Budget Impact Analysis of Faricimab for Treating Patients With Diabetes Macular Edema or Neovascular Age-Related Macular Degeneration in El Salvador, Honduras & Dominican Republic

EE712

Hidalgo J[1], Santos M[2], Deras P[3], Castro A[4], Flores M[4], Roy R[5], Gonzáles A[5], Asilis Mera J[6] ⬭ [1]Roche, Alajuela, Costa Rica, [2]Instituto Hondureño de Seguridad Social, Tegucigalpa, Honduras, [3]Hospital San Felipe, Tegucigalpa, Honduras, [4]Instituto de Seguridad Social de El Salvador, San Salvador, El Salvador, [5]Private Clinic, Santo Domingo, Dominican Republic, [6]Private Clinic, Santiago de Los Caballeros, Dominican Republic

Introduction

The severe eye conditions of diabetic macular edema (DME) and neovascular age-related macular degeneration (nAMD) can lead to irreversible vision loss if not treated [1,2]. In Honduras, El Salvador & Dominican Republic, these conditions affect a significant proportion of the population, and the current treatment options can be expensive and burdensome. Recently, a new treatment called faricimab has been approved, which offers a more convenient dosing schedule and has shown promising results in clinical trials [3-5]. Therefore, it is crucial to assess the potential impact on a budget for integrating faricimab into the healthcare system of Honduras, El Salvador & Dominican Republic, ensuring that patients receive the best care possible.

This study aims to present the findings of a budget impact analysis (BIA) of using faricimab to treat DME and nAMD patients in Honduras, El Salvador & Dominican Republic. The results of this BIA can provide valuable insights into the financial implications of implementing faricimab as a new treatment for these debilitating eye conditions in these countries.

Methods

This BIA aims to evaluate the financial implications of implementing faricimab in the public system as a treatment for patients with DME or nAMD in Honduras, El Salvador & Dominican Republic. To estimate the number of DME patients, the model used variables such as the distribution of the population aged 18-64 and > 65 years, the prevalence of diabetes, the proportion of DME in diabetic patients, and the proportion of patients diagnosed and eligible for anti-VEGF therapy. Based on these factors, the model predicts that in 2023, 275,238 DME patients in these countries will be eligible for treatment with faricimab, of which 48 % will have bilateral disease. In addition, the model estimated an annual growth rate of new patients requiring therapy at 6.4 %.
For nAMD patients, the model considered variables such as the population > 50 years, the proportion of patients who probably have nAMD, the ratio of patients diagnosed, and patients eligible for anti-vascular endothelial growth factor (anti-VEGF) therapy. The model estimated that 14,876 nAMD patients would qualify for faricimab treatment in 2023, with 36 % assumed to have bilateral disease. The model also projected an annual growth rate of new patients needing therapy to be 11 %.

Table 1 presents the number of patients and eyes eligible for faricimab treatment from 2023 to 2026 for both DME and nAMD patients in Honduras, El Salvador & Dominican Republic. The model assumes that in 2023, no patients will receive faricimab, the majority of them will receive bevacizumab (ranibizumab in the case of El Salvador), and the least will receive aflibercept. The model also predicts that faricimab's market share will increase by 3 % per year from 2024 to 2026 at the expense of the bevacizumab (ranibizumab in the case of El Salvador) market. The analysis is from the perspective of a third-party payer, and the model costs are in USD 2023. Table 2 presents the dosage per injection (in mg) and the annual number of injections required for faricimab and anti-VEGF comparators for both DME and nAMD. The information is based on data reported by clinical trials of faricimab [1-3] and a meta-analysis of anti-VEGF [5]. Additionally, the BIA compares the total costs of faricimab treatment over three years with those of anti-VEGF comparators.

Table 1. Health care resources used in Honduras, El Salvador & Dominican Republic; in patients with DME & nAMD, 2023.

Year	DME						nAMD					
	Honduras		El Salvador		Dominican Republic		Honduras		El Salvador		Dominican Republic	
	# of patients	# of eyes	# of patients	# of eyes	# of patients	# of eyes	# of patients	# of eyes	# of patients	# of eyes	# of patients	# of eyes
2023	38,755	57,358	35,468	52,493	201,015	297,502	3,378	4,594	4,016	5,461	7,482	10,176
2024	39,103	57,872	35,787	52,964	202,818	300,170	3,408	4,635	4,052	5,510	7,550	10,267
2025	39,440	58,371	36,095	53,420	204,566	302,757	3,438	4,675	4,087	5,558	7,615	10,356
2026	39,766	58,854	36,394	53,863	206,258	305,262	3,466	4,714	4,121	5,604	7,678	10,442

Table 2. The numbre of anti-VEGF injections in the first year and from the second year, and the drug dose in each injection in patients with DME / nAMD.

