the global supply chain for low-cost DAAs is robust, with generic sofosbuvir/velpatasvir manufactured in India for the domestic market now deemed cost-effective. Industry engagement is needed to bring affordable generic glecaprevir/pibrentasvir (G/P) to market.

Indications for the current class of DAAs continue to expand with the recent FDA approval of G/P for adolescents, the first pangenotypic regime available for patients aged 12–17 years. In 2020 results are expected from ongoing trials in pregnant persons for cure and prevention of vertical transmission. China also reported phase II/III trial results showing high cure rates from three novel DAAs combinations (abstract #999, #1000 and #1001). However, these formulations are unlikely to be available outside of China.

Emerging difficult to treat GT4r and non-1a/1b, non-4a/4d subtypes have been observed in patients in sub-Saharan Africa and among African migrants in Europe. Identifying and effectively treating these patients will challenge under-resourced HCV programs in African countries, and programs serving migrants from the region. This also highlights the public health impact of the lack of ethnic and geographic diversity in clinical registration trials.

Recent modeling studies suggest that achieving the WHO 2030 target of diagnosing 90 percent of people living with HCV infection is a prerequisite for achieving elimination goals, even with universal treatment access and comprehensive harm reduction services in place. Without reduction in the high cost of diagnostics—for both patients and public health systems—low- and middle-income countries (LMICs) will simply not benefit from low-cost generics. The scope of the challenge we face is such that all points in the care cascade must be affordable for LMICs in order to bring cure to all.

The refrain should be familiar by now: we possess the therapeutic tools to eliminate HCV infection as a public health threat—at affordable prices and across all genotypes—if they can be delivered before patients develop decompensated cirrhosis. We also know these tools are effective among the key population driving incidence: people who inject drugs. Shall we go forward with this knowledge? Or shall we continue to wait?

Advocacy points

For companies:

- Ensure generic sofosbuvir and daclatasvir is registered and available for sale in all countries covered under voluntary licenses.
- Accelerate registration and access to generic glecaprevir/pibrentasvir (G/P) via voluntary licenses—and facilitate access to branded product for patients who would benefit (such as those with end-stage renal disease).
- Complete phase II/III clinical trials of sofosbuvir/ravidasvir (SOF/RAV) in genotype 5 and 6 patients to confirm pangenotypic activity.
- Complete phase II/III clinical trials of sofosbuvir-based regimes in patients younger than 6 years and weighing less than 17 kilograms.
- Conduct phase II/III clinical trials of pangenotypic regimes—including sofosbuvir/daclatasvir (SOF/DAC), and SOF/RAV—in patients younger than 17 years and children weighing less than 35 kilograms.
- Conduct phase II/III clinical trials of G/P in patients younger than 12 years and weighing less than 35 kilograms.
- Complete phase II/III clinical trials in pregnant people to assess the safety and efficacy of DAAs as curative treatment and prophylaxis to prevent vertical transmission.
- Conduct phase II/III trials of short-term (less than eight-week) treatment courses for acute infection.

For governments:

- Waive any requirement for in-country clinical registration trials for proven DAA combinations from validated generic manufacturers.
- Decriminalize the possession and distribution of harm reduction tools and interventions: syringe service programs, direct purchase and possession of syringes, and safe drug consumption spaces/safe-injection facilities.
- Ensure competition between generics manufacturers.
- Explore all available means to accelerate and expand access to generics: compulsory licenses using TRIPS flexibilities or other legal approaches, parallel importation, and patent challenges.
- For high-income countries, refrain from retaliatory trade practices in response to the use of TRIPS flexibilities for access to medicines.
- Enact opt-out HCV screening of all people upon incarceration, with robust linkage to care during incarceration and after release.
- Align public health system payment/reimbursement to expand HCV screening beyond individuals born between 1945 and 1965 (the birth cohort) and people with identified high risk, with particular attention to pregnant people.

