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HCSP FACT SHEET

•HCV DRUGS IN DEVELOPMENT•

Drugs in Development: Phase 3, Genotype 1

BMS's Daclatasvir plus Sofosbuvir Combination

Written by: Alan Franciscus, Editor-in-Chief

Foreword

The combination of daclatasvir plus sofosbuvir was one of the first drug combinations to treat hepatitis C that were being developed by different pharmaceutical companies. While the cooperation to develop the drugs between the companies didn't continue, the development of this combination continues, which is a win for patients.

The information below is from a Phase 2 study published in the *New England Journal of Medicine*. A journal article provides the best type of information since it is peer-reviewed and, in this case, has been published in a prestigious medical journal.

This fact sheet will only list the information about the results from the group of HCV genotype 1 patients. For the data about HCV genotype 2 and 3 patients that was included in this journal article see *Drugs in Development: Phase 3, Genotype 2 & 3 BMS's Daclatasvir Plus Sosfosbuvir.*

The medications used in the studies included:

- HCV polymerase inhibitor, 400 mg sofosbuvir—dosed once a day
- HCV NS5A inhibitor, 60 mg daclatasvir—dosed once a day

The treatment period was 24 weeks.

Genotype1: Treatment Naïve

- Group A: Sofosbuvir – 7 Days followed by sofosbuvir/daclatasvir for 23 weeks
- Group C: Daclatasvir/sofosbuvir for 24 weeks
- Group E: Daclatasvir/sofosbuvir/ribavirin for 24 weeks
- Group G: Daclatasvir/sofosbuvir for 12 weeks
- Group H: Daclatasvir/sofosbuvir/ribavirin for 12 weeks

The median age was 54 yo to 56 yo; male (47% to 54%); White (73% to 80%); genotype 1a (71% to 83%); F0-F1 (27% to 43%); F2-F3 (40% to 54%); F4 (7% to 20%)..

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Genotype 1 – Daclatasvir plus Sofosbuvir

The cure rates ranged from 93% to 100% (see table below).

Genotype 1: Treatment Experienced

- Group I: Daclatasvir/sofosbuvir for 24 weeks
- Group J: Daclatasvir/sofosbuvir/ribavirin for 24 weeks

The median age was 57 yo to 59 yo; male sex (60% to 62%); mostly White (90%); genotype 1a (76% & 85%); F0 or F1 (10% & 15%); F2 or F3 (55% & 67%); F4 (14% & 30%).

The cure rates were 100% (21 of 21 pts) in Group I and 95% (19 of 20 pts) in Group J.

The most common side effects in all of the groups were fatigue, headache and nausea.

Comments: The study is small, but the results are impressive. The combination of the two drugs are currently in Phase 3 studies—it will be interesting to see what the cure rate and side effect profile are when they are tested in a larger patient population.

Group	A	C	E	G	H	I	J
Cure Rates	Cure: 93% (14 of 15 pts)	Cure: 100% (14 of 14 pts)	Cure: 100% (15 of 15 pts)	Cure: 95% (39 of 41 pts)	Cure: 93% (38 of 41 pts)	Cure: 100% (21 of 21 pts)	Cure: 95% (19 of 20 pts)

Related publications:

- **Drugs in Development: Phase 3 Genotype 1 – AbbVie's 3 Drug Combination Therapy**
  www.hcvadvocate.org/hepatitis/factsheets_pdf/Phase_3_Genotype_1_AbbVie.pdf
- **Drugs in Development: Phase 3 Genotype 1 – Sovaldi (sofosbuvir)/ledipasvir**
  www.hcvadvocate.org/hepatitis/factsheets_pdf/Phase_3_Genotype_1_SOF-LDV.pdf
- **Drugs in Development: Phase 3, Genotype 1 BMS's Daclatasvir Plus Asunaprevir**
  www.hcvadvocate.org/hepatitis/factsheets_pdf/GT_1b_DAC_ASV.pdf

For more information

- **American Association for the Study of LIver Diseases**
  www.aasld.org
- **Centers for Disease Control and Prevention**
  www.cdc.gov
- **Food and Drug Administration (FDA):**
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