# LONG-ACTING CABOTEGRAVIR+RILPIVIRINE IN OLDER ADULTS: POOLED PHASE 3 WEEK 48 RESULTS

#### Authors:

Benn PD¹, Dakhia S¹, Wu S², Hudson KJ³, Wang Y², D'Amico R³, Chounta V¹, Ford SL⁴, Van Solingen-Ristea R⁵, Vanveggel S⁵, Van Eygen V⁵, Polli JW³, Smith KY³, Spreen WR³, Gray L⁶\*

<sup>1</sup> ViiV Healthcare, Brentford, UK, <sup>2</sup> GlaxoSmithKline, Collegeville, PA, USA, <sup>3</sup> ViiV Healthcare, Research Triangle Park, NC, USA, <sup>4</sup> GlaxoSmithKline, Research Triangle Park, NC, USA, <sup>5</sup> Janssen Research and Development, Beerse, Belgium, <sup>6</sup> ViiV Healthcare, Abbotsford, Australia

## Background:

Cabotegravir (CAB) and rilpivirine (RPV) long-acting (LA) dosed intramuscularly every 4 weeks (Q4W) or every 8 weeks (Q8W) was noninferior to daily oral standard-of-care (SoC) antiretroviral therapy (ART) in Phase 3 studies. Due to the effectiveness of modern ART, an increasing proportion of people living with HIV (PLWH) are aged ≥50 years.

### Methods:

Efficacy, safety, adherence, and treatment satisfaction outcomes stratified by age (≥50y and <50y) across ATLAS, FLAIR, and ATLAS-2M studies at Week (W) 48 are reported. For participants in ATLAS-2M who transitioned from ATLAS, only data from ATLAS were included. W48 primary and secondary efficacy endpoints were Snapshot proportions of participants with plasma HIV-1 RNA ≥50 c/mL (virologic nonresponse) and HIV-1 RNA <50 c/mL (virologic suppression), respectively. Adherence, safety, incidence of confirmed virologic failure (CVF; two consecutive measurements of ≥200 c/mL), and treatment satisfaction (measured by HIVTSQs) at W48 were secondary endpoints.

## **Results:**

Among 1836 participants included in this study, 399 were aged ≥50y (Q8W, n=89; Q4W, n=185; SoC, n=125). Virologic outcomes were similar across arms and age groups; rates of virologic suppression were 92–97%, and rates of nonresponse were ~2%. CVF rates were low across arms and age groups. Safety profiles across age groups were similar for both LA regimens; few adverse events led to withdrawal. Injection site reactions were similar in frequency and severity across LA arms and age groups (median duration, 3 days). Treatment satisfaction was higher in LA arms vs. SoC and comparable between age groups (Q8W W48: ≥50y, 5.0; <50y, 4.8; Q4W W44: ≥50y, 5.6; <50y, 4.0; SoC W44: ≥50y, 0.4; <50y, 0.7).

## **Conclusion:**

CAB+RPV LA demonstrated similar efficacy, safety, and tolerability between participants aged ≥50y and <50y. Treatment satisfaction improved from baseline and was comparable by age. These data support the therapeutic potential of CAB+RPV LA in older PLWH.

<sup>\*</sup>Presenting on behalf of the authors.

## **Disclosure of Interest Statement:**

PD Benn, S Dakhia, KJ Hudson, R D'Amico, V Chounta, JW Polli, KY Smith, WR Spreen, and L Gray are employees of ViiV Healthcare and may own stock in GlaxoSmithKline. S Wu, Y Wang, and SL Ford are employees of and may own stock in GlaxoSmithKline. R Van Solingen-Ristea, S Vanveggel, and V Van Eygen are employees of Janssen Research and Development and may own stock in Johnson & Johnson. This study was funded by ViiV Healthcare and Janssen Research and Development.