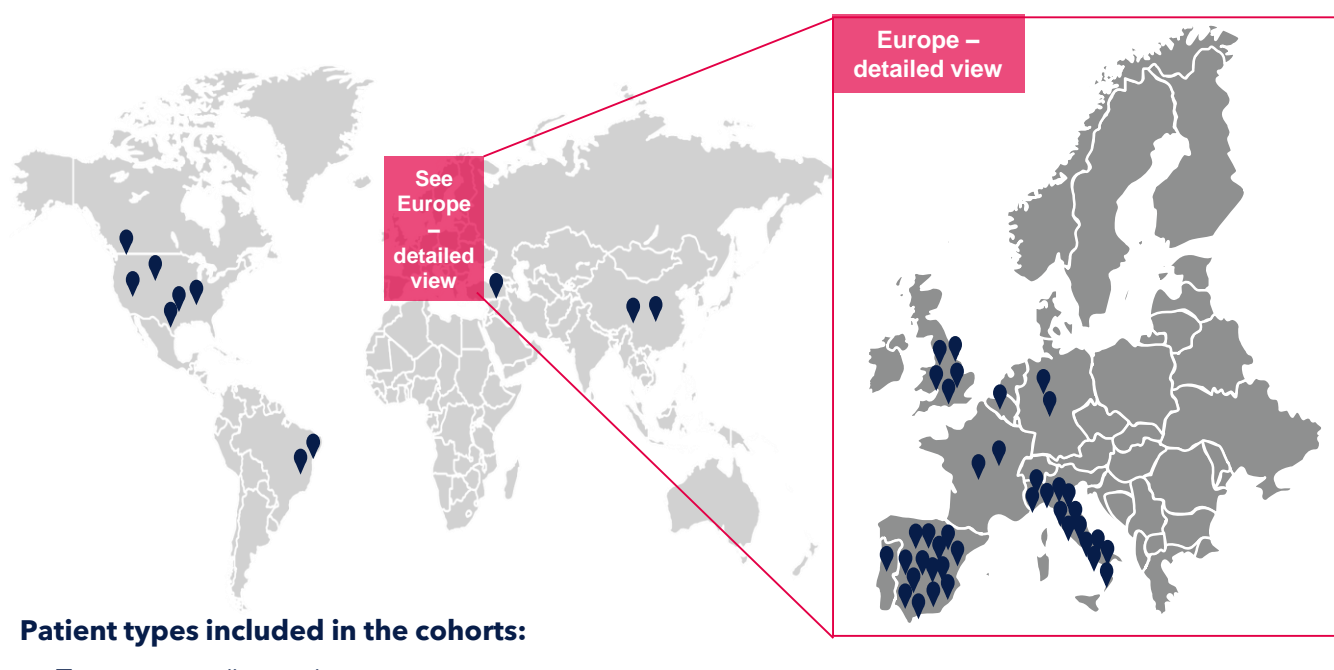


A growing body of real-world data has been presented in > 10,000 patients treated with *Dovato* (dolutegravir + lamivudine [DTG + 3TC]) or the individual components as a 2-drug regimen which showed results consistent with the DTG/3TC clinical development program.<sup>1-48</sup>

## Real-world distribution of > 40 cohorts



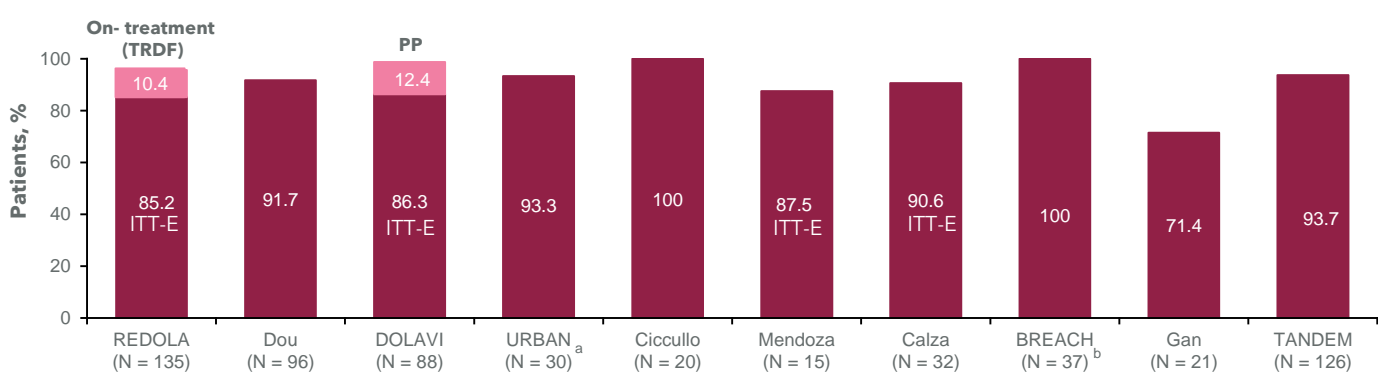
### Patient types included in the cohorts:

- Treatment-naïve patients
- Treatment-experienced patients
- Patients with various comorbidities
- Patients with a history of VF.

