THE ERA OF ORAL ADVANCED THERAPIES IS HERE

The number of oral advanced therapies[a] available for patients with UC has significantly increased in recent years.[1–10]

The first oral advanced therapy for UC was approved in 2018.[2,3]

4 more oral advanced therapies have been approved since: **2** JAK inhibitors and **2** S1P receptor modulators.[4–10]

14 new oral advanced therapies are currently under investigation.[11,b]

The growing number of oral advanced therapies[1–10] means **physicians can deliver on their patients' preference** for oral treatment options while also **bringing active UC under control.**[12]

Among patients naive to advanced therapies,[13,c]

85% preferred the oral route of administration

However, currently only[14,d]

8% are prescribed oral advanced therapies

Not an actual patient.

[a]Advanced therapies in UC are defined as biologics, S1P receptor modulators, and JAK inhibitors[1]; [b]Therapies were selected from a search refined by indication (UC), trial phase (phase 2, phase 2/3, phase 3, or phase 3/4), trial status (ongoing, not recruiting; ongoing, recruiting; and ongoing and recruiting by invitation), and route of administration (oral)[11]; [c]Results from a cross-sectional study of patients with UC naive to biologic therapy (N=82), in which 85% (n=70) of patients preferred the oral route of administration[13]; [d]Data were collected in the United States in the Adelphi Real World Disease Specific Programme™ for IBD between January 2020 and March 2021. Among patients with moderately to severely active UC in the 2020–2021 cohort (N=448) who were receiving advanced therapy as monotherapy (n=143), 92% were receiving non-oral advanced therapies (TNF inhibitor, n=83 [58%]; integrin receptor antagonist, n=33 [23%]; IL-12/23 antagonist, n=16 [11%]) and 8% were receiving oral advanced therapies (JAK inhibitor, n=11 [8%]).[14]

PFIZER PROVIDES MULTIPLE ORAL ADVANCED THERAPY OPTIONS ALONG THE ORAL ROUTE[15,18]

Velsipity® (etrasimod) 2mg tablets ▼

XELJANZ® [tofacitinib]

SUMMARY OF PRODUCT CHARACTERISTICS

Scan for VELSIPITY prescribing information

Scan for XELJANZ prescribing information

AE, adverse event; HCP, healthcare professional; IBD, inflammatory bowel disease; IL, interleukin; IV, intravenous; JAK, Janus kinase; OLE, open-label extension; PY, patient-years; S1P, sphingosine-1-phosphate; SC, subcutaneous; TNF, tumor necrosis factor; UC, ulcerative colitis.

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▼ This drug is subject to additional follow-up. It is a priority to report suspected adverse reactions associated with this medicinal product.

ON THE ORAL ROUTE, CLINICAL GOALS AND PATIENT PREFERENCES CONVERGE

Pfizer

DISCOVER THE POSSIBILITIES ON THE ORAL ROUTE

CLINICAL NEEDS AND PATIENT PREFERENCES CAN NOW CONVERGE ON THE ORAL ROUTE

For patients with moderately to severely active UC who choose the Oral Route, **DRIVE FORWARD** from conventional therapy **with VELSIPITY.**

VELSIPITY is an effective first-line advanced therapy[e] with a favourable safety profile and convenient once-daily oral dosing.[1]

Velsipity® (etrasimod) 2mg tablets

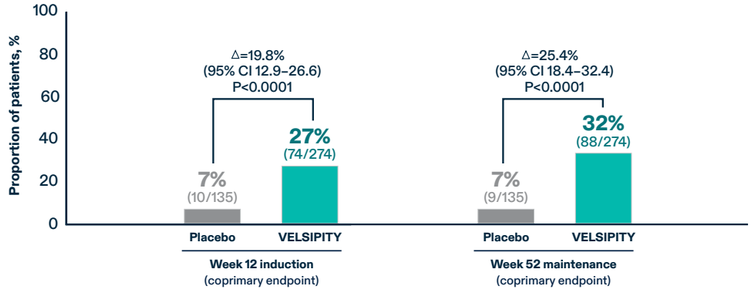
VELSIPITY is indicated for the treatment of patients 16 years of age and older with moderately to severely active UC who have had an inadequate response, lost response, or were intolerant to either conventional therapy, or a biological agent.[15]

[e]Advanced therapies in UC are defined as biologics, S1P receptor modulators, and JAK inhibitors.[1]

AN EFFECTIVE ORAL UC TREATMENT

Significant and sustained clinical remission[f] was achieved by patients receiving VELSIPITY versus placebo in a phase 3, randomised, placebo-controlled clinical trial[1,g]

