EP-110 - HIGH SVR RATES WITH EIGHT AND TWELVE WEEKS OF PANGENOTYPIC GLECAPREVIR/PIBRENTASVIR: INTEGRATED EFFICACY AND SAFETY ANALYSIS OF GENOTYPE 1-6 PATIENTS WITHOUT CIRRHOSIS

Massimo Puoti[1]; Graham Foster[2]; Stanley Wang[3]; David Mutimer[4]; Edward Gane[5]; Christophe Moreno[6]; Ting T Chang[7]; Sam Lee[8]; Rui T. Marinho[9]; Jean-Francois Dufour[10]; Stanislas Pol[11]; Christophe Hezode[12]; Stuart C. Gordon[13]; Simone I. Strasser[14]; Paul J. Thuluvath[15]; Ran Liu[3]; Tami Pilot-Matias[3]; Federico Mensa[3]
1 - AO Ospedale Niguarda Ca Granda, Milan, Italy; 2 - Queen Mary University of London, Barts Health, London, United Kingdom; 3 - AbbVie, North Chicago, United States; 4 - Queen Elizabeth Hospital and NIHR Liver Biomedical Research Unit, Birmingham, United Kingdom; 5 - University of Auckland, Auckland, New Zealand; 6 - CUB Hôpital Erasme, Université Libre de Bruxelles, Brussels, Belgium; 7 - National Cheng Kung University Hospital, Tainan City, Taiwan; 8 - University of Calgary, Calgary, Canada; 9 - Hospital S. Maria, Medical School of Lisbon, Lisbon, Portugal; 10 - Hepatology, University clinic for visceral surgery and medicine, Bern University Hospital, Bern, Switzerland; 11 - Groupe Hospitalier Cochin-Saint Vincent De Paul, Paris; 12 - Hôpital Henri Mondor, AP-HP, Université Paris-Est, Créteil, France; 13 - Henry Ford Health System, Detriot, United States; 14 - Royal Prince Alfred Hospital, Sydney, Australia; 15 - Mercy Medical Center & University of Maryland School of Medicine, Baltimore, United States

Introdução e Objetivos

Pangenotypic DAAs glecaprevir (formerly ABT-493; NS3/4A inhibitor developed by AbbVie and Enanta) and pibrentasvir (formerly ABT-530; NS5A inhibitor), comprise the interferon (IFN) - and ribavirin (RBV)-free regimen G/P. In seven phase 2/3 trials, G/P achieved SVR12 rates of 92-100% across all six major HCV genotypes (GTs). We present an integrated analysis from these studies on the efficacy of 8 and 12 weeks of G/P treatment in non-cirrhotic patients with GT1-6 infection.

Material

Data were pooled from the phase 2 SURVEYOR-I and –II, and phase 3 EXPEDITION-4 and ENDURANCE 1, 2, 3 and 4 studies. Patients with chronic HCV GT 1-6 infection without cirrhosis received G/P without RBV for either 8 or 12 weeks. Patients were treatment-naïve or treatment-experienced with IFN-based or sofosbuvir (SOF)- based regimens. Patients experienced with a DAA other than SOF were excluded. Efficacy was evaluated as the rate of sustained virologic response (HCV RNA <lower limit of quantification) 12 weeks after the end of treatment (SVR12).

Sumário dos Resultados

1981 patients without cirrhosis were enrolled and 1975 received study drug. Baseline characteristics shown in Table 1. SVR12 rates by treatment duration and genotype, excluding 22 patients that were treated for 16 weeks, shown in Figure 1. The intent-to-treat population (ITT), 1911/1953 (98%) patients achieved SVR12, with similar rates of 97% and 98% in patients treated for 8 and 12 weeks, respectively. Across all genotypes, there were 4 breakthroughs (0.2%), 14 relapses (0.7%) and 11 discontinuations (0.6%). G/P was well-tolerated; discontinuations due to adverse events, DAA-related serious adverse events and grade 3 or higher laboratory abnormalities were rare.

Conclusões

G/P regimen yielded high SVR12 rates across all genotypes, regardless of prior treatment experience or treatment duration. Results from this integrated analysis suggest that G/P regimen could provide an effective 8- week IFN- and RBV-free treatment option for patients with HCV GT1-6 infection without cirrhosis.