DUET-1 and DUET-2 are ongoing, randomized, double-blind, placebo-controlled trials of identical design with a similar phase III study: DUET-1 involves patients with chronic hepatitis B or C and DUET-2 involves patients with chronic hepatitis B. Patients with chronic hepatitis C were randomized to receive either TMC125 or placebo in a 2:1 ratio. Each group was stratified by hepatitis C viral load and baseline viremia. The primary endpoints were safety, tolerability, and viral response. The results of the DUET-1 trial were presented at the 2016 International AIDS Conference, and the results of the DUET-2 trial were presented at the 2017 International Congress on Drug Therapy for HIV.

DUET-1 study design and major inclusion criteria

- **Participants**: 1,293 patients with chronic hepatitis C were randomized to receive either TMC125 or placebo in a 2:1 ratio. Each group was stratified by hepatitis C viral load and baseline viremia.

- **Interventions**: Patients received either TMC125 or placebo for 48 weeks.

- **Primary endpoints**: Safety, tolerability, and viral response.

- **Follow-up**: Time points included baseline, weeks 24 and 48, and 12 months post-treatment.

- **Outcomes**: The results of the DUET-1 trial were presented at the 2016 International AIDS Conference, and the results of the DUET-2 trial were presented at the 2017 International Congress on Drug Therapy for HIV.

DUET-1 efficacy results

- **Hepatic AEs by coinfection status**: The incidence and severity of hepatic AEs with TMC125 were generally similar to placebo, irrespective of hepatitis coinfection status. TMC125 does not appear to increase hepatic toxicity in patients with hepatitis coinfection.

- **Conclusions**: Irrespective of coinfection status, the safety and tolerability of TMC125 was generally comparable to placebo.

- **Overview of AEs: total population**: The incidence and severity of hepatic AEs with TMC125 were generally similar to placebo, irrespective of hepatitis coinfection status.

- **Baseline characteristics**: Population with hepatitis data

- **Baseline characteristics: population with hepatitis data**

- **Hepatic grade 3 or 4 laboratory parameters by coinfection status**

- **Frequency of AEs by coinfection status**

- **AEs of specific interest analyzed by coinfection status**

Acknowledgments

- **Presented at HEP DART: Frontiers in Drug Development for Antiretroviral Therapies, Hawaii, USA, December 9–13 2007. This poster is available on-line at www.tibotec.com Supported by Tibotec.**

- **Presented at HEP DART: Frontiers in Drug Development for Antiretroviral Therapies, Hawaii, USA, December 9–13 2007. This poster is available on-line at www.tibotec.com Supported by Tibotec.**

- **Presented at HEP DART: Frontiers in Drug Development for Antiretroviral Therapies, Hawaii, USA, December 9–13 2007. This poster is available on-line at www.tibotec.com Supported by Tibotec.**