

# US Post Marketing Commitments

Product/ Compound	Description of Commitment	NDA Number	Agreement Date	Projected Completion Date	Status
Benicar (olmesartan medoxomil) 5/20/40 MG	Pediatric assessment.	21-286	4/25/2002	Complete	Fulfilled
Benicar (olmesartan medoxomil) 5/20/40 MG	A study to evaluate olmesartan for effects on hERG and hNav1.5 currents in whole cell voltage clamp studies using ion channels expressed in a mammalian cell line.	21-286	5/26/2011	Complete	Fulfilled
Benicar (olmesartan medoxomil) 5/20/40 MG	Perform a thorough QT/QTc study for olmesartan in accordance with the FDA Guidance, "Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Anti-arrhythmic Drugs.	21-286	5/26/2011	Complete	Fulfilled

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Benicar (olmesartan medoxomil) 5/20/40 MG	Conduct an epidemiologic study using claims or electronic health records data to evaluate the comparative incidence of sudden cardiac death, in hospital fatal myocardial infarction and total mortality in olmesartan users vs. users of other angiotensin receptor blockers and in olmesartan users vs. ACE inhibitor users.	21-286	5/26/2011	Complete	Fulfilled
Benicar (olmesartan medoxomil) 5/20/40 MG	Conduct a patient-level meta-analysis evaluating the incidence of major cardiovascular events and total mortality in olmesartan treated patients compared to control patients in randomized clinical trials.	21-286	5/26/2011	Complete	Fulfilled

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Savaysa (edoxaban)	Pediatric Development in VTE (AF waived) Single-dose PK/PD study	206316	01/08/2015	12/31/2017	Ongoing
Savaysa (edoxaban)	Phase 3 multicenter, randomized, active control study of Edoxaban in pediatric patients with documented venous thromboembolism	206316	01/08/2015	6/30/2022	Ongoing
Welchol for Oral Suspension PMC	1-year, pediatric efficacy and safety study under PREA for the treatment of type 2 Diabetes in pediatric patients ages 10 to 17 years.	22362 & 21176/S- 022	10/02/2009	11/30/2019	Ongoing

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Welchol (colesevelam HCl) tablets	To study Welchol as monotherapy treatment for type 2 diabetes mellitus.	21176	05/26/2000	Complete	Fulfilled
Welchol (colesevelam HCl) tablets	To study Welchol in combination with thiazolidinediones as treatment for type 2 diabetes mellitus.	21176	05/26/2000	Complete	Fulfilled