STANDARD THERAPY + TAVNEOS®

## IN SEVERE ACTIVE ANCA-ASSOCIATED VASCULITIS, THE FIGHT AGAINST GPA & MPA NEEDS A TWO ON ONE APPROACH<sup>1</sup>

Add TAVNEOS® to standard therapy to achieve and sustain remission for patients experiencing new, relapsing, or persistent disease activity<sup>1-3</sup>

TAVNEOS<sup>®</sup> is the only oral targeted therapy designed for patients with severe active GPA or MPA.

### INDICATION

TAVNEOS (avacopan) is indicated as an adjunctive treatment of adult patients with severe active anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] and microscopic polyangiitis [MPA]) in combination with standard therapy including glucocorticoids. TAVNEOS does not eliminate glucocorticoid use.

## IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

Serious hypersensitivity to avacopan or to any of the excipients.



## For patients living with severe active GPA or MPA, disease burden remains high

Despite advancements in therapy, patients grappling with these chronic, progressive conditions still suffer from a long journey to diagnosis, a high risk of relapse, treatment-related toxicities, and a diminished quality of life<sup>4-8</sup>



- → GPA and MPA are part of a rare group of small- to medium-vessel vasculitides called ANCA-associated vasculitis, or AAV<sup>9-11</sup>
  - An AAV diagnosis can be made in part through the clinical assessment of impaired function in one or multiple organs<sup>12,13</sup>



- → Severe vasculitis is defined by the American College of Rheumatology/Vasculitis Foundation (ACR/VF) guidelines as having life-threatening or organ-threatening manifestations. This is inclusive of multi-organ and localized symptoms<sup>2</sup>
  - Approximately 80% to 90% of patients with AAV present with renal or other organ-threatening disease activity<sup>14</sup>



- → Current treatment regimens can elevate the risk of toxicity<sup>15-17</sup>
  - Commonly used treatment options such as glucocorticoids can still pose serious risks, even at reduced doses



- → The attainment of sustained remission remains an elusive goal for many patients<sup>5</sup>
  - In a recent clinical trial, the 5-year relapse rate for patients who received rituximab in maintenance for 18 months\* was **35%** (23% for major relapses<sup>†</sup> and 12% minor relapses<sup>‡</sup>)<sup>18,19</sup>

→ ACR/VF guidelines define "active" as new, persistent, or worsening signs and/or symptoms attributed to GPA or MPA, and not related to prior damage<sup>2</sup>

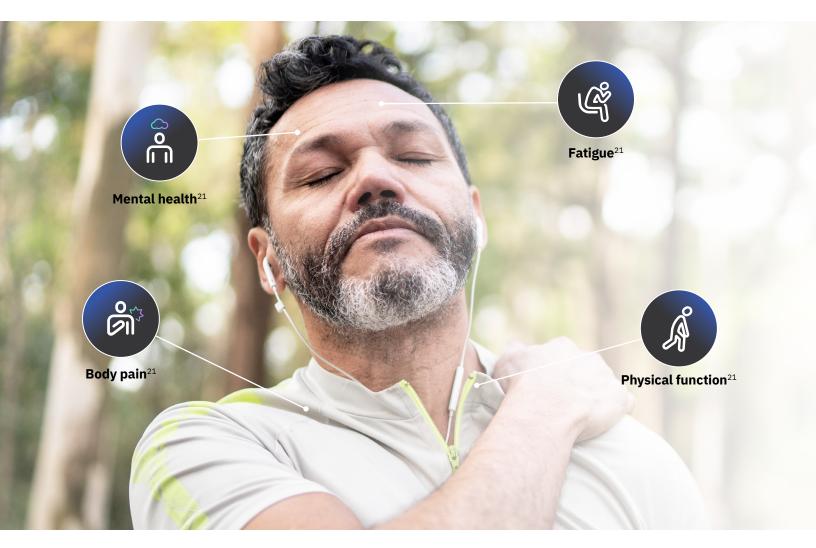
<sup>\*</sup>Patients in the clinical trial were treated with combined glucocorticoids and 'pulse' IV cyclophosphamide to achieve complete remission before being randomized to receive either azathioprine for 22 months or rituximab for 18 months as maintenance treatment. In this trial, prednisone was started and tapered gradually and maintained at a low dose (5 mg) for at least 18 months after randomization.<sup>19</sup>

