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a series of fact sheets written by experts in the field of liver disease

HCSP FACT SHEET

•HCV DRUGS IN DEVELOPMENT•

Drugs in Development: Phase 3, Genotype 2 & 3

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 HCV genotype 2 and 3. For the data about HCV genotype 1 that was included in this journal article see *Drugs in Development: Phase 3, Genotype 1 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

This was a small study and, unfortunately, the genotype 2 and 3 data was combined in the three arms

There were three arms in the study:

- Group B: Sofosbuvir for 7 days, sofosbuvir/Daclatasvir for 23 weeks
- Group D: Daclatasvir/sofosbuvir for 24 weeks
- Group F: Daclatasvir/sofosbuvir/ribavirin for 24 weeks

The median age was 50yo to 52yo; male (36% to 69%); White (86% to 100%); Genotype 2 (9, 8, 9); Genotype 3 (7, 6, 5); F0-F1 (38% to 43%); F2-F3 (43%-50%); F4 (7%-19%).

The total cure rates across all of the arms were 88 to 100% (see table below).

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Genotype 2 & 3 – Daclatasvir plus Sofosbuvir

The most common side effects were fatigue, headache and nausea.

Comments: This is a very small study and BMS has announced that larger Phase 3 studies will begin shortly if not already. There will be separate clinical trials for genotype 3 and genotype 4. It should be noted that over half of the study population in this study had genotype 2 which is generally easier to treat than genotype 3.

	Group B	Group D	Group F
Cure Rates	88%	100%	100%

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):**
  www.fda.gov
- **Mayo Clinic**
  www.mayoclinic.com

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