Anti-VEFG therapy	Dose per injection (mg)	# of injections per year			
		DME		nAMD	
	Probability of use	Year 1	Year 2+	Year 1	Year 2+
Faricimab	6.00	8.4	4.9	6.79	4.69
Aflibercept	2.00	9.4	5.0	8.00	5.63
Bevacizumab	1.25	9.9	5.5	10.06	8.44
Ranibizumab	0.50	9.5	5.4	9.13	7.14

Results

Table 3 shows the number of patients per comparator who would receive treatment for DME & nAMD in Honduras, El Salvador & Dominican Republic in the current scenario without faricimab and in the plan with faricimab. The budgetary impact of including 3 % of patients with DME and nAMD in these countries is shown in Figure 1.

Table 3. The number of patients per comparator who would receive treatment for DME & nAMD in Honduras, El Salvador & Dominican Republic in a scenario with/without faricimab.

	DME												nAMD											
	Honduras				El Salvador				Dominican Republic				Honduras				El Salvador				Dominican Republic			
	Scenario without Faricimab (100% Bevacizumab)				Scenario without Faricimab (100% Ranibizumab)				Scenario without Faricimab (10% Bevacizumab & 10% Ranibizumab)				Scenario without Faricimab (100% Bevacizumab)				Scenario without Faricimab (100% Ranibizumab)				Scenario without Faricimab (49% Bevacizumab, 7% Aflibercept & 10% Ranibizumab)			
	2023 (baseline)	2024	2025	2026	2023 (baseline)	2024	2025	2026	2023 (baseline)	2024	2025	2026	2023 (baseline)	2024	2025	2026	2023 (baseline)	2024	2025	2026	2023 (baseline)	2024	2025	2026
Faricimab	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Aflibercept	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	75	76	76	77
Bevacizumab	38,755	39,103	39,440	39,766	0	0	0	0	180,914	182,536	184,109	185,632	3,378	3,408	3,438	3,466	0	0	0	0	6,659	6,720	6,777	6,833
Ranibizumab	0	0	0	0	35,468	35,787	36,095	36,394	20,102	20,282	20,457	20,626	0	0	0	0	4,016	4,052	4,087	4,121	748	755	762	768
Scenario with Faricimab																								
Faricimab	0	1,173	2,366	3,579	0	1,074	2,166	3,275	0	6,085	12,274	18,563	0	102	206	312	0	122	245	371	0	227	457	691
Aflibercept	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	75	76	76	77
Bevacizumab	38,755	37,930	37,074	36,187	0	0	0	0	180,914	176,452	171,835	167,069	3,378	3,306	3,232	3,154	0	0	0	0	6,659	6,493	6,320	6,142
Ranibizumab	0	0	0	0	35,468	34,713	33,929	33,119	20,102	20,282	20,457	20,626	0	0	0	0	4,016	3,930	3,842	3,750	748	755	762	768

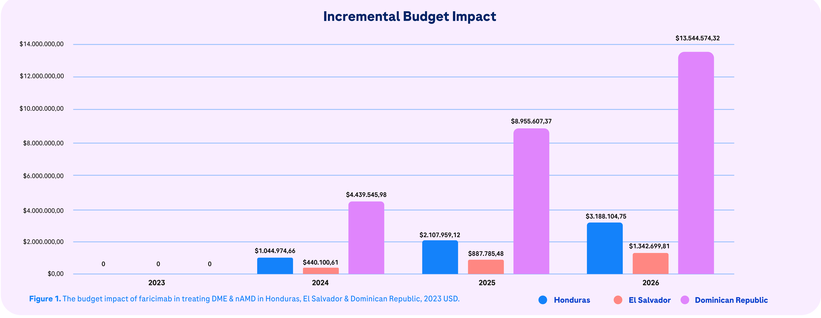

Figure 1. The budget impact of faricimab in treating DME & nAMD in Honduras, El Salvador & Dominican Republic, 2023 USD.