Potential overlap between cohorts cannot be ruled out.

## Effectiveness in Treatment-Naïve Patients Who Received *Dovato*

- Ten unique cohorts have reported various effectiveness outcomes which ranged from **71.4% - 100%** with data up to 2 years.<sup>5,7,11,12,24,32,37,42,43,45,49</sup>
- VF ranged from **0% - 6.7%**, with no resistance mutations reported (resistance data was not reported in TANDEM).

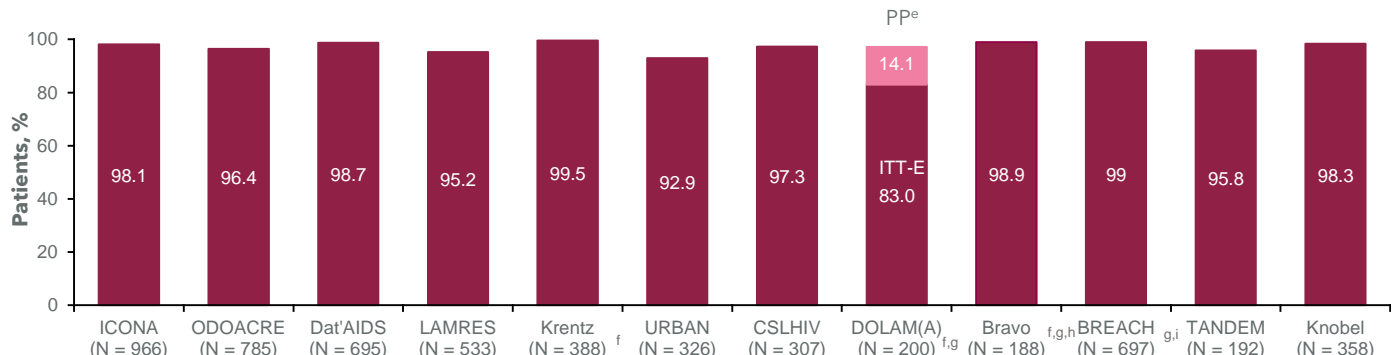


Time point	48 weeks <sup>5</sup>	24 weeks <sup>12</sup>	48 weeks <sup>11</sup>	1 year <sup>32</sup>	≥ 6 months <sup>c,7</sup>	48 weeks <sup>24</sup>	6 months <sup>37</sup>	48 weeks <sup>50</sup>	24 weeks <sup>43</sup>	1.3 years <sup>d,45</sup>
Effectiveness outcome	HIV-1 RNA < 50 c/mL (TRDF, ITT-E)	HIV-1 RNA < 50 c/mL or 50-200 c/mL with subsequent HIV-1 RNA < 50 c/mL (MEX analysis)	HIV-1 RNA < 50 c/mL (ITT-E, PP analysis)	HIV-1 RNA < 50 c/mL or 50-200 c/mL with subsequent HIV-1 RNA < 50 c/mL (MEX analysis)	HIV-1 RNA < 50 c/mL (ITT-E analysis) <sup>c</sup>	HIV-1 RNA < 50 c/mL (ITT-E analysis)	HIV-1 RNA < 20 c/mL (analysis not stated)	HIV-1 RNA < 50 c/mL (on-treatment analysis)	HIV-1 RNA < 50 c/mL (analysis not stated)	HIV-1 RNA < 50 c/mL (analysis not stated)

Reported effectiveness outcomes vary between unique cohorts

## Effectiveness in Treatment-Experienced Patients Who Switched to *Dovato*

- Several unique cohorts have reported various effectiveness which ranged from **83.0% - 99.5%** with data up to week 240, in treatment-experienced patients (N > 100) who switched to *Dovato*.<sup>4,9,10,14,20,21,25,32,39,42,45,51-53</sup>
- VF ranged from **0% - 4.8%** (and 0.9-3.34 per 100 PYFU).
- Treatment-emergent resistance has been reported in 2 patients: 1 patient at BL had T215Y and M184V and at VF had T215CNSY, M184MV, and M41ML, and a single case study reported plasma HIV-1 genotypic deep sequencing showed R263K and S230N.<sup>14,54</sup>

