12 Weeks of Daclatasvir in Combination With Sofosbuvir for HIV–HCV Coinfection (ALLY-2 Study): Efficacy and Safety by Black Race

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BACKGROUND

• HIV and HCV are frequent co-infections. Daclatasvir (DCV) and sofosbuvir (SOF) are effective and well tolerated in treatment-naive and -experienced patients.

METHODS

• The ALLY-2 study randomized patients to SOF 400 mg QD or SOF 400 mg QD + DCV 60 mg QD for 12 weeks.

RESULTS

• Overall SVR12 in ALLY-2

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<tr>
<th>Race</th>
<th>Non-Black (N=103)</th>
<th>Black (N=50)</th>
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<td>SVR12, %</td>
<td>95.0</td>
<td>100</td>
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• KEY FINDINGS

1. Black patients achieved higher SVR12 (100%) than non-Black (95%) patients.
2. The higher SVR12 rate in Black patients was driven by improved efficacy in Black treatment-naive patients: 100% vs. 90% in treatment-experienced patients.
3. SVR12 by treatment group:
   - SOF 400 mg QD: 95% (Non-Black) vs. 100% (Black)
   - SOF 400 mg QD + DCV 60 mg QD: 95% (Non-Black) vs. 100% (Black)

• SAFETY

1. There were no differences in adverse events between Black and non-Black patients.
2. The most common adverse events were headache, fatigue, nausea, vomiting, and pruritus.
3. One patient died of non-related cardiac arrest at post-treatment Week 4, and one patient was lost to follow up at Week 4 due to incarceration.

• CONCLUSIONS

1. Daclatasvir and sofosbuvir are effective and well tolerated in Black and non-Black patients with HIV–HCV coinfection.
2. Black patients achieved higher SVR12 rates compared to non-Black patients, particularly in Black treatment-naive patients.
3. Further studies are needed to determine the reasons for the observed differences in efficacy between Black and non-Black patients.