For donors:

- Commit to multilateral and bilateral funding for universal access to generic DAA treatment in LMICs.
- Facilitate the integration of disease-specific programs by supporting treatment of HCV-monoinfected people who are at risk for HIV and other infectious diseases.
- Expand access to regional and central procurement platforms, such as the Global Fund's Pooled Procurement Mechanism, beyond HIV, TB, and malaria, at a minimum for DAA treatment for those with coinfections.

Table 1: Branded DAAS

Compound	Class/Type	Company/Sponsor	Patient Population	Status
SOF/RAV	**NS5B/NS5A inhibitor**	**DNDi/Pharco**	**Genotypes 1a/b, 2, 3, 4, 6; HIV coinfection; PWID**	**Approval pending**
STORM-C-1 phase II/III trial, stage 1, of 12 weeks sofosbuvir/ravidasvir in non-cirrhotic patients and 24 weeks in cirrhotic patients ■ N = 300, overall 97% SVR12 (intent to treat analysis), 98.3% SVR12 rate per protocol analysis (288/293) ■ HIV coinfected 97% SVR12 (87/90) ■ Minimal enrollment of GT6 patients, 81% SVR12 (13/16), GT5/6 trials ongoing Efficacy in GT4 treatment-naive and interferon-experienced patients with and without cirrhosis previously established: ■ N = 298, 95.3% SVR 12 overall				
G/P	**NS3-4A/NS5A inhibitor**	**AbbVie**	**GT1-6 without cirrhosis; +/- HIV coinfection**	**FDA approved**
Integrated analysis of GT1-6 patients without cirrhosis: includes 9 phase II (N = 201)/III (N = 1840) trials: SURVEYOR-I Part 2; SURVEYOR-II Parts 1 and 2, Part 4; ENDURANCE-1 (HIV coinfection) -2 -3 -4; EXPEDITION-2 (HIV coinfection) -4 ■ 98% SVR12 (943/965) with 8 wks ■ 99% SVR12 (1060/1076) with 12 wks ■ Overall ≥95% SVR12 across patient subgroups ■ No difference in SVR between TN and TE patients with 8 wks ■ TN GT3 had ≥95% SVR12 at both 8 and 12 wks ■ 99% SVR12 (no VF) with HIV-1 coinfection ■ 98% SVR12 (no VF) with severe renal impairment ■ Non-inferior as retreatment regime among GT1a patients without cirrhosis: relapse with SOF/VEL/VOX 8 wks = 8%, SOF/VEL 12 wks = 0%, G/P 8 wks = 0% ■ Most common AE were headache and fatigue, reported by 13-18% of patients in both durations ■ 1 DAA-related serious AE, 10 AE leading to discontinuation, 3 DAA-related AE leading to discontinuation ■ Patients with HBV and TE with non-SOF-based DAAs were excluded				
G/P	**NS3-4A/NS5A inhibitor**	**AbbVie**	**GT5, 6**	**FDA approved**
ENDURANCE-5,6: a phase IIIb multicenter, open-label trial of TE and TN patients +/- compensated cirrhosis conducted in 24 hospitals and clinics in Europe (Belgium, France); Oceania (Australia, New Zealand); North America (Canada, U.S.); South Africa; and southeast Asia (Singapore, Vietnam); 8 weeks for patients without cirrhosis, 12 weeks for patients with compensated cirrhosis ■ N = 84, 98% (82/84) SVR12 ■ GT5 = 22/23 SVR12, GT6 = 60/61 SVR12 ■ N = 5 serious AE reported, but none was related to TX or resulted in discontinuation ■ One patient with GT6f with cirrhosis had VF at week 12; one patient with GT5a w/ SVR4 relapsed at week 12 post TX ■ 1 Black patient, 1 Multirace patient; 91% of GT5 patents were White; 92% of GT6 patients were from Vietnam, China and Cambodia ■ HBV and HIV coinfection were exclusion criteria ■ Only 5 participants reported history of IDU (all GT6) ■ No impact of baseline polymorphisms on SVR12 ■ All results consistent with registration trials				

Compound	Class/Type	Company/Sponsor	Patient Population	Status
G/P	**NS3-4A/NS5A inhibitor**	**AbbVie**	**Retreatment after DAA failure**	**FDA approved**

MAGELLAN-3: phase IIIb open-label trial G/P + SOF + RBV for retreatment of G/P failure. Patients without cirrhosis, and NS3-4A/NS5A inhibitor treatment naive prior to VF with G/P received 12 weeks of treatment; patients with GT3 and/or compensated cirrhosis and/or experience with NS3-4A/NS5A inhibitors prior to VF with G/P received 16 weeks of treatment.