<sup>&</sup>lt;sup>†</sup>Major relapse: reappearance or worsening of disease with BVAS >0 and involvement of at least one major organ, a life-threatening manifestation, or both.<sup>18</sup>

<sup>&</sup>lt;sup>‡</sup>Minor relapse: reappearance or worsening of disease with BVAS >0, not corresponding to a major relapse but requiring mild treatment intensification.<sup>18</sup>

## Patients with severe active GPA or MPA have experienced substantial impact to their quality of life<sup>20</sup>

A gap exists between the clinical standards for disease control and what patients expect remission to feel like<sup>20,21</sup>



Patients with GPA or MPA may have persistent symptoms, which can negatively impact their quality of life<sup>3,21</sup>

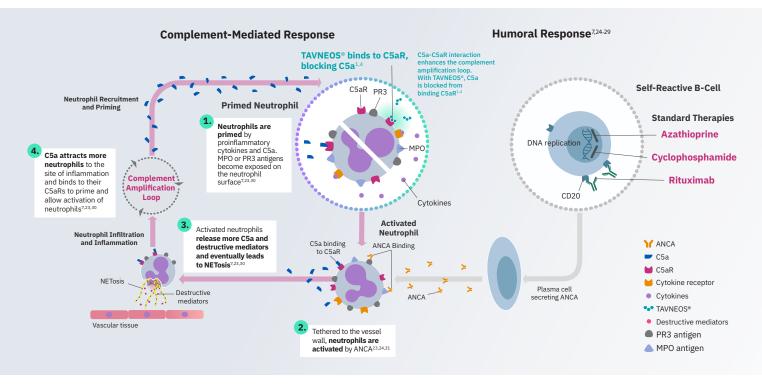


of patients are satisfied with their medication's ability to control symptoms while maintaining a good quality of life<sup>20,\*</sup>



of patients, even in remission, vasculitis symptoms are debilitating<sup>20,\*</sup>

### Add TAVNEOS<sup>®</sup> to standard therapy to target another pathway that drives vascular inflammation in GPA and MPA<sup>1,4,7,22,23</sup>



The precise mechanism by which TAVNEOS® exerts a therapeutic effect in patients with severe active GPA or MPA has not been definitively established.<sup>1</sup>

## In GPA and MPA, progressive inflammation and vascular injury by neutrophils are perpetuated through a vicious feedback loop that is fueled in part by a complement-mediated pathway<sup>23</sup>

- → The initial injury to vessel walls may result in hemorrhage and release of plasma proteins (including coagulation factors) into vessel walls and adjacent extravascular tissue<sup>30</sup>
- → Activated coagulation factors produce fibrin that forms at sites of injury which, in time, leads to necrosis<sup>30</sup>
- → Severe injury to a vessel could manifest in one or more organ systems<sup>2,32,33</sup>

TAVNEOS<sup>®</sup> is a complement 5a receptor (C5aR) antagonist and blocks C5a-mediated neutrophil activation and migration.<sup>34</sup>

### **IMPORTANT SAFETY INFORMATION** (CONT'D) WARNINGS AND PRECAUTIONS

**Hepatotoxicity:** Serious cases of hepatic injury have been observed in patients taking TAVNEOS, including life-threatening events. Obtain liver test panel before initiating TAVNEOS, every 4 weeks after start of therapy for 6 months and as clinically indicated thereafter. Monitor patients closely for hepatic adverse reactions, and consider pausing or discontinuing treatment as clinically indicated (refer to section 5.1 of the Prescribing Information). TAVNEOS is not recommended for patients with active, untreated, and/or uncontrolled chronic liver disease (e.g., chronic active hepatitis B, untreated hepatitis C, uncontrolled autoimmune hepatitis) and cirrhosis. Consider the risks and benefits before administering this drug to a patient with liver disease.

ANCA = anti-neutrophil cytoplasmic autoantibody; C5aR = C5a receptor; MAC = membrane attack complex of complement; MPO = myeloperoxidase; NET = neutrophil extracellular traps; PR3 = proteinase.



