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Baseline characteristics of French patients with wet age-related macular degeneration (wAMD) enrolled in the LUMINOUS study

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INTRODUCTION

- The efficacy and safety profile of ranibizumab (RBZ) is well established based on the data from several randomized clinical trials (RCTs) across all approved indications (neovascular [wet] age-related macular degeneration [wAMD], diabetic macular edema, branch retinal vein occlusion, central retinal vein occlusion, and myopic choroidal neovascularization),[1-4] and is supported by data from over 3.1 million patient-treatment years of exposure.[5]
- However, there is a need for additional safety and effectiveness data from non-interventional studies, for a longer time period, in a more diverse population than those included within the clinical studies.
- Safety and efficacy data in clinical practice are complementary to such data from clinical trials in informing physicians regarding optimizing patient outcomes.
- LUMINOUS (NCT01318941) is the largest prospective observational trial in medical retina designed to evaluate the long-term safety, effectiveness, treatment patterns, and health-related quality of life outcomes in patients treated with RBZ in routine clinical practice across all approved indications.[3]
- LUMINOUS has enrolled over 30,000 patients, spanning over 550 sites across 45 countries worldwide between March 2011 and December 2014. This milestone was achieved 4 months ahead of the March 2015 target date (**Figure 1**).[1,3]

Figure 1: LUMINOUS: 5-year, observational, non-interventional, multicenter, global study

CLINICAL PRACTICE SETTING

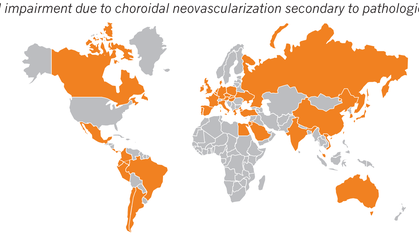
Ranibizumab treatment as per approved local product label:

Neovascular (wet) AMD

Visual impairment due to DME

Visual impairment due to macular edema secondary to RVO

Visual impairment due to choroidal neovascularization secondary to pathologic myopia



Countries involved in the LUMINOUS study

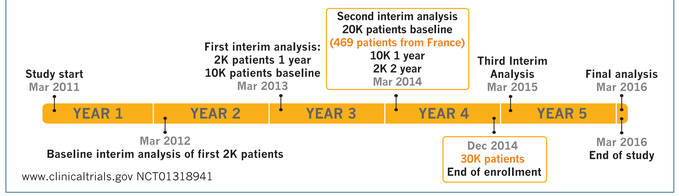
Study enrollment: 30,000 patients, 550 sites, 45 countries

AMD, age-related macular degeneration; DME, diabetic macular edema; RVO, retinal vein occlusion

PURPOSE

- To describe the baseline characteristics of the French patients with wAMD who were recruited prior to March 2014 in the LUMINOUS study (**Figure 2**).

Figure 2: The LUMINOUS prospective study design



www.clinicaltrials.gov NCT01318941

METHODS

- LUMINOUS is an ongoing, global, 5-year, multicenter, observational, non-interventional, open-label, single-arm study.
- The data were analyzed by indication and by treatment status of the primary-treated eye (treatment naïve, prior RBZ treatment or prior other ocular treatment).

Inclusion criteria

- Consenting patients (≥18 years) who a) have previously been treated with, who are currently being treated with, or are initiating treatment with RBZ for any approved indication included in the local product label or b) were treated with other ocular treatments or c) were treatment naïve.

Exclusion criteria

- Simultaneous administration of any other investigational drug or procedure.
- Use of vascular endothelial growth factor (VEGF) inhibitors other than RBZ within 3 months of start of the study (protocol amendment [January 2014]: 1 month for other ocular VEGF inhibitors).

RESULTS

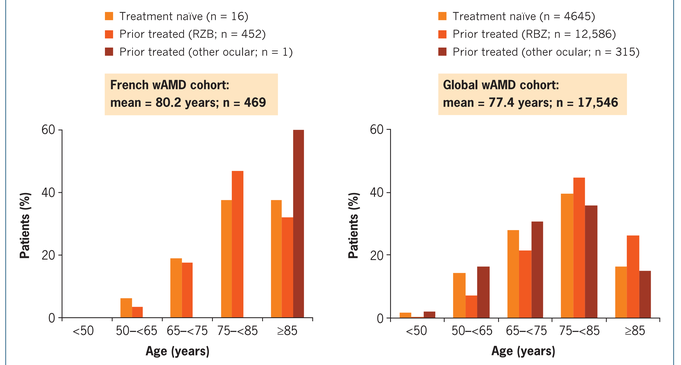
- Of the 17,546 adult patients with wAMD enrolled globally prior to March 2014, 469 were from France. Of these, 16 (3.4%) patients were treatment naïve, 452 (96.4%) had received prior RBZ treatment, and 1 (0.2%) had previously received other ocular treatments for treatment of wAMD.
- The baseline characteristics of the French/Global wAMD cohorts were: mean age 80.2/77.4 years and 32.4/42.0% were male, and 93.8/79.0% were Caucasian (**Table 1**). Overall, a wider age range of patients with wAMD were recruited than in pivotal trials (**Figure 3**).

