## Mini-Oral Abstract Presentations 2

# #14 Patient-Reported Outcomes After Direct-Acting Antiviral Treatment for Chronic Hepatitis C in West And Central Africa: The ANRS 12311 TAC Trial

Fabienne Marcelin, France

# Patient-reported outcomes after direct-acting antiviral treatment for chronic hepatitis C in West and Central Africa: the ANRS 12311 TAC trial

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# Patient-reported outcomes in the era of direct-acting antivirals (DAA)

Patient-reported outcomes (PROs):

*"Any report of the status of a patient's health condition that comes directly from the patient, without interpretation by a clinician or anyone else"* (U.S. Department of Health and Human Services. Health Qual Life Outcomes 2006)

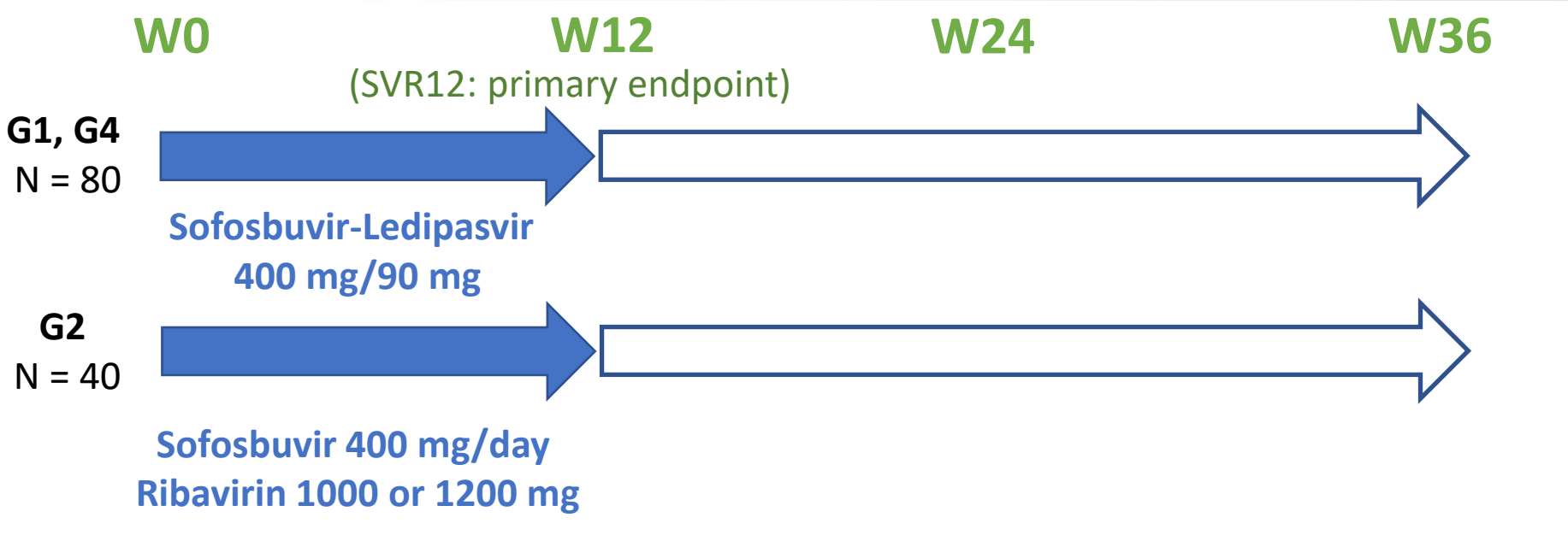
- **PROs improve during treatment and after sustained virological response**

↓ fatigue, ↑ health-related quality of life, ↑ work productivity

(Younossi ZM et al. Clin Gastro & Hepatol, 2020; Marcellin F et al. Expert Rev Gastro & Hepatol, 2017)

- **Lack of PROs data in the African setting**
- **Lack of data on self-reported symptoms in clinical trials**

# The ANRS 12311 TAC trial: Sofosbuvir-based treatment safe and effective in treatment-naïve HCV-chronic patients in West and Central Africa (Senegal, Cameroon, Côte d'Ivoire)




**89.2% patients with SVR-12 overall**(Lacombe K et al. CROI 2018)

# Analysis of PROs in the ANRS 12311 TAC trial

- **PROs assessed:** - health-related quality of life (HRQL) (**MOS SF-12 v2 scale**)[1]

  - fatigue (3 items from the **Piper fatigue scale**)[2]

  - self-reported symptoms (35 symptoms from the **ANRS AC24 scale**) [3]

- **Schedule of assessments (face-to-face questionnaires):**

  Before (**W0**), during (**W2, 4, 8** and **12**), and after treatment (**W24** and **W36**)

- **First statistical analyses:**

  Comparison between **W0** and **W36** (Wilcoxon rank-sum test, Mc Nemar test)

[1]Ware J et al., Med Care. 1996; [2]Piper B et al., Medicine. 1989; [3](Rosenthal E. et al., HIV Med. 2017)