### ADVOCATE was a large phase 3, global, multicenter clinical trial evaluating TAVNEOS® across a range of severe active GPA and MPA manifestations<sup>1,4</sup>

The phase 3 ADVOCATE trial compared a **TAVNEOS®** arm to an Active Control arm in 330 newly diagnosed or relapsing patients with GPA or MPA over 52 weeks in a randomized, double-blind, double-dummy, active-controlled fashion<sup>1,3</sup>

- → TAVNEOS® arm = TAVNEOS® + rituximab, or cyclophosphamide (followed by azathioprine or mycophenolate mofetil\*)<sup>1</sup>
- → Active Control Arm = Prednisone taper + rituximab or cyclophosphamide (followed by azathioprine or mycophenolate mofetil\*)<sup>1</sup>
- → The primary endpoints of the trial assessed achievement of remission<sup>†</sup> at Week 26 and sustained remission<sup>‡</sup> at Week 52<sup>1</sup>



→ Glucocorticoids were allowed as pre-medication for rituximab to reduce hypersensitivity reactions, taper after glucocorticoids given during the screening period, treatment of persistent vasculitis, worsening of vasculitis, or relapses, as well as for non-vasculitis reasons such as adrenal insufficiency.<sup>1</sup>

### Differences in glucocorticoid exposure were evaluated throughout the duration of the ADVOCATE trial<sup>35</sup>

\*If azathioprine not tolerated.

<sup>‡</sup>Sustained remission was defined as remission at Week 26 and at Week 52 and no use of glucocorticoids for the treatment of GPA or MPA for 4 weeks before Week 52, without relapse between Week 26 and Week 52. Relapse was defined as the occurrence of at least 1 major item, at least 3 non-major items, or 1 or 2 non-major items for at least 2 consecutive visits based on BVAS after a BVAS of 0 had been achieved.<sup>1,4</sup>

<sup>§</sup>Also received prednisone-matching placebo for 20 weeks.<sup>1</sup>

<sup>¶</sup>Also received TAVNEOS<sup>®</sup>-matched placebo twice daily for 52 weeks.<sup>1</sup>

eGFR = estimated glomerular filtration rate; MPO = myeloperoxidase; PR3 = proteinase.

### **IMPORTANT SAFETY INFORMATION (CONT'D)**

### WARNINGS AND PRECAUTIONS

**Serious Hypersensitivity Reactions:** Cases of angioedema occurred in a clinical trial, including 1 serious event requiring hospitalization.



<sup>&</sup>lt;sup>†</sup>Remission was defined as achieving a Birmingham Vasculitis Activity Score (BVAS) of 0 and not taking glucocorticoids for treatment of GPA or MPA within 4 weeks prior to Week 26.<sup>1,3</sup>

### Patients in ADVOCATE presented with a wide spectrum of clinical manifestations<sup>1,3</sup>

### The treatment arms were well balanced regarding baseline demographics and disease characteristics of patients:1,3

Patients had active disease: At least one major item (62.4%), or at least three minor items (87.3%), or at least two renal items of proteinuria and hematuria (35.5%) on the BVAS<sup>3,4,\*</sup>

<b>Baseline Characteristics</b> <sup>4</sup> (N = 330)	n (%)
Newly diagnosed	229 (69.4%)
Relapsed	101 (30.6%)
GPA	181 (54.8%)
MPA	149 (45.2%)
Anti-PR3	142 (43.0%)
Anti-MPO	188 (57.0%)
Renal and Other (RBC Casts and/or Glomerulonephritis) involvement	268 (81.2%)
General organ involvement	225 (68.2%)
Ear/nose/throat involvement	144 (43.6%)
Chest involvement	142 (43%)
Rituximab Standard Therapy base	214 (64.8%)
IV/oral cyclophosphamide Standard Therapy base	116 (35.2%)

→ The baseline mean eGFR (mL/min/1.73 m<sup>2</sup>) was 45.6 in the Active Control arm and 44.6 in the TAVNEOS<sup>®</sup> arm<sup>4</sup>

→ Patients' mean duration of GPA and MPA was 21.54 months<sup>4</sup>

### Click to download data on patients with ear, nose, and throat (ENT) or respiratory manifestations at baseline

\*The Birmingham Vasculitis Activity Score (BVAS) provides a standardized measure of current disease activity. There are 56 clinical features, grouped into 9 organ systems plus an "Other" category, each of which is given a numerical value according to its perceived clinical relevance as decided by expert consensus.<sup>4,36</sup>

eGFR = estimated glomerular filtration rate; IV = intravenous.