- 96% (22/23) SVR12
- 1 participant with GT1a with compensated cirrhosis experienced VF at 4 weeks post TX (patient had previously failed SOF/LDV and G/P)
- Results informed EASL guidelines recommending triple combo of SOF + PI + NS5Ai for retreatment
- SOF/VEL/VOX is the only regime FDA approved specifically for retreatment (based on POLARIS-1 study results)

G/P	**NS3-4A/NS5A inhibitor**	**AbbVie**	**Children and adolescents 12–17 years old; GT1, 2, 3, 4**	**FDA approved April 2019**

DORA Study, Part 1: phase II/III non-randomized open-label multicenter trial to evaluate pharmacokinetics, safety and efficacy of glecaprevir/pibrentasvir in patients aged 12–17 years without cirrhosis or with compensated cirrhosis. Patients were TN or TE with peg-INF or SOF+peg-INF +/- ribavirin. G/P (300 mg/120 mg) was taken with food for 8 or 16 wks based on cirrhosis stage, genotype and treatment history as per adult treatment guidelines.

- 100% (47/47) SVR12
- Most common AE reported were nasopharyngitis (26%) and upper respiratory tract infection (19%)
- No treatment discontinuations due to AE
- Along with data in adult patients these results were used as basis for FDA approval

SOF/LDV	**NS5B/NS5A inhibitor**	**Gilead**	**GT4 MSM +/- HIV coinfection**	**FDA approved for 12 weeks**

HEPNED-001 study: open-label, single-arm prospective study of 8 weeks of sofosbuvir/ledipasvir in TN non-cirrhotic GT4 MSM patients in 10 centers in the Netherlands and Belgium

- 95% (37/39) SVR12 overall
- 93% (28/30) SVR12 among HIV+; 100% (9/9) SVR12 among HIV-
- Patients above F3 excluded
- All participants had HCV RNA load <10M IU/mL
- 2 treatment failures = 1 subtype 4c, the other not typable
- Post SVR12 = 4 reinfections in HIV+ participants (1 genotype switch, 3 phylogenetically distinct), and 2 relapses among HIV+ participants
- Results and enrollment comparable to number included in phase III GT4 registration trials for the approved 12-wk regime

SOF/LDV	**NS5B/NS5A inhibitor**	**Gilead**	**GT4 subtypes**	**FDA approved**

SHARED: open-label, single-arm, single-site prospective study in Rwanda among adults with GT4, according to the authors, the first to report DAA outcomes in sub-Saharan Africa. Subtypes 4k, 4r, 4q and 4v observed.

- N = 300, 87% (261/300) SVR12 overall
- Subtypes: 4k = 134 (45%), 4r = 48 (16%), 4q 42 (14%), 4v = 24 (8%)
- 56% (27/48) SVR12 among participants with GT4r
- No treatment-related discontinuations
- Adherence was high among 296 patients with pill counts, with 92% demonstrating 100% adherence and only 1 patient with <90% adherence

Compound	Class/Type	Company/Sponsor	Patient Population	Status
SOF/LDV	**NS5B/NS5A inhibitor**	**Gilead**	**Children 6–11 years old; GT1, 3, 4**	**FDA approved**

Safety and efficacy of SOF/LDV +/- RBV in children ages 6–11: open-label study conducted in Australia, New Zealand, UK, and U.S.; patients received LDV 45mg/SOF 200 mg as two fixed-dose combination tablets once daily, with or without ribavirin, for 12 or 24 weeks, depending on GT and cirrhosis.