Table 1: Demographic characteristics of patients at baseline—French and Global wAMD cohorts

	French wAMD cohort (n = 469)	Global wAMD cohort (n = 17,546)
Mean (SD) age, years	80.2 (7.67)	77.4 (9.46)
Gender, male/female, %	32.4/67.6	41.6/58.4
Race*, %		
Caucasian	93.8	78.9
Black	0.6	0.2
Asian	0.4	18.0
Native American	0	0.1
Other	1.5	2.1

*Missing data: 3.6% for French wAMD cohort and 0.7% for Global wAMD cohort.
SD, standard deviation; n, number of patients; wAMD, wet age-related macular degeneration

Figure 3: Patient disposition by age group at baseline—French and Global wAMD cohorts



Pre-treatment status defined by the primary-treated eye.
n, number of patients; RBZ, ranibizumab; wAMD, wet age-related macular degeneration

- In the French/Global wAMD cohorts, the mean duration of treatment for the prior RBZ-treated patients was 2.5/1.7 years and the mean number of injections/year was 5.2/5.8.
- The French wAMD cohort had similar mean baseline visual acuity (VA, Early Treatment Diabetic Retinopathy Study [ETDRS] letter score) and central retinal thickness (CRT, µm) compared with the Global (French/Global wAMD cohorts: VA, 58.6/54.3 and CRT, 294.0/297.9; **Table 2**).

Table 2: Mean baseline VA and CRT—French and Global wAMD cohorts

	VA (ETDRS letter score)			CRT* (µm)		
	Treatment naïve	Prior treatment (RBZ)	Prior treatment (other ocular)	Treatment naïve	Prior treatment (RBZ)	Prior treatment (other ocular)
French wAMD cohort, n	15	435	1	14	415	1
Mean (SD)	49.4 (21.66)	58.9 (19.22)	80.0 (0)	434.9 (192.71)	289.2 (95.76)	291.0 (0)
Global wAMD cohort, n	4320	11,994	295	3303	9516	228
Mean (SD)	48.8 (22.16)	56.4 (19.89)	51.4 (21.46)	356.2 (145.04)	276.6 (105.25)	345.0 (144.45)

Pre-treatment status defined by the primary-treated eye; *CRT measurements optional.
CRT, central retinal thickness; RBZ, ranibizumab; SD, standard deviation; VA, visual acuity; ETDRS, Early Treatment Diabetic Retinopathy Study

- A higher proportion of patients in the French wAMD cohort had pigment epithelium detachment (PED) than the Global wAMD cohort (68.0% versus 42.4%).
- At baseline, the French/Global wAMD cohorts had a similar proportion of non-ocular comorbidities (**Table 3**).

Table 3: Key non-ocular comorbidities at baseline—French and Global wAMD cohorts

Non-ocular comorbidities, %	French wAMD cohort (n = 469)	Global wAMD cohort (n = 17,546)
Myocardial infarction	5.5	7.3
Stroke	5.5	5.6
Other thromboembolic events	4.9	4.9
Family history of coronary artery disease	14.1	14.9
Diabetes	10.7	14.5
Hypertension	51.4	56.7
Obesity (BMI >30kg/m²)	11.5	10.0

n, number of patients; wAMD, wet age-related macular degeneration; BMI, body mass index

CONCLUSIONS

- The French wAMD patients enrolled in the LUMINOUS study were slightly older, had similar baseline VA and CRT, a greater proportion had PED, and a similar proportion had non-ocular comorbidities at baseline compared with the Global cohort.
- In both French and Global cohorts, prior ranibizumab treated patients had higher mean VA and lower CRT at baseline than treatment naïve patients.
- Future follow-up data from this cohort of French patients will provide an indispensable source of information from a diverse group of patients currently underrepresented in RCTs.

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