### **IMPORTANT SAFETY INFORMATION (CONT'D)**

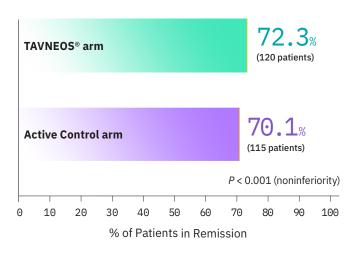
### WARNINGS AND PRECAUTIONS

Serious Hypersensitivity Reactions (CONT'D): Discontinue immediately if angioedema occurs and manage accordingly. TAVNEOS must not be readministered unless another cause has been established.



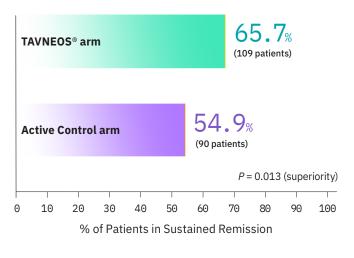
## The TAVNEOS<sup>®</sup> arm was superior compared to the Active Control arm in sustaining remission at 1 year<sup>1,3</sup>

At Week 26, the TAVNEOS® arm was non-inferior to the Active Control arm in achieving remission<sup>3,\*</sup>



TAVNEOS® arm (n = 166)<sup>3</sup>

At Week 52, the TAVNEOS® arm was superior to the Active Control arm in sustaining remission<sup>1,3,†</sup>



Active Control arm (n = 164)<sup>3</sup>

of TAVNEOS<sup>®</sup> patients who achieved remission at Week 26 sustained remission at Week 52 vs **78% of patients in the Active Control arm**<sup>3</sup>

\*Remission was defined as achieving a Birmingham Vasculitis Activity Score (BVAS) of 0 and not taking glucocorticoids for treatment of GPA or MPA within 4 weeks prior to Week 26.<sup>1,3</sup>

<sup>†</sup>Sustained remission was defined as remission at Week 26 and at Week 52 and not taking glucocorticoids for treatment of GPA or MPA within 4 weeks before Week 52, without relapse between Week 26 and Week 52. Relapse was defined as the occurrence of at least 1 major item, at least 3 non-major items, or 1 or 2 non-major items for at least 2 consecutive visits based on BVAS after a BVAS of 0 had been achieved.<sup>1,4</sup>

### **IMPORTANT SAFETY INFORMATION (CONT'D)**

#### WARNINGS AND PRECAUTIONS

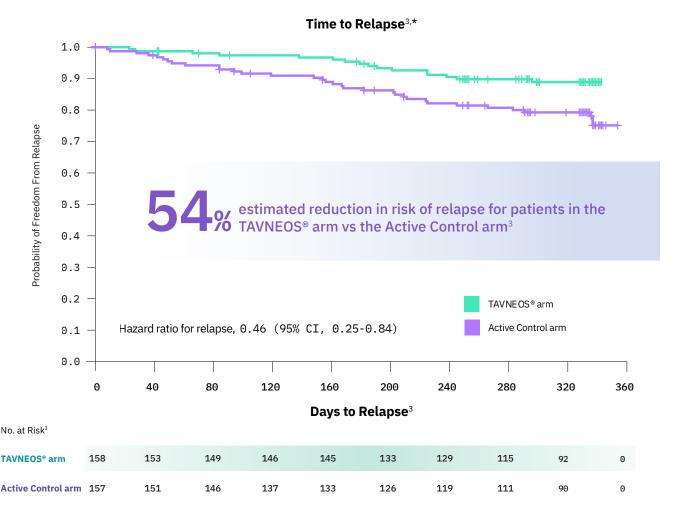
91%

**Hepatitis B Virus (HBV) Reactivation:** Hepatitis B reactivation, including life-threatening hepatitis B, was observed in the clinical program. Screen patients for HBV. For patients with evidence of prior infection, consult with physicians with expertise in HBV and monitor during TAVNEOS therapy and for 6 months following.



### The TAVNEOS<sup>®</sup> arm saw a reduced risk of relapse by half compared to the Active Control arm<sup>3</sup>

## **10.1%** of patients in the TAVNEOS® arm experienced a relapse, compared with **21%** of patients in the Active Control arm<sup>3</sup>



Prespecified secondary endpoint not adjusted for multiplicity and subject to post-randomization variable dependence. Results should be interpreted with caution.<sup>3</sup>

Relapse is defined as the occurrence of one of the following after remission (BVAS of 0) had been achieved:1,3