- N = 92, 99% (91/92) SVR12
- 1 GT1a patient with cirrhosis who received 12 wks without RBV relapsed 4 wks post SVR12
- 23% (21) of patients were TE
- 2 GT3 patients treated +RBV for 24 wks achieved SVR12
- 2 patients with confirmed cirrhosis

SOF/LDV	**NS5B/NS5A inhibitor**	**Gilead**	**Children 3–6 years old; GT1, 4**	**Approval pending**

Sofosbuvir/ledipasvir in children 3 to <6 years old: open-label study of 12 weeks of weight based SOF/LDV (150 mg/33.75 mg for patients weighing <17 kg or 200 mg/45 mg for patients ≥17 kg). Patients were GT1 (N = 33) or GT4 (N = 1). All patients were TN and were infected via vertical transmission. No patients had confirmed cirrhosis. Appropriate dose was confirmed via pharmacokinetic sampling of the first 14 patients treated.

- 97% (33/34) SVR12
- 29% (10) weighed <17 kg
- 3 year old patient discontinued treatment on day 5 due to “abnormal drug taste”
- Most common reported AE were vomiting (24% of patients), cough (21%), and fever (21%)
- No serious AE

SOF/VEL	**NS5B/NS5A inhibitor**	**Gilead**	**GT1–6**	**FDA approved**

Phase III open-label, single-arm, multisite study conducted across 38 sites in China, Thailand, Vietnam, Singapore, and Malaysia, among TN and TE patients with and without compensated cirrhosis. All GT3b patients had baseline resistance-associated substitutions.

- N = 375, 97% (362/375) SVR12 overall
- 89% (25/28) SVR12 among participants with GT3b and without cirrhosis
- 50% (7/14) SVR12 among participants with GT3b and with cirrhosis
- No treatment discontinuations due to AE, however, 36 patients (10%) reported upper respiratory infections

SOF/VEL/VOX	**NS5B/NS5A/NS3-4A protease inhibitor**	**Gilead**	**Retreatment after DAA failure**	**FDA approved**

POLARIS-1 substudy: open-label investigation of deferred treatment in patients with previous failure with NS5A inhibitor regime conducted in 73 hospitals and clinics in U.S., France, Canada, UK, Germany, Australia, New Zealand

- N = 147, 97% (143/147) SVR12
- 4 patients with GT1a experienced virologic failure, one also had compensated cirrhosis
- Study population was 79% male and 82% white
- Previous NS5Ai treatment included LDV, DAC, and ombitasvir
- No serious TX-related AE and no AE-related discontinuations
- Baseline NS5A or NS3 RASs were found in 89% of patients, with no impact on SVR
- Combined with primary study outcomes = 97% (396/410) cure

Compound	Class/Type	Company/Sponsor	Patient Population	Status
EBR/GZR	**NS5A/NA3-4A + NS5B inhibitor**	**Merck**	**GT1, 4 MSM with acute infection +/- HIV coinfection**	**FDA approved for chronic HCV**

DAHHS2 study: single-arm, open-label, multicenter phase IIIb study of elbasavir/grazoprevir for 8 weeks in acute infection among a cohort of MSM without cirrhosis

- N = 80, overall 99% (79/80) SVR12
- 4 reinfections (94% SVR12 if reinfection considered TX failure)
- 98.6% (72/73) of HIV+ patients on ART achieved SVR12
- No serious TX-related AE and no study discontinuations
- Non-inferior to 93% SVR12 achieved with 12-wk regime in C-EDGE registration trial
- Acute infection defined as positive anti-HCV Ab or positive HCV RNA + documented negative anti-HCV Ab or negative HCV RNA in the last 12 months; in absence of documented negative test, positive RNA + increased ALT, any negative Ab, and no other explanation for increased ALT
- Despite not testing for baseline polymorphisms before treatment, all 14 patients with NS5A polymorphisms achieved SVR12
- 2017 European AIDS Clinical Society guidelines recommend off-label DAA TX as prevention for acute HCV

Table 2: Efficacy of Generic DAAs

Compound	Class/Type	Company/Sponsor	Patient Population	Status
SOF/DAC or SOF/LDV +/- RBV	**NS5B/NS5A inhibitor**	**Egypt**	**Adults**	**FDA approved**

High efficacy of generic and brand DAAs: patients without cirrhosis were treated with SOF/DAC or SOF/LDV for 12 weeks, with the addition of ribavirin for patients with cirrhosis or TE with sofosbuvir. Ribavirin intolerant patients with cirrhosis were treated for 24 weeks.

