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Baseline Characteristics Among Early Initiators of Donanemab In the U.S.: A Real-world Study

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OBJECTIVE

To date, there are no published real-world studies of donanemab. This study's purpose was to describe baseline demographic and clinical characteristics of early donanemab initiators.

CONCLUSION

This cohort study provides insights into the early initiators of donanemab in routine care. Since the characteristics of the study population reflect the specific data source used, findings may not be broadly generalizable. Additional analyses of donanemab utilization and monitoring during follow-up will be presented at the conference.

LIMITATIONS

This is a placeholder

International Conference on Alzheimer's and Parkinson's Diseases and Related Neurological Disorders (ADPD) – 19th Annual Conference; Copenhagen, Denmark; March 17-21, 2026

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METHODS

Data Source

- Data for this descriptive, new user cohort study were derived from the OM1 Real World Data Cloud (OM1, Inc., Boston, MA), a real-world dataset with linked claims and electronic medical record (EMR) data on patients in the US.
- The study population included adult patients initiating donanemab between July 2024 and September 2025, the first 15 months following FDA approval. Patients were also required to have a recorded diagnosis of mild cognitive impairment or Alzheimer's disease and at least one claim or EMR encounter in the 365 days prior to treatment initiation.
- Baseline characteristics of donanemab initiators were tabulated and included demographics, insurance type, clinical comorbidities, medication use and use of diagnostic testing procedures.

RESULTS

- The final eligible cohort comprised 1,143 patients (Figure 1) [mean age in years (standard deviation (SD)) = 76.6 (6.4)] (Figure 2) who initiated donanemab.
- Patients were predominantly female (53.4%), white race (93.7%), and resided in the South (74.8%) (Figure 2).
- 63.9% had a diagnosis of MCI and 81.5% (Table 1) had a diagnosis of AD reflecting real-world coding patterns and the inability to capture exact disease severity.
- The first dose for most patients (71.6%) (Table 2) was 350 mg, consistent with the modified dosing regimen.
- Comorbidities were frequent with most common being dyslipidemia (78.9%), hypertension (71.3%) and prior malignancy (27.7%) (Figure 5).