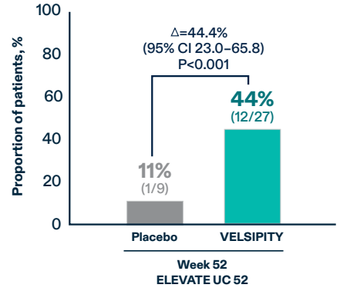
Clinical remission in overall population in ELEVATE UC 52[1]



100% steroid-free remission[1,h]
All patients who achieved clinical remission at Week 52 with VELSIPITY were steroid free.[1]

The first and only advanced therapy clinically studied and proven effective in a phase 3 trial across all extents of UC disease, including isolated proctitis.[16,i]

Clinical remission in isolated proctitis subgroup in ELEVATE UC 52[16,f]



[f]Clinical remission was defined as a stool frequency subscore of 0 (or of 1 with a ≥1-point decrease from baseline), a rectal bleeding subscore of 0, and an endoscopy subscore ≤1 (excluding friability) by independent, centrally read assessment[1]; [g]ELEVATE UC 52 used a treat-through trial design where patients remained on their assigned treatment arm throughout the entire study without re-randomisation[1]; [h]Corticosteroid-free clinical remission was defined as clinical remission at Week 52 without receiving corticosteroids for ≥12 weeks prior to Week 52[1]; [i]Patients with isolated proctitis at baseline (<10 cm rectal involvement) were allowed to enrol provided they met all other eligibility criteria. This subpopulation was capped at 15% of the total patients.[16]

A FAVOURABLE INFECTIOUS SAFETY PROFILE

VELSIPITY is well tolerated by patients, with mostly mild-to-moderate AEs, supported by up to 4 years of clinical data.[1,17]

	2.5 years safety			4 years safety
	Placebo-controlled cohort (phase 2 and phase 3 studies)[j]		All UC cohort (phase 2 and phase 3 OLE)[k,l,m]	All UC cohort (phase 2 and phase 3 OLE)[k]
% of patients with an event (exposure-adjusted incidence rates)*	VELSIPITY (n=629; 288.1 PY)	Placebo (n=314; 115.1 PY)	VELSIPITY (n=956; 769.3 PY)	VELSIPITY (n=1196; 1619.5 PY)
Any AE leading to study treatment discontinuation	5% (0.11)	3% (0.07)	7% (0.08)	11% (0.08)
Serious infections	1% (0.01)	2% (0.04)	2% (0.02)	2% (0.02)
Herpes zoster	<1% (<0.01)	1% (0.02)	1% (<0.01)	1% (<0.01)
Opportunistic infections	<1% (<0.01)	<1% (<0.01)	<1% (<0.01)	-

*This table includes only infection related information and is not a complete list of AEs reported in clinical trials studying VELSIPITY.[1,17] For a full list of AEs please refer to the VELSIPITY SmPC.[15]

No increased risk of herpes zoster or serious or opportunistic infections vs placebo.[1,17]

THE CONVENIENCE OF ONE PILL, ONCE DAILY

No injections, or infusions, and the same dose right from the start — no titration required.[15]

Consistent effective dose regardless of body weight[o] or age from 16 to 80 years of age.[15]

Not an actual patient.

[j]Placebo-controlled cohort: patients who received either placebo or VELSIPITY as part of 1 phase 2 study (VELSIPITY 1 or 2 mg for 12 weeks; NCT02447302) or 2 phase 3 studies (VELSIPITY 2 mg for 12 or 52 weeks; NCT03945188 and NCT03996369)[17]; [k]All UC cohort: all patients who received ≥1 dose of VELSIPITY (NCT02447302, NCT03945188, NCT03996369, NCT02536404, NCT03950232, and open-label period of NCT04176588; data cutoff January 31, 2022)[17]; [l]1 event of death occurred in the all UC cohort; this was a serious AE of neuroendocrine tumour resulting in death that was assessed by the investigator as not related to study treatment[17]; [m]No events of posterior reversible encephalopathy syndrome were reported[17]; [n]All patients who received ≥1 dose of VELSIPITY (NCT02447302, NCT02536404, NCT03945188, NCT03996369 and ongoing NCT03950232, data cut-off 30 August 2023, and NCT04176588, data snapshot 30 August 2022)[17]; [o]In patients with body weight below 40 kg, an approximately 1.5-fold increase in exposure is predicted.[15]