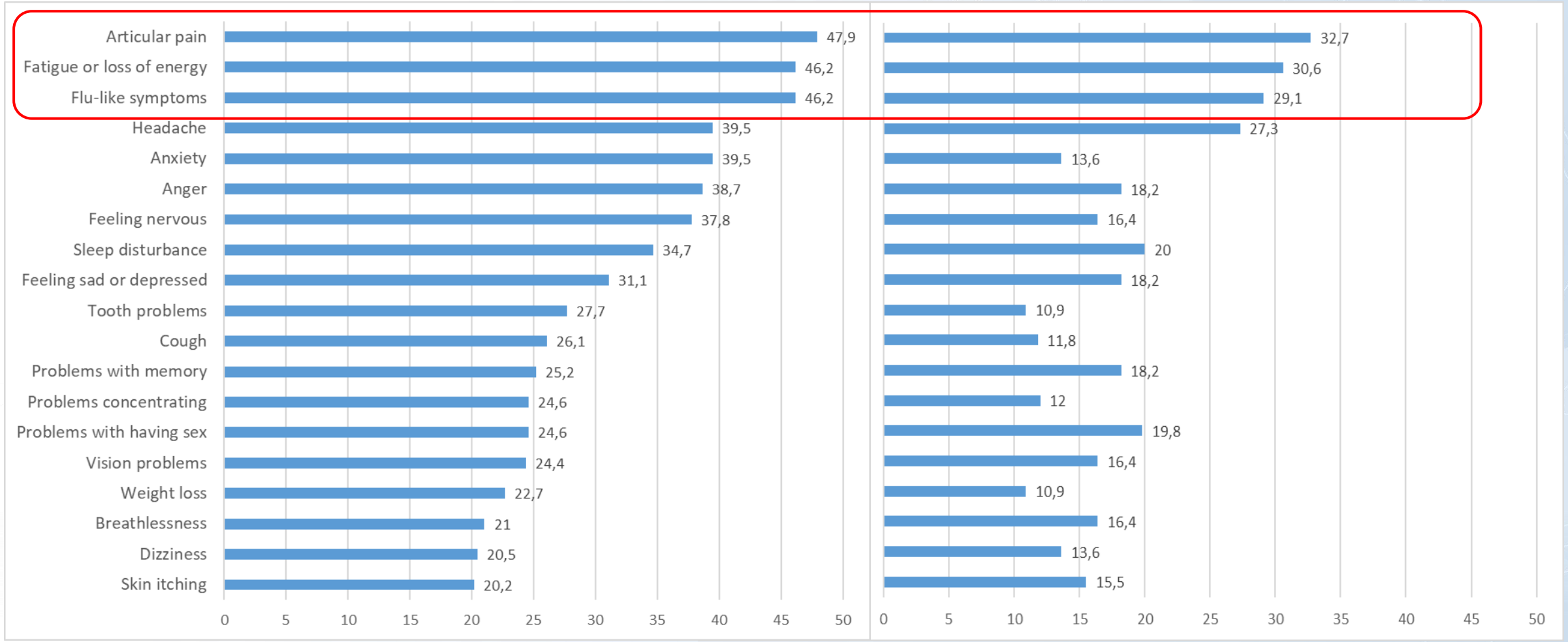
# Changes in PROs between W0 and W36 in the ANRS 12311 TAC trial

| Type of PROs | W0 | W36 | |
|---|---|---|---|
| | median [interquartile range] or no. of patients (%) | | *P-value*[1] |
| | N=116 | N=114 | |
| **Physical HRQL** (PCS score 0-100) | **49.3 [38.6 - 54.8]** | **52.3 [46.4 - 56.1]** | *0.003* |
| **Mental HRQL** (MCS score 0-100) | **48.6 [41.3 - 52.8]** | **51.0 [44.3 - 54.4]** | *0.013* |
| | N=120 | N=118 | |
| **Fatigue score** (0 - 10) | **3.5 [2.0 - 5.0]** | **2.0 [0.0 - 4.0]** | *<0.001* |
| **Discomforting fatigue** | **30 (28.3)** | **12 (13.5)** | *<0.001* |
| | N=119 | N=110 | |
| **Total no. of self-reported symptoms** (0 - 35) | **7 [3 - 11]** | **3 [0 - 7]** | *<0.001* |
| **No. of discomforting symptoms** (0 - 35) | **5 [2 - 9]** | **2 [0 - 6]** | *0.010* |

[1] Wilcoxon rank-sum test for continuous variables, Mc Nemar test for categorical ones.

# Type of symptoms reported at W0 and W36 in ANRS 12311 TAC

Symptoms reported by more than 20% of patients




**W0** **W36**

# Conclusion & next steps

- **Significant improvement of PROs six months after end of SOF-based treatment in treatment-naïve patients from West and Central Africa**
- **Encouraging results for DAA scale-up in the African setting**
- **Ongoing analyses: Longitudinal models of changes in PROs during follow-up**

# Thank you for your attention !

## Acknowledgements