

10th ANNIVERSARY



10th

PARIS
HEPATOLOGY
CONFERENCE

30 & 31 January 2017

AROUND THE WORLD TABLE: ACCESS TO THERAPY

Italy



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Main issues about HCV and DAAs in Italy

- Large population of patients with chronic HCV infection, > 70% > 60 years
 - HCV-related deaths \approx 10,000/year
 - 60-80,000 patients with F4 fibrosis
 - \approx 2-3,000 currently decompensated
 - \approx 500 OLT/yr
 - 150-250,000 patients with F0-F3
 - 65,000 (F4 and F3) already eradicated with DAAs
- Reimbursability for DAAs granted according to urgency of need (F4/F3/comorbidities). F0-F2 currently not allowed, but will change in 2017
- Pricing of DAAs negotiated centrally with price/volume agreements and pay-per-patient reimbursement, *regardless of treatment duration*
- Current cost per patient: 12,000-15,000 € (presumed to be < 10,000 € in 2017)



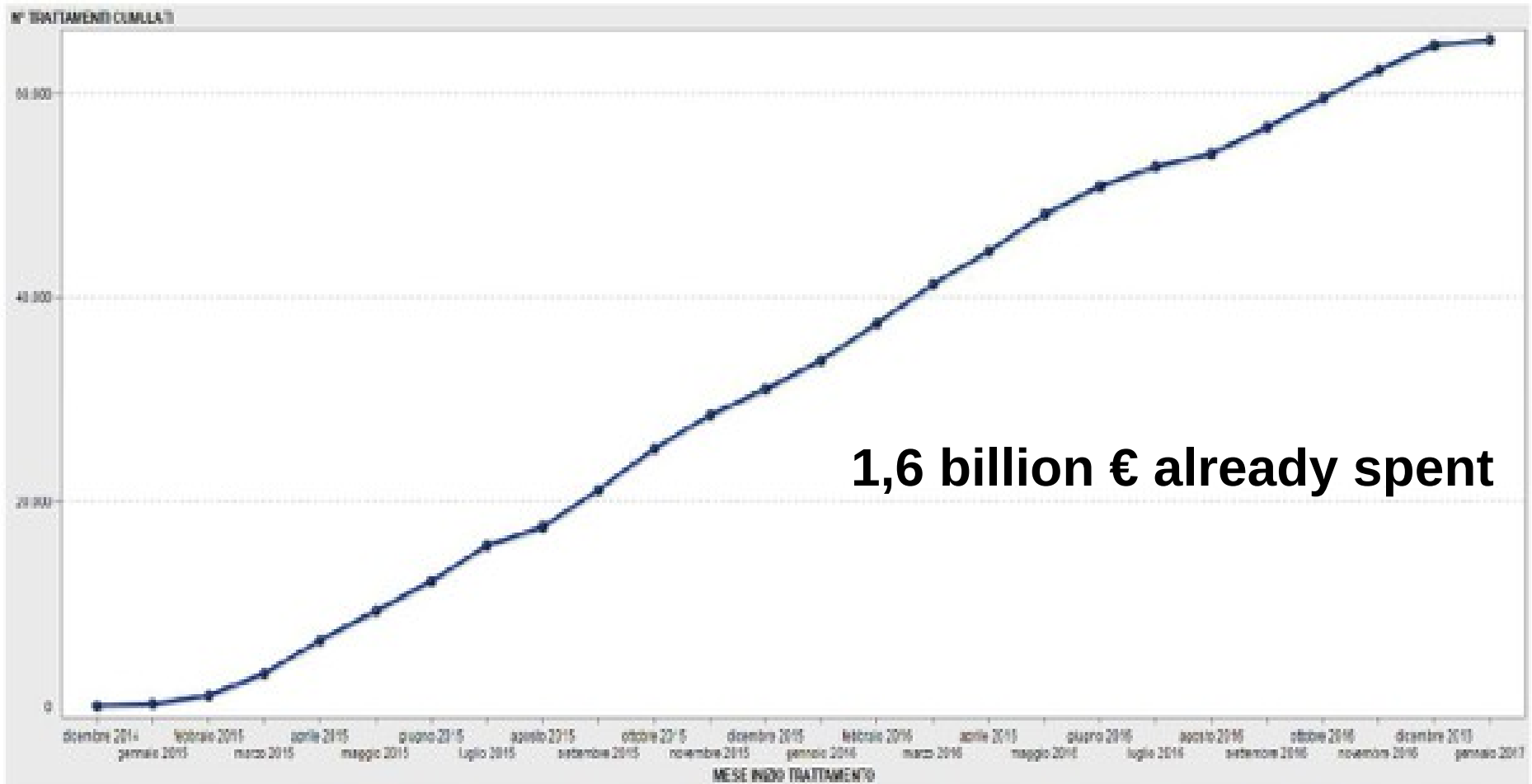
Timing of availability of DAAs in Italy

	EMA approval	Reimbursability in Italy
SOFOSBUVIR	January 2014	December 2014
SIMEPREVIR	May 2014	February 2015 
DACLATASVIR	August 2014	May 2015
SOFOSBUVIR + LEDIPASVIR	November 2014	May 2015
PAR/OMB/RTV + DAS	January 2015	May 2015
SOFOSBUVIR + VELPATASVIR	July 2016	Pending
GRAZOPREVIR + ELBASVIR	July 2016	Pending