≥1 major item in the BVAS, or

≥3 minor items in the BVAS, or

1-2 minor items in the BVAS recorded at ≥2 consecutive visits

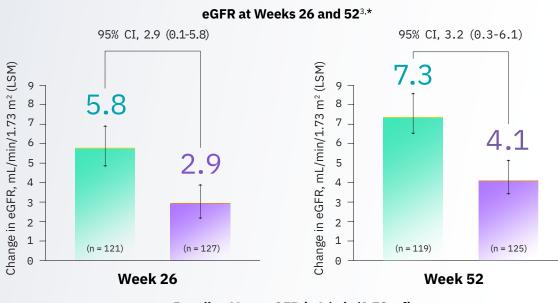
\*Adapted from Jayne DRW, et al. *N Engl J Med*. 2021;384:599-609. CI = confidence interval.

#### **IMPORTANT SAFETY INFORMATION** (CONT'D) WARNINGS AND PRECAUTIONS

**Hepatitis B Virus (HBV) Reactivation** (CONT'D): If patients develop HBV reactivation, immediately discontinue TAVNEOS and concomitant therapies associated with HBV reactivation, and consult with experts before resuming.



### The TAVNEOS® arm improved renal function, as measured by eGFR, from baseline compared to the Active Control arm<sup>3</sup>



Baseline Mean eGFR (mL/min/1.73 m<sup>2</sup>)

TAVNEOS® arm = 44.6 (n = 131) Active Control arm = 45.6 (n = 134)

- → 81.2% of patients in the trial had renal involvement based on the BVAS prior to treatment<sup>3</sup>
- → Discontinuation of treatment with TAVNEOS<sup>®</sup> at Week 52 resulted in the reduction of treatment-induced difference in eGFR<sup>4</sup>

Prespecified secondary endpoint not adjusted for multiplicity and should be considered exploratory. Results should be interpreted with caution.<sup>3</sup>

In a subgroup analysis, patients with stage 4 kidney disease at baseline experienced eGFR improvement:<sup>3,37</sup>



improvement from baseline in the TAVNEOS® arm vs 38% in the Active Control arm<sup>3,37</sup>

Visit TAVNEOSPRO.com to access additional subset data for patients with:

- → eGFR <30 and ≥15 mL/min/1.73 m<sup>2</sup>
- → eGFR ≤20 and ≥15 mL/min/1.73 m<sup>2</sup>

## Results of prespecified subgroup analysis in the 100 patients with eGFR <30 mL/min/1.73 m² and ≥15 mL/min/1.73 m² at baseline.<sup>3,4,38</sup>

### Results from this exploratory subgroup analysis should be interpreted with caution.<sup>3</sup>

\*Change from baseline to Week 52 in eGFR in patients with renal involvement at baseline based on the BVAS. LSM = least-squares mean.

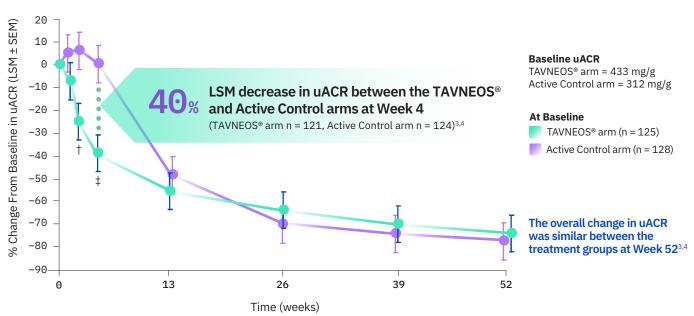
### **IMPORTANT SAFETY INFORMATION (CONT'D)**

### WARNINGS AND PRECAUTIONS

**Serious Infections:** Serious infections, including fatal infections, have been reported in patients receiving TAVNEOS.



## Patients in the TAVNEOS® arm saw a decrease in albuminuria by Week 4<sup>3,\*</sup>



### Change in Urinary Albumin-Creatinine Ratio (uACR) Over 52 Weeks (ITT Population)<sup>3,4</sup>

## Prespecified secondary endpoint of patients with renal disease and albuminuria at baseline; analysis not adjusted for multiplicity and should be considered exploratory. Results should be interpreted with caution.<sup>3</sup>

- → Elevated proteinuria may reflect underlying impairment of kidney function<sup>39,40</sup>
- → Percent changes from baseline are based on ratios of geometric means of visit over baseline<sup>3</sup>
- → The uACR analysis was only performed in patients who met BVAS criteria for renal disease at baseline and who also had a uACR ≥10 mg albumin/g creatinine<sup>3</sup>

\*Based on percent change from baseline in uACR in patients with baseline renal involvement and baseline uACR ≥10 mg/g (52-week study period).<sup>3</sup>

ITT = intent to treat; LSM = least squares mean; SEM = standard error of the mean.

