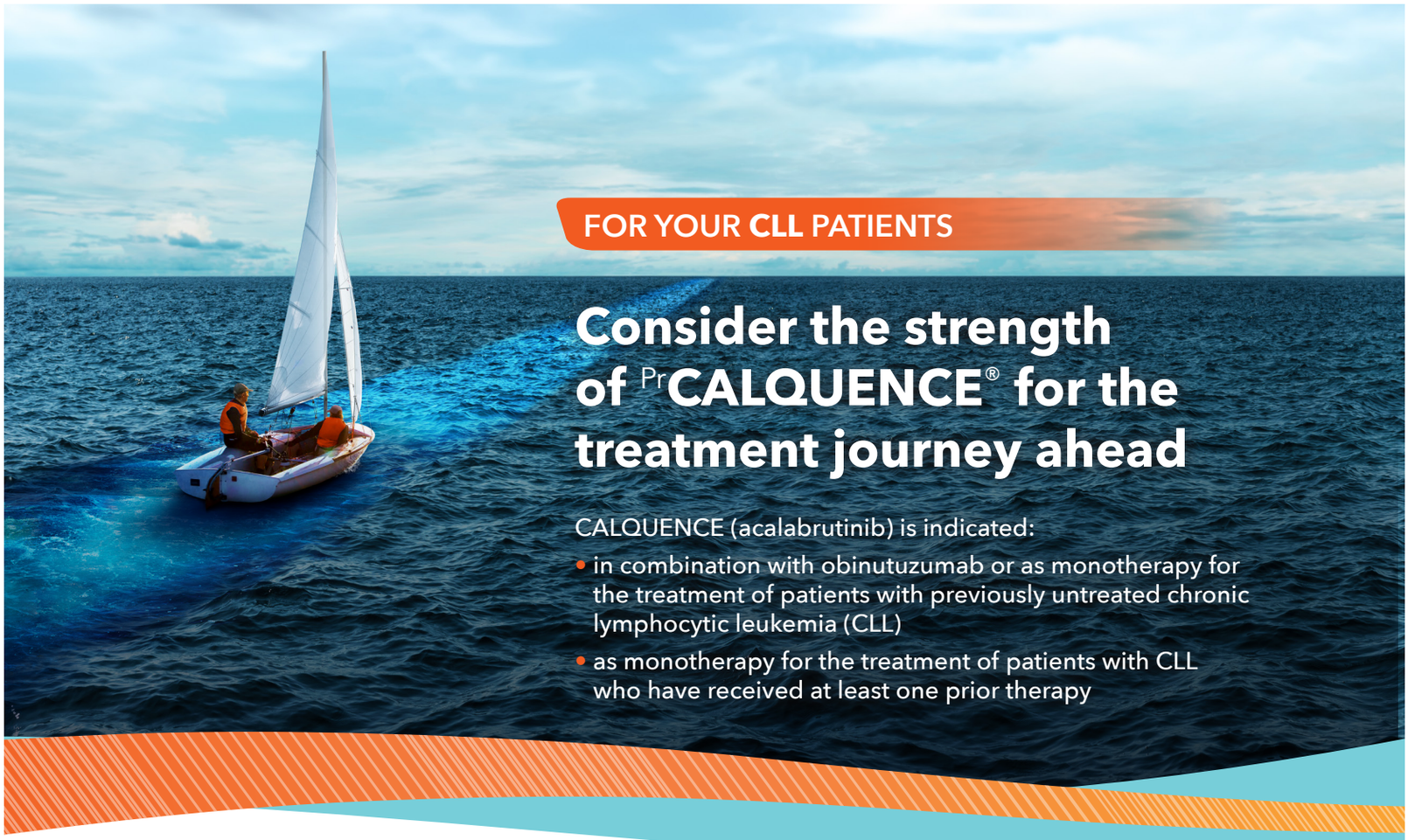

In previously untreated CLL,

90 % statistically significant reduction in the risk of disease progression or death with CALQUENCE + obinutuzumab (14 (7.8%)) compared to obinutuzumab + chlorambucil (93 (52.5%)) (HR=0.10 [95% CI: 0.06–0.17]; *p*<0.0001).[1†]

The open-label ELEVATE-TN clinical trial had a median follow-up of **28.3 months**:

- At the time of analysis, median overall survival was not reached in any arm, with fewer than 10% of patients experiencing an event.

Clinical use:
The safety and effectiveness of CALQUENCE in patients <18 years of age has not been established.

Contraindications:
- Hypersensitivity to CALQUENCE or any ingredient in the formulation or component of the container.

Most serious warnings and precautions:
Treatment with CALQUENCE: Should be initiated and supervised by a qualified physician experienced in the use of anticancer therapies.

Drug Interactions: Concomitant use of CALQUENCE with a strong CYP3A inhibitor should be avoided.

Serious Hemorrhage: Monitor for bleeding and manage appropriately.

Other relevant warnings and precautions:
- Atrial fibrillation; monitor all patients for symptoms of cardiac arrhythmia
- Second primary malignancies including skin and other solid tumours
- Cytopenias; monitor complete blood counts regularly
- Hemorrhage; monitor all patients for signs of bleeding
- Infections including hepatitis B reactivation and progressive multifocal leukoencephalopathy; monitor patients for signs and symptoms of infection and other opportunistic infections
- Driving and operating machinery
- CALQUENCE should not be used during pregnancy and women of childbearing potential should be advised to avoid becoming pregnant while receiving CALQUENCE
- Breast-feeding mothers are advised not to breast-feed during treatment with CALQUENCE and for 2 weeks after receiving the last dose

For more information:
Please consult the CALQUENCE Product Monograph at http://azinfo.ca/calquence/pm225 for important information relating to adverse reactions, drug interactions, and dosing information which have not been discussed in this piece. The Product Monograph is also available by calling 1-800-668-6000.

† In a randomized, multi-centre, open-label, Phase 3 trial (ELEVATE-TN) of 535 patients with previously untreated CLL. Patients were randomized to receive either CALQUENCE plus obinutuzumab, CALQUENCE monotherapy, or obinutuzumab plus chlorambucil. CALQUENCE + obinutuzumab: CALQUENCE 100 mg was administered twice daily starting on Cycle 1 Day 1 until disease progression or unacceptable toxicity. Obinutuzumab was administered starting on Cycle 2 Day 1 for a maximum of 6 treatment cycles. Obinutuzumab 1000 mg was administered on Days 1 and 2 (100 mg on Day 1 and 900 mg on Day 2), 8 and 15 of Cycle 2 followed by 1000 mg on Day 1 of Cycles 3 up to 7. Each cycle was 28 days. CALQUENCE monotherapy: CALQUENCE 100 mg was administered twice daily until disease progression or unacceptable toxicity. Obinutuzumab and chlorambucil: administered for a maximum of 6 treatment cycles. Obinutuzumab 1000 mg was administered on Days 1 and 2 (100 mg on Day 1 and 900 mg on Day 2), 8 and 15 of Cycle 1 followed by 1000 mg on Day 1 of Cycles 2 up to 6. Chlorambucil 0.5 mg/kg was administered on Days 1 and 15 of Cycles 1 up to 6. Each cycle was 28 days. Progression-free survival (PFS) as assessed by an Independent Review Committee (IRC) was per International Workshop on Chronic Lymphocytic Leukemia (IWCLL) 2008 criteria with incorporation of the clarification for treatment-related lymphocytosis (Cheson, 2012).[1]

Reference: 1. PrCALQUENCE® Product Monograph. AstraZeneca Canada Inc. November 28, 2019.

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