BICNOW Clinical Trial: PRELIMINARY RESULTS OF RAPID TEST AND TREAT BIC/FTC/TAF STUDY IN NAIJVE PLHIV.

CARMEN HIDALGO TENORIO1, Sergio Sequeira1, Antonio Collado2, David Vinuesa3, María J. Vivancos4, Ignacio De Los Santos5, Patricia Sorni6, Noemi Cabello5, Marta Montero1, Alberto Terron6, Onofre Martinez10, Mohamed Omar-Mohamed11, P.Ryan12, MJ Galindo13, Juan Pasquau1, Rosario Javier1, Miguel Ángel López-Ruiz1, Coral Garcia Vallecillos1.

University Hospital Virgen de las Nieves, Granada, Spain, IBIS-GRANADA1, Hospital Universitario Torrecardenas, Almeria, Spain2, Hospital Universitario San Cecilio, Granada, Spain3, Hospital Ramón y Cajal, Madrid, Spain4, Hospital Universitario de La Princesa, CIBERINFEC, Madrid, Spain5, Hospital Son Llatzer, Palma de Mallorca, Spain6, Hospital Clinico San Carlos Madrid, Spain7, Hospital Universitario La Fe, Valencia, Spain8, Hospital Universitario de Jerez, Cádiz, Spain9, Hospital Universitario Santa Lucia, Cartagena, Spain10, Complejo Hospitalario de Jaén.

Background: The global HIV epidemic is still not under control, even in high-income countries. To reduce the number of new diagnoses, several strategies have been implemented, including pre-exposure prophylaxis (PrEP) or rapid initiation (test and treat) of antiretroviral therapy (ART). The single-tablet regimen BIC/FTC/TAF is an ideal drug for rapid initiation. We present the preliminary data (baseline and 24 week) from the BIC-NOW trial.

Patients/methods: In this Phase IV, multi-center, open label, single-arm, 48-week study, adult participants were enrolled from Dec 2020 to Jun 2022 with follow-up through 48 weeks (w) at baseline, 4, 24, and 48w. Adherence to treatment was assessed using the SMAQ questionnaire. The EudraCT number: 2019-003251-11.

Results:

### Table 3. Analytical and anthropometric data (baseline and 24w)

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>24 Weeks</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>CD4 (cell/μL), mean ± SD</td>
<td>393± 246.9</td>
<td>589± 352.7</td>
<td>0.0001</td>
</tr>
<tr>
<td>CD4/CD8 ratio, mean ± SD</td>
<td>0.43±0.29</td>
<td>0.71±0.5</td>
<td>0.0001</td>
</tr>
<tr>
<td>Creatinine clearance (mL/h), mean ± SD</td>
<td>110±15.03</td>
<td>102±20.5</td>
<td>0.0001</td>
</tr>
<tr>
<td>Total cholesterol (mg/dL), mean ± SD</td>
<td>159±38.3</td>
<td>168±38.3</td>
<td>0.006</td>
</tr>
<tr>
<td>HDL cholesterol (mg/dL), mean ± SD</td>
<td>41.2±10.3</td>
<td>47.2±9.9</td>
<td>0.0001</td>
</tr>
<tr>
<td>LDL cholesterol (mg/dL), mean ± SD</td>
<td>105.6±54.2</td>
<td>107.8±31.6</td>
<td>0.053</td>
</tr>
<tr>
<td>TC/HDL ratio, mean ± SD</td>
<td>6.1±12.2</td>
<td>3.9±1.07</td>
<td>0.013</td>
</tr>
<tr>
<td>Triglycerides (mg/dL), mean ± SD</td>
<td>106.2±49.9</td>
<td>107.8±57.5</td>
<td>0.9</td>
</tr>
<tr>
<td>Bilirubin (mg/dL), mean ± SD</td>
<td>0.6±0.2</td>
<td>0.6±0.3</td>
<td>0.794</td>
</tr>
<tr>
<td>GPT (UI/l), mean ± SD</td>
<td>42.4±61.7</td>
<td>23.1±12.4</td>
<td>0.003</td>
</tr>
<tr>
<td>GGT (UI/l), mean ± SD</td>
<td>43.6±65.6</td>
<td>28.9±28.2</td>
<td>0.01</td>
</tr>
<tr>
<td>FA (UI/l), mean ± SD</td>
<td>80.7±48.1</td>
<td>74.1±24.8</td>
<td>0.85</td>
</tr>
<tr>
<td>Weight (Kg), median (IQR)</td>
<td>73.5 (65.7-83)</td>
<td>76 (67.8-87.1)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Body mass index, median (IQR)</td>
<td>24.3 (21.5-26.3)</td>
<td>25 (23-27)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Abdominal circumference (cm), median (IQR)</td>
<td>85 (78-94)</td>
<td>90 (81-95)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

### Table 2. Outcomes at 24 weeks

<table>
<thead>
<tr>
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<th>N=160</th>
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</thead>
<tbody>
<tr>
<td>Intention-to-treat analysis (ITT)</td>
<td></td>
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<tr>
<td>- VL&gt;50 copies, n (%)</td>
<td>142 (88.8)</td>
</tr>
<tr>
<td>- VL&lt;100 cpl/mL, n(%)</td>
<td>160 (100)</td>
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<tr>
<td>Dropped treatment, n (%)</td>
<td>0</td>
</tr>
<tr>
<td>Focolarines, doses pills, n (%)</td>
<td>0</td>
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<tr>
<td>Adverse events, n (%)</td>
<td></td>
</tr>
<tr>
<td>- Grade 3-4</td>
<td>0</td>
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<tr>
<td>- Adverse events leading to drug withdrawal</td>
<td>0</td>
</tr>
</tbody>
</table>

Conclusions: BIC/FTC/TAF is a suitable option for the rapid initiation of ART in naïve individuals infected with HIV. Treatment was associated with a rapid reduction in viral load, significant increase in CD4 count, and, as expected in ART-naïve patients, a small increase in weight, BMI, abdominal circumference and some lipid components, but TC/HDL ratio decreased. This study was funded by Gilead Sciences. Investigator Sponsored Research ISR-ES-19-10727.