### **IMPORTANT SAFETY INFORMATION (CONT'D)**

### WARNINGS AND PRECAUTIONS

**Serious Infections** (CONT'D): The most common serious infections reported in the TAVNEOS group were pneumonia and urinary tract infections. Avoid use of TAVNEOS in patients with active, serious infection, including localized infections. Consider the risks and benefits before initiating TAVNEOS in patients with chronic infection, at increased risk of infection, or who have been to places where certain infections are common.



## Patients in the TAVNEOS® arm experienced improved quality of life and reduction in glucocorticoid exposure<sup>4</sup>

Patients in the TAVNEOS<sup>®</sup> arm reported greater improvements across physical and mental health-related quality-of-life metrics at Weeks 26 and 52 compared to patients in the Active Control arm<sup>4,\*</sup>



### PHYSICAL MEASURES<sup>41,†</sup>

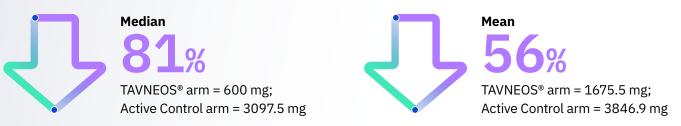
Week 26	Week 52
TAV = 4.45	TAV = 4.98
AC = 1.34	AC = 2.63
TAV = 7.31	TAV = 9.55
AC = 1.88	AC = 4.82
TAV = 14.75	TAV = 16.12
AC = 9.82	AC = 11.87
TAV = 16.78	TAV = 17.12
AC = 7.52	AC = 12.27
TAV = 3.12	TAV = 5.84
AC = -2.89	AC = -0.17
	TAV = 4.45 AC = 1.34 TAV = 7.31 AC = 1.88 TAV = 14.75 AC = 9.82 TAV = 16.78 AC = 7.52 TAV = 3.12

### MENTAL MEASURES<sup>41,†</sup>

Category	Week 26	Week 52
Mental Component Score	TAV = 4.85 AC = 3.27	TAV = 6.39 AC = 4.69
Vitality	TAV = 12.03 AC = 6.42	TAV = 14.36 AC = 10.48
Mental Health	TAV = 8.29 AC = 6.84	TAV = 10.89 AC = 9.66
Role-Emotional‡	TAV = 7.32 AC = 1.40	TAV = 9.38 AC = 4.14
Social Functioning	TAV = 14.50 AC = 11.09	TAV = 18.06 AC = 13.56

Prespecified secondary endpoint not adjusted for multiplicity and should be considered exploratory. Results should be interpreted with caution. The SF-36 was not specifically validated for GPA and MPA.<sup>3</sup>

Total glucocorticoid dose decreased for patients in the TAVNEOS  $^{\circ}$  arm by  $^{35,\$}$ 



- → Glucocorticoids were allowed as pre-medication for rituximab to reduce hypersensitivity reactions, taper after glucocorticoids given during the screening period, treatment of persistent vasculitis, worsening of vasculitis, or relapses, as well as for non-vasculitis reasons, such as adrenal insufficiency<sup>1</sup>
  - The incidence of this additional glucocorticoid exposure was balanced between both arms<sup>37</sup>
- → Results are descriptive

\*As assessed by the 36-Item Short Form Health Survey (SF-36), version 2. SF-36 scores range from 0 (worst) to 100 (best).<sup>3</sup> <sup>†</sup>Scores reflect change from baseline (least squares mean ± standard error of the mean).<sup>4</sup>

<sup>‡</sup>Role-Physical is one of the eight SF-36 domains. It assesses the limitations in routine activities because of physical health capabilities.<sup>42</sup>

<sup>‡</sup>Role-Emotional is one of the eight SF-36 domains. It assesses the limitations on routine activities because of emotional factors.<sup>42</sup> <sup>§</sup>Prednisone equivalent dose per patient.

TAV = TAVNEOS® arm; AC = Active Control arm.