Cumulative trend of DAA treatments in Italy

(updated 28 Jan, 2017)



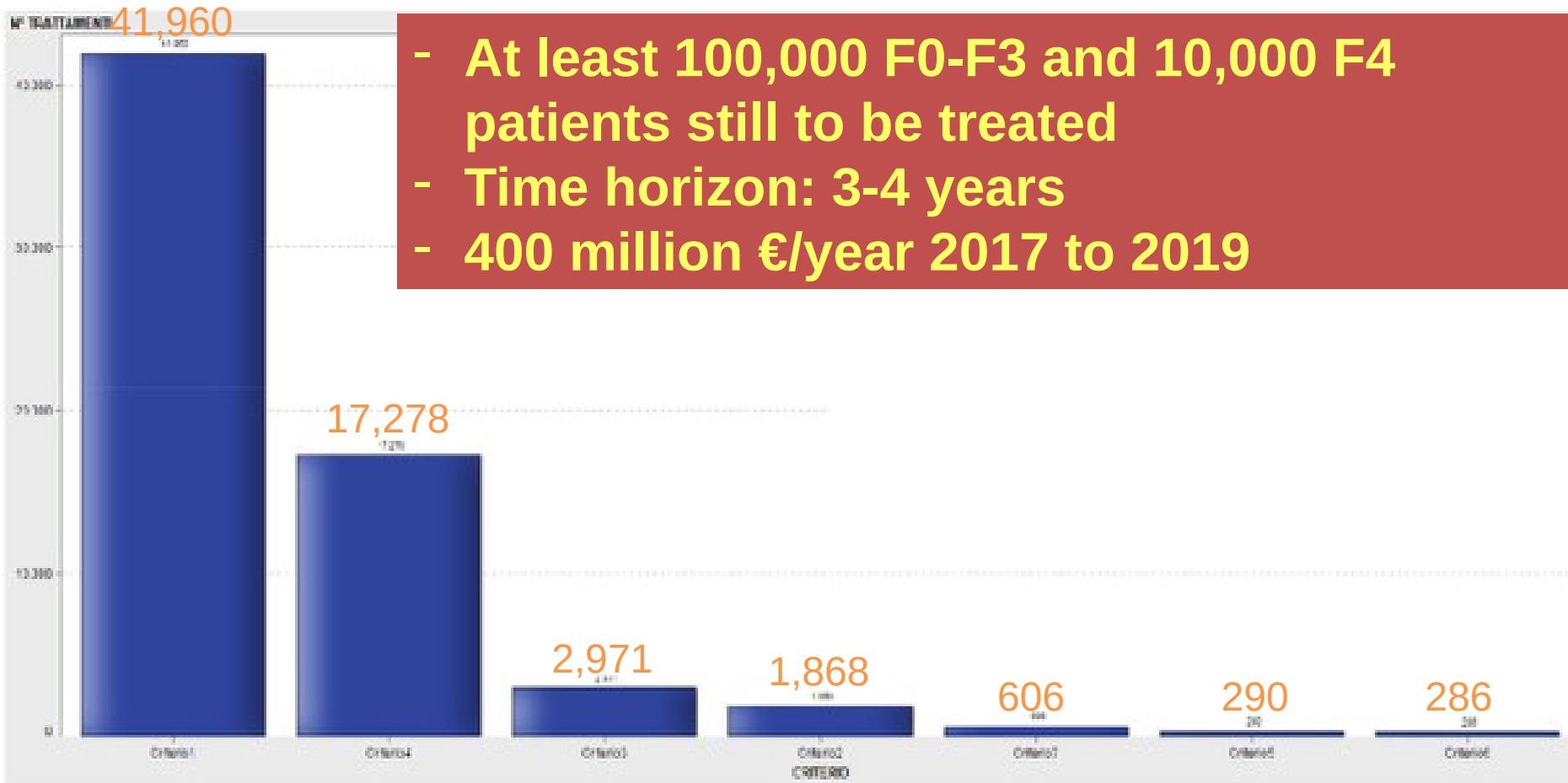
65.259 HCV patients eligible to be treated with a DAA regimen according to AIFA criteria (average delay between registration and actual treatment < 4 weeks)





Trend of DAA use by AIFA criteria

(updated 28 Jan, 2017)



Cirrhosis

F3 CHC

**Extrahepatic
manifestations**

**Post OLT
recurrence**

**< F 3 CHC
(P/R + SIM)**

**Listed for OLT
MELD < 25
± HCC**

**CHC with
nonliver or
BM
transplant**





The HCV treatment scenario in Italy