- N = 971
- 98.1% SVR12 for brand DAAs
- 98.2% SVR12 for generic DAAs
- Results also consistent across regimes

SOF+RBV, SOF/LDV, SOF/DAC	**NS5B/NS5A inhibitor**	**India**	**GT1, 3 patients with chronic kidney disease**	**FDA approved**

Generic SOF-based DAAs in HCV-infected patients with chronic kidney disease: full-dose sofosbuvir in combination with ribavirin (N = 26, 24 weeks, 69.2% GT1, 30.8% GT3), ledipasvir (N = 26, 12 weeks, all GT1), or daclatasvir (N = 19, 12 weeks, all GT3)

- N = 71, 100% SVR12
- 84.5% of patients on hemodialysis, 23.9% with cirrhosis
- 1 patient in SOF/LDV arm relapsed at 24-wk follow-up post SVR12, 1 patient in SOF+RBV arm relapsed at 48-wk follow-up post SVR12

Compound	Class/Type	Company/Sponsor	Patient Population	Status
SOF/DAC +/- RBV	**NS5B/NS5A inhibitor**	**Egypt**	**Adults +/- cirrhosis**	**FDA approved**
High sustained virologic response rate using generic DAAs in the treatment of chronic HCV Egyptian patients: single-site observational study, patients sorted into two groups: group A (101 patients) received brand DAC and brand SOF, group B (134 patients) received generic DAC and generic SOF. All patients treated for 12 weeks with or without ribavirin. ■ N = 234 ■ Group A = 99% SVR12 ■ Group B = 100% SVR12 ■ AE were mild				
SOF/DAC or SOF/LDV +/- RBV	**NS5B/NS5A inhibitor**	**China**	**HIV coinfected**	**FDA approved**
Tolerable and curable treatment in HIV/HCV coinfected patients using anti-HCV DAAs: patients were treated with SOF + DAC ± RBV (N = 99), SOF + LDV ± RBV (N = 60), and SOF + RBV ± PEG-IFN regimens (N = 17), for 12 or 24 weeks. 151/176 HIV-1/HCV coinfected patients finished the treatment and 12-week follow-up. ■ N = 151, 99% (149/151) SVR12 ■ Among patients who completed treatment and follow-up, no differences in AE or SVR12 were correlated to CD4+ T cell count or between patients who received PEG-IFN and RBV and those who did not				
SOF/DAC	**NS5B/NS5A inhibitor**	**Egypt**	**GT4 children and adolescents ages 8–18**	**FDA approved**
Safety and efficacy of combined SOF/DAC treatment of children and adolescents with chronic hepatitis C GT4: multisite study of treatment-naive children or adolescents age 8–18 or weighing at least 17 kg. Patients received SOF (400 mg/day or 200 mg/day for patients above or below 45 kg, respectively) and DAC (60 mg/day or 30 mg/day for patients above or below 45 kg, respectively). All patients were treated for 12 weeks. ■ N = 40, 97.5% SVR12, 95% SVR24 ■ 45% of patients were below 12 years of age ■ 27.5% were mixed GT1/4 ■ AEs were mild				
SOF/LDV, SOF/VEL, SOF/DAC	**NS5B/NS5A inhibitor**	**UK**	**MSM**	**FDA approved**
Use of generic DAAs in a cohort of MSM with acute HCV infection: observational study of patients accessing treatment through the National Health Service (NHS), clinical trials, or self-sourced generic DAAs via buyers' clubs or online pharmacy services. These patients received 12 weeks of treatment. ■ N = 60, 49/60 (82%) accessed DAA treatment, 23/49 self-sourced generic DAAs ■ 100% SVR12 among of those who self-sourced generic DAAs: 18/23 SOF/LDV, 4 SOF/VEL, 1 SOF/DAC ■ Median time to treatment initiation was shortest among those using buyers' clubs (114 days), vs. clinical trials (132 days) and NHS (278 days)				
SOF/DAC or SOF/VEL +/- RBV	**NS5B/NS5A inhibitor**	**Myanmar**	**GT3, 6**	**FDA approved**
High sustained virologic response in GT3 and 6 with generic NS5A inhibitor and SOF regimens in chronic HCV: real-world study of two generic combination oral regimes among patients treated for 12 or 24 weeks between December 2015 and November 2017. ■ N = 522 ■ 96.1% (299/311) SVR12 for patients receiving SOF/DAC ± RBV ■ 95.3% (201/211) SVR12 for patients who received SOF/VEL ± RBV ■ TN status and inclusion of RBV for patients with cirrhosis were significant independent predictors of achieving SVR12				