### IMPORTANT SAFETY INFORMATION (CONT'D)

ADVERSE REACTIONS

The most common adverse reactions (≥5% of patients and higher in the TAVNEOS group vs. prednisone group) were nausea, headache, hypertension, diarrhea, vomiting, rash, fatigue, upper abdominal pain, dizziness, blood creatinine increased, and paresthesia.



## The safety of TAVNEOS<sup>®</sup> was studied in one of the largest clinical trials for GPA and MPA<sup>43</sup>

### An established safety profile from a targeted therapy through 52 weeks<sup>1</sup>

Adverse reaction	<b>TAVNEOS</b> <sup>®</sup> <b>arm</b> (N = 166), n (%)	Active Control arm (N = 164), n (%)
Nausea	39 (23.5)	34 (20.7)
Headache	34 (20.5)	23 (14.0)
Hypertension	30 (18.1)	29 (17.7)
Diarrhea	25 (15.1)	24 (14.6)
Vomiting	25 (15.1)	21 (12.8)
Rash	19 (11.4)	13 (7.9)
Fatigue	17 (10.2)	15 (9.1)
Upper abdominal pain	11 (6.6)	10 (6.1)
Dizziness	11 (6.6)	10 (6.1)
Blood creatinine increased	10 (6.0)	8 (4.9)
Paresthesia	9 (5.4)	7 (4.3)

### Most common adverse reactions reported in ≥5% of patients and higher in the TAVNEOS® arm vs the Active Control arm in a phase 3 trial<sup>1</sup>

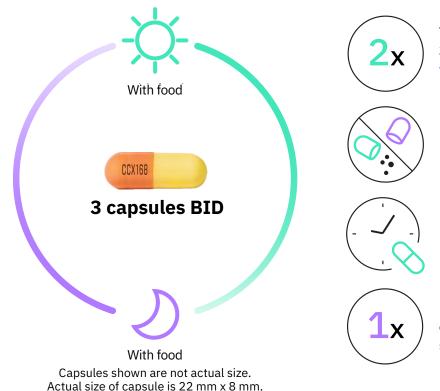
The incidence of infection was 68.1% in the TAVNEOS® arm vs 75.6% in the Active Control arm<sup>3</sup>

N = number of patients randomized to treatment group in the Safety Population; n = number of patients in specified category.



### TAVNEOS<sup>®</sup> is an oral treatment that can be added to standard therapy for adults with severe active GPA or MPA during induction or maintenance treatment<sup>1</sup>

TAVNEOS<sup>®</sup> is the only oral targeted therapy designed for patients with severe active GPA or MPA experiencing new, relapsing, or persistent disease activity



The recommended dose of TAVNEOS® is **30 mg** (three 10 mg capsules) **twice daily,** with food<sup>1</sup>

Advise patients that TAVNEOS® capsules should not be crushed, chewed, or opened<sup>1</sup>

If a dose is missed, instruct the patient to wait until the usual scheduled time to take the next regular dose. Instruct the patient not to double the next dose<sup>1</sup>

Reduce the dosage of TAVNEOS® to 30 mg once daily when used concomitantly with strong CYP3A4 inhibitors<sup>1</sup>

BID = twice daily; CYC = cyclophosphamide; CYP3A4 = cytochrome P450 3A4; EULAR = European Alliance of Associations for Rheumatology; GPA = granulomatosis with polyangiitis; MPA = microscopic polyangiitis; RTX = rituximab.

EULAR guidelines recommend initiating RTX or CYC in combination with glucocorticoids or avacopan for the induction of remission in patients with active GPA or MPA with organ- or life-threatening manifestations. Avacopan may be considered as part of a strategy to reduce exposure to glucocorticoids substantially.<sup>44</sup>

### **IMPORTANT SAFETY INFORMATION** (CONT'D) **DRUG INTERACTIONS**

Avoid co-administration of TAVNEOS with strong and moderate CYP3A4 enzyme inducers. Reduce TAVNEOS dose when co-administered with strong CYP3A4 enzyme inhibitors to 30 mg once daily. Consider dose reduction of CYP3A4 substrates when co-administering TAVNEOS. Co-administration of avacopan and 40 mg simvastatin increases the systemic exposure of simvastatin. While taking TAVNEOS, limit simvastatin dosage to 10 mg daily (or 20 mg daily for patients who have previously tolerated simvastatin 80 mg daily for at least one year without evidence of muscle toxicity). Consult the concomitant CYP3A4 substrate product information when considering administration of such products together with TAVNEOS.

TAVNEOS is available as a 10 mg capsule.