Figure 1: Cohort Formation

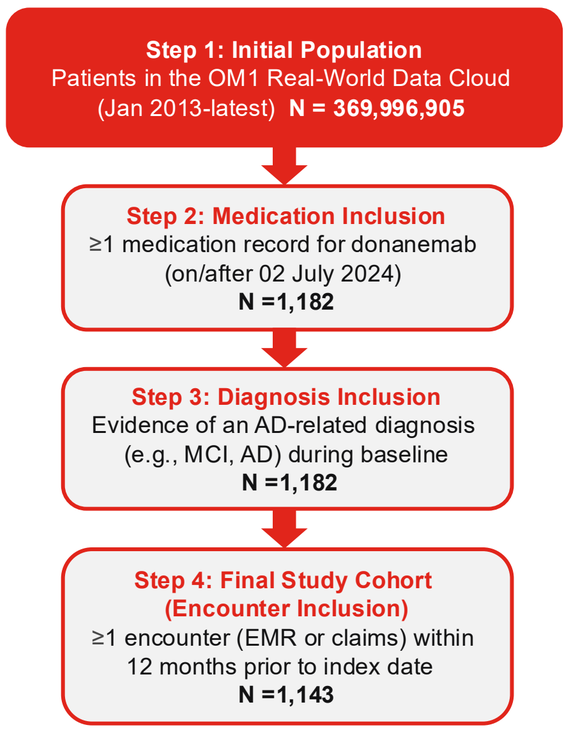

Figure 2: Baseline Demographic of Donanemab Initiators

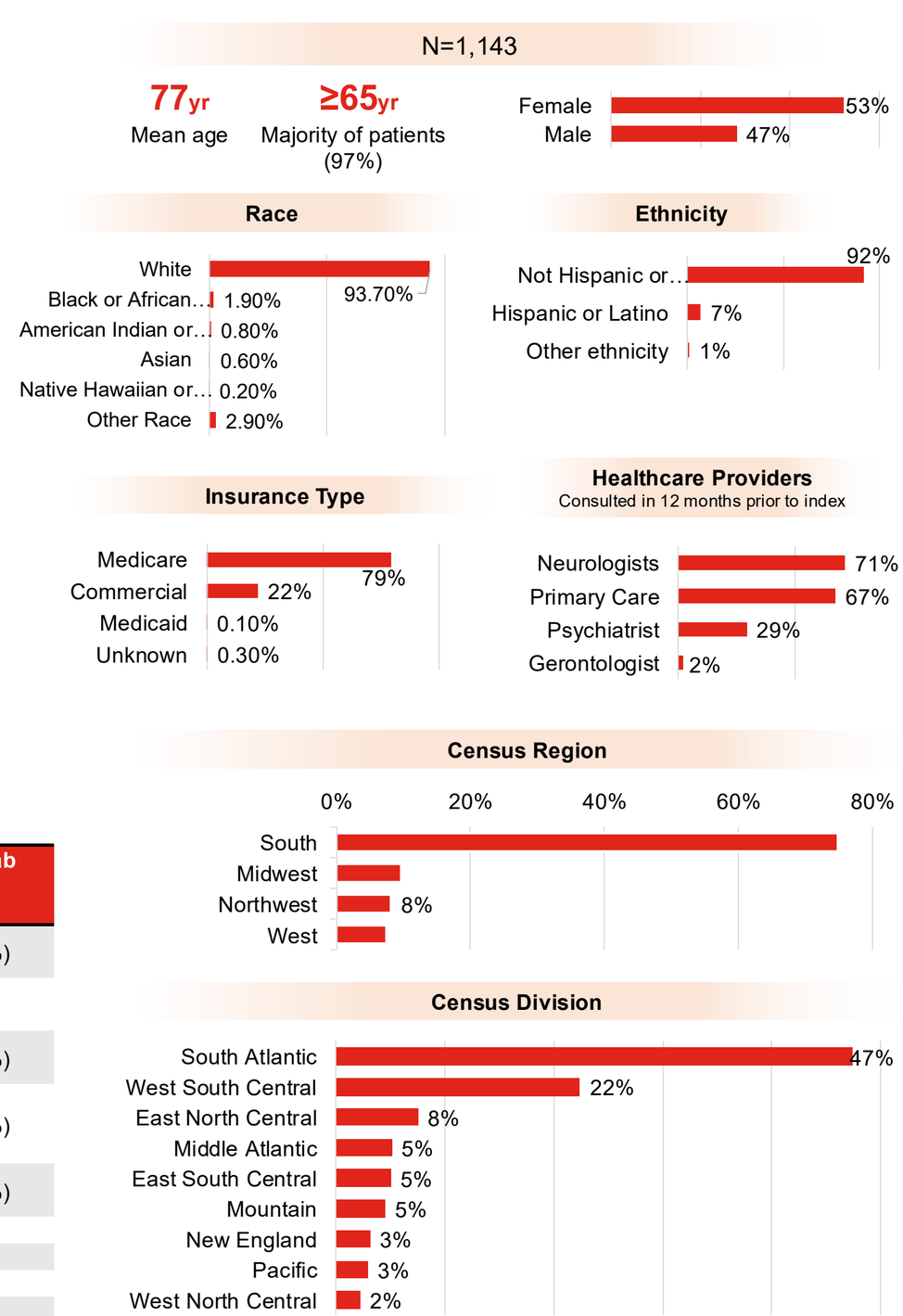

Table 1. Baseline Clinical and Diagnostic Testing Characteristics of Donanemab Initiators

Characteristics		Donanemab Initiators (N=1,143)
Charlson Comorbidity Index Score	n	1,140
	Mean (s.d.)	3.3 (2.1)
	Median (Q1-Q3)	3 (2-4)
Charlson Comorbidity Index Score, categorical	0-1	99 (8.7%)
	2-3	631 (55.4%)
	4-5	278 (24.4%)
	6+	132 (11.6%)
	Unknown	3
AD-Related Diagnosis Codes (Prior to Index)	Mild Cognitive Impairment (MCI)	730 (63.9%)
	Alzheimer's disease	931 (81.5%)
	Mild	62 (5.4%)
	Moderate	8 (0.7%)
	Severe	0 (0.0%)
	Unknown	861 (75.3%)
	Other dementias	41 (3.6%)
	Record of Montreal Cognitive Assessment (MoCA)	4 (0.3%)
Diagnostic Testing (Prior to Index)	Amyloid PET	394 (34.5%)
	Brain MRI	641 (56.1%)
	Alzheimer's specific CSF analysis	74 (6.5%)
	ApoE testing	33 (2.9%)
	Other blood-based biomarkers[1]	34 (3.0%)

[1]Other blood-based biomarkers includes Neurofilament Light chain (NfL), Glial fibrillary acidic protein (GFAP), Phosphorylated tau (P-tau181and P-tau217), p-Tau217/ß-Amyloid 1-42 Plasma Ratio, Aß-42/40 ratio, and P-tau217/N-P-tau217 ratio.

Table 2. Baseline Medication Use of Donanemab Initiators

Characteristic		Donanemab Initiators (N=1,143)
Donanemab initiation dose	350 mg (Modified Titration Regimen)	818 (71.6%)
	700 mg (Standard Titration Regimen)	74 (6.5%)
	Other/Undetermined Regimen	251 (22.0%)
Prior AD-Related Medication Use Baseline Period	Acetylcholinesterase inhibitors	565 (49.4%)
	N-methyl-D-aspartate (NMDA) antagonists	366 (32.0%)
	Brexpiprazole	12 (1.0%)
	Lecanemab	64 (5.6%)
	Aducanumab	3 (0.3%)
Prior Concomitant Medication Use Baseline Period, Selected Classes	Anti-platelets	238 (20.8%)
	Anticoagulants	177 (15.5%)
	Glucose-lowering agents	222 (19.4%)
	Anti-hypertensives	719 (62.9%)
	Corticosteroids	853 (74.6%)
	Lipid-lowering agents	753 (65.9%)
	Anti-psychotics	130 (11.4%)

Figure 3. Baseline Comorbidities of Donanemab Initiators