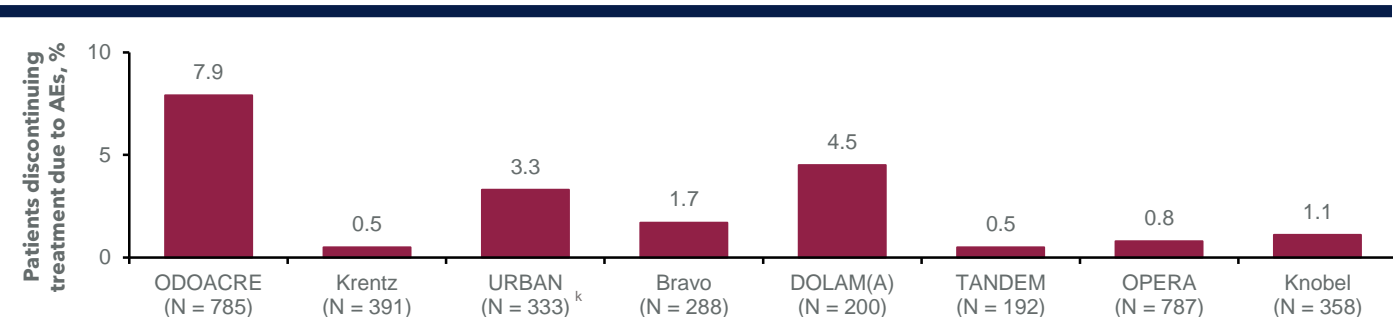


Time point	1505 PYFU <sup>20</sup>	2014.7 PYFU, up to Week 240 <sup>25</sup>	Median FU 1.2 years <sup>9</sup>	2 years <sup>21</sup>	1 year <sup>39</sup>	1 year <sup>32</sup>	1 year <sup>14</sup>	Week 48 <sup>10</sup>	Week 24 <sup>4</sup>	Week 48 <sup>50</sup>	Over mean time of 1.5 years <sup>45</sup>	Median FU 41.9 weeks <sup>47</sup>
Effectiveness outcome	Remained free of VF <sup>i</sup>	Estimated probability of maintaining viral suppression <sup>i</sup>	Remained free of VF <sup>i</sup>	Probability of remaining free of VF <sup>i</sup>	VL < 400 c/mL (MEX)	Achieved/ maintained viral suppression <sup>i</sup> (MEX)	Estimated probability of remaining free of VF <sup>i</sup>	VL < 50 c/mL (PP, ITT)	VL < 50 c/mL (MEX)	VL < 50 c/mL	VL < 50 c/mL	VL < 50 c/mL

Reported effectiveness outcomes vary between studies

## Safety

Discontinuation due to AEs in treatment-experienced patients who switched to *Dovato*



Time point	2014.7 PYFU, up to Week 240 <sup>25</sup>	1 year <sup>39</sup>	1 year <sup>32</sup>	Up to Week 48 <sup>14</sup>	Week 48 <sup>10</sup>	1.5 years <sup>m,45</sup>	1.1 years FU <sup>46</sup>	Median FU 41.9 weeks <sup>47</sup>
Study type	Retrospective, multicentre	Retrospective, single centre	Prospective, multicentre	Retrospective, multicentre	Retrospective, multicentre	Retrospective analysis of prospective cohort, multicenter	Retrospective, multicenter	Retrospective, single center

### PI

Important safety information is found in the Prescribing Information.

## For more information



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### FOOTNOTES:

<sup>a</sup>One patient was excluded from URBAN due to missing data; <sup>b</sup>N = 37 treatment-naïve patients at BL, n at Week 48 not reported; <sup>c</sup>Study reports "all patients achieved virologic suppression in the first 6 months from treatment initiation and maintained viral suppression during follow-up time with no viral blips registered" and "we did not observe any adverse event or treatment discontinuation;" therefore, this is considered an ITT-E analysis; <sup>d</sup>Mean time over which treatment-naïve patients became suppressed was 14.1 weeks; <sup>e</sup>Only DOLAM(A) reports PP data; <sup>f</sup>Patients excluded due to missing data or not being treated per protocol: Krentz n = 3, URBAN n = 10, DOLAM(A) n = 29; Bravo n = 100; <sup>g</sup>Patients viraemic at BL: URBAN n = 7; DOLAM(A) n = 8; Bravo n = 16; BREACH n = 20; <sup>h</sup>Data available at a later timepoint for Bravo (n = 66 at Week 48) but not included as the number of patients is below the threshold to be included on this slide; <sup>i</sup>N = 697 treatment-experienced patients at BL; n at Week 48 not reported; <sup>j</sup>Definitions of VF: ICONA, confirmed HIV-1 RNA > or ≥50 c/mL; ODOACRE, confirmed HIV-1 RNA ≥ 50 c/mL or single HIV-1 RNA ≥ 1000 c/mL; DatAIDS and LAMRES, confirmed HIV-1 RNA > 50 c/mL or single HIV-1 RNA 200 c/mL or ≥ 200 c/mL, respectively; CSLHIV, confirmed HIV-1 RNA > 50 c/mL or single HIV-1 RNA > 50 c/mL followed by treatment modification or single HIV-1 RNA > 1000 c/mL; viral suppression in URBAN was defined as HIV-1 RNA < 50 c/mL in visit window 9-15 months or 50-200 c/mL with subsequent HIV-1 RNA < 50 c/mL; <sup>k</sup>Three patients were excluded from URBAN due to missing data; <sup>l</sup>Not all patients had reached this timepoint (Bravo n = 66 at Week 48); <sup>m</sup>Mean time from *Dovato* initiation to discontinuation.

### ABBREVIATIONS:

AE = adverse event; c/mL = copies per milliliter; BL = baseline; FU = follow up; HIV-1 = human immunodeficiency virus-1; ITT = intention-to-treat; ITT-E, intention-to-treat exposed; MEX = missing equals excluded; PP = per protocol; PYFU = patient-years of follow-up; RNA = ribonucleic acid; TRDF = treatment-related discontinuation equals failure; VF = virologic failure; VL = viral load.

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