To report a suspected adverse event, call 1-833-828-6367. You may report to the FDA directly by visiting www.fda.gov/medwatch or calling 1-800-332-1088.



## TAVNEOS<sup>®</sup> Connect is designed to support eligible patients throughout their TAVNEOS<sup>®</sup> journey

Visit TAVNEOS<sup>®</sup> Connect and download the Start Form





### TAVNEOS® Connect offers a wide range of support for patients\*

### **TAVNEOS® Connect can**

- → Help patients understand insurance benefits and assist eligible patients with their copay<sup>†</sup>
- → Offer resources to help patients learn about TAVNEOS®
- → Connect patients with communities that can support them during their treatment journey
- → Provide medication to eligible patients who do not have insurance and meet other program criteria

## The TAVNEOS® Connect Quick Start Program initially provides up to a 30-day supply of TAVNEOS $^{\otimes \dagger}$

- → For eligible patients whose insurance plan requires a prior authorization and you believe a delay in therapy could lead to negative clinical outcomes
- → For eligible patients being discharged from an inpatient setting to support continuity of care

### **TAVNEOS® Connect Copay Program:**

Eligible commercially insured patients may pay as little as **\$0 for a month supply of TAVNEOS**<sup>®</sup>

### **TAVNEOS® Patient Assistance Program**

or

For eligible patients who are uninsured or are unable to afford their medication, the Patient Assistance Program may help provide access to TAVNEOS®

### **Choose ONE submission option to get your patient started on TAVNEOS®**



or

Submit Start Form via fax (with the prescription section completed or eRx)



ePrescribe to a Network Specialty Pharmacy

Submit online enrollment at tavconnectrxhcp.iassist.com

A one-time registration is required to become a validated Prescriber in order

to submit online enrollments.

\*TAVNEOS® Connect services are available for adult patients whose diagnosis is aligned with the FDA-approved indication for TAVNEOS®. Additional eligibility criteria may apply.

<sup>†</sup>Terms, conditions and program maximums apply. Other restrictions may apply. This program is not open to patients receiving prescription reimbursement under any federal-, state-, or government-funded healthcare program, or for cash patients. This is not insurance or a guarantee of payment. No cash value. Void where prohibited by law.



# Achieve and sustain remission by adding TAVNEOS® to standard therapy<sup>1,3</sup>

TAVNEOS<sup>®</sup> is an oral adjunctive therapy that can be used in patients with severe active ANCA-associated vasculitis (GPA or MPA), experiencing new, relapsing or persistent disease activity<sup>1,2</sup>

### In the Phase 3 ADVOCATE trial, patients in the TAVNEOS® arm experienced:

**W** Remission and superior sustained remission<sup>1,3</sup>

- **Remission at Week 26: 72.3%** in the TAVNEOS® arm vs 70.1% in the Active Control arm (non-inferiority, *P* < 0.001)
- Sustained remission at Week 52: 65.7% in the TAVNEOS<sup>®</sup> arm vs 54.9% in the Active Control arm (Superiority, *P* = 0.013)
- Renal improvement as measured by eGFR<sup>3,\*</sup> The TAVNEOS® arm saw an eGFR improvement of 7.3 vs 4.1 mL/min/1.73 m<sup>2</sup> in the Active Control arm at Week 52 (LSM)

### **Oecreased glucocorticoid load**<sup>3,35</sup>

**81%** median and **56%** mean decrease in glucocorticoid load for patients in the TAVNEOS<sup>®</sup> arm at Week 52. Results are descriptive

**Fewer relapses**<sup>3,\*</sup>

The TAVNEOS<sup>®</sup> arm saw a 54% estimated reduction in risk of relapse

- **10.1%** of patients in the TAVNEOS® arm experienced a relapse compared to 21% of patients in the Active Control arm

### **Improved quality of life**<sup>41,\*</sup>

Patients in the TAVNEOS® arm reported greater improvements in both Physical Component Score and Mental Component Score at Weeks 26 and 52 vs the Active Control arm



## To learn more about TAVNEOS® visit TAVNEOSPRO.com

\*Prespecified secondary endpoint not adjusted for multiplicity and should be considered exploratory. Results should be interpreted with caution.<sup>3</sup>

LSM = least-squares mean.

### IMPORTANT SAFETY INFORMATION CONTRAINDICATIONS

Serious hypersensitivity to avacopan or to any of the excipients.

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