Discussion

Including faricimab in treating DME and nAMD in Honduras, El Salvador & Dominican Republic represents a budget impact of $6.34 million, $2.67 million & $26.94 million; respectively, for the country's health system in three years, with a market share in which the proportion of patients receiving faricimab increases by 3 % each year. Also, the additional cost per-patient of using Faricimab vs standard of care (Bevacizumab or Ranibizumab) per year in Honduras, El Salvador & Dominican Republic are respectively: $819.37, $368.24 & $706.37; using the standard of care public known price (estimated by 2020-2023 public purchases) and faricimab private price per market as no purchase has been made from the public healthcare sector at the moment of this investigation. Due to this fact, its certain known that Faricimab could potentially be a cost-saving strategy if an agreement could be stablished between the company and the public healthcare system, as it represents a benefit in terms of reduction of visits and intravitreal applications, reducing waiting lists (a problem reiterated by the doctors interviewed) and improving patients quality of life as a reduction in the number of intravitreal injections.

The main weakness of this economic model is that it does not estimate the costs of adverse events related to the intravitreal applications as the model assumes that they do not exist (physicians mentioned that the number of this adverse events are low). However, subconjunctival hemorrhages, vitreous hemorrhages, and endophthalmitis, among others, have been described in the literature [8]. The main strength of this economic model is that a group of expert retinal ophthalmologists who attend to patients with DME and nAMD in Honduras, El Salvador & Dominican Republic estimated the cost of healthcare resources.

Conclusion

The inclusion of faricimab for the treatment of DME and nAMD in Honduras, El Salvador & Dominican Republic has a budget impact of of $6.34 million, $2.67 million & $26.94 million; respectively, as at the moment of this investigation there´s no agreement between the healthcare system and the company that could reduce the economic impact of the drug, as an economic benefit is obtained by faricimab as per the reduction of clinical visits and intravitreal applications.

References

1. Klein R, Knudtson MD, Lee KE, et al. The Wisconsin Epidemiologic Study of Diabetic Retinopathy XXIII: the twenty-five-year incidence of macular edema in persons with type 1 diabetes. Ophthalmology. 2009 Mar;116(3):497-503.
2. Mathur R, Bhaskaran K, Edwards E, et al. Population trends in the 10-year incidence and prevalence of diabetic retinopathy in the UK: a cohort study in the Clinical Practice Research Datalink 2004-2014. BMJ Open. 2017 Feb 28;7(2):e014444.
3. Wykoff CC, Abreu F, Adamis AP, Basu K, Eichenbaum DA, et al; YOSEMITE and RHINE Investigators. Efficacy, durability, and safety of intravitreal faricimab with extended dosing up to every 16 weeks in patients with diabetic macular oedema (YOSEMITE and RHINE): two randomised, double-masked, phase 3 trials. Lancet. 2022 Feb 19;399(10326):741-755.
4. INEC Guatemala. Estadísticas Vitales. [Internet]. Available in: https://inec.cr/es/tematicas/listado?topics=91%252C799 Updated on March 29, 2023. Consulted in March 2023.
5. Pham B, Thomas SM, Lillie E, et al. Anti-vascular endothelial growth factor treatment for retinal conditions: a systematic review and meta-analysis. BMJ Open. 2019 May 28;9(5):e022031.
6. Khanani AM, Patel SS, Ferrone PJ, Osborne A, Sahni J, Grzeschik S, et al. Efficacy of Every Four Monthly and Quarterly Dosing of Faricimab vs Ranibizumab in Neovascular Age-Related Macular Degeneration: The STAIRWAY Phase 2 Randomized Clinical Trial. JAMA Ophthalmol. 2020 Sep 1;138(9):964-972.
7. Heier JS, Khanani AM, Quezada Ruiz C, Basu K, Ferrone PJ, et al; TENAYA and LUCERNE Investigators. Efficacy, durability, and safety of intravitreal faricimab up to every 16 weeks for neovascular age-related macular degeneration (TENAYA and LUCERNE): two randomised, double-masked, phase 3, non-inferiority trials. Lancet. 2022 Feb 19;399(10326):729-740.
8. Zehden JA, Mortensen XM, Reddy A, et al. Systemic and Ocular Adverse Events with Intravitreal Anti-VEGF Therapy Used in the Treatment of Diabetic Retinopathy: a Review. Curr Diab Rep. 2022 Oct;22(10):525-536.

Sponsored by:

Roche