Compound	Class/Type	Company/Sponsor	Patient Population	Status
SOF+RBV, DAC +/- RBV, LDV +/- RBV	**NS5B/NS5A inhibitor**	**India**	**Real-world patients including those with compensated & de-compensated cirrhosis**	**FDA approved**
Efficacy of generic oral DAAs in patients with HCV infection: observational study of TN and TE patients treated with generic regimes for 12 or 24 weeks; GT3 was the most prevalent at 75.9% (372), followed by GT1 at 19.8% (97). ■ N = 490, 95.9% (470/490) SVR12 overall for all treatment regimens ■ 97.0% (419/432) among TN patients; 87.9% (51/58) SVR12 among TE patients ■ 24.5% (N = 120) of patients with compensated cirrhosis; 6.4% (N = 31) decompensated cirrhosis ■ Similar SVR12 between 12- and 24-wk regimes ■ No serious AE				
SOF+RBV, SOF/LDV, SOF/DAC, SOF/VEL	**NS5B/NS5A inhibitor**	**Taiwan**	**+/- HIV and HBV coinfection**	**FDA approved**
Generic SOF-based interferon-free DAAs for patients with chronic HCV infection: a real-world multicenter observational study of TN and TE patients receiving 12 or 24 weeks of generic SOF-based treatment conducted in 4 academic centers in Taiwan ■ N = 517, 95.4% SVR12 overall ■ 15 patients relapsed post treatment completion ■ 7 patients who were lost to follow-up had undetectable RNA at last visit ■ Patients who received SOF+RBV had lowest SVR12 at 85.3% (29/34)				

ABBREVIATIONS

Ab: Antibody

AE: Adverse events

ALT: Alanine aminotransferase

DAA: Direct-acting antiviral

DAC: Daclatasvir

DNDi: Drugs for Neglected Diseases Initiative

EASL: European Association for the Study of the Liver

EBR/GRZ: Elbasvir/grazoprevir

F0-F4: Fibrosis stage range

GT: Genotype

G/P: Glecaprevir/pibrentasvir

HCV: Hepatitis C virus

HIV: Human immunodeficiency virus

HRCs: Harm reduction centers

IDU: Injection drug use

IU/mL: International unit per milliliter

LDV: Ledipasvir
LMIC: Low- and middle-income countries
MSM: Men who have sex with men
ND: No data
PEG-IFN: Pegylated-interferon
PI: Protease inhibitor
PWID: People who inject drugs
RAV: Ravidasvir
RAS: Resistance-associated substitutions
RBV: Ribavirin
RNA: Ribonucleic acid, or HCV RNA test
SOF: Sofosbuvir
SVR: Sustained virological response
TE: Treatment experienced
TN: Treatment naive
TRIPS: Trade-Related Aspects of Intellectual Property Rights
TX: Treatment
uL: Microliter, a unit of liquid volume equal to one millionth of a liter
VF: Virologic failure
VEL: Velpatasvir
VL: Viral load
VOX: Voxilaprevir
Wk: Week
WHO: World Health Organization

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