

- To characterize the tolerability profile of pegunigalsidase alfa using data from 5 clinical trials that had been completed by 2021, with a focus on the incidence of IRRs and change in infusion duration over time

EOW, every other week; ERT, enzyme replacement therapy; Q4W, every 4 weeks; SD, standard deviation

PA dose (mg/kg)	IRR Severity classification	IRR Description	Patients (n = 5, all men)	IRRs, n	
2.0	Mild	Infusion-related reaction	1	11	
		Nausea	1	1	
		Ataxia	1	1	
		Pain	1	1	
		Chest discomfort	1	1	
		Paresthesia	1	1	
		Tremor	1	1	
	Moderate	Total		17	
		Infusion-related reaction	3	4	
		Pain	1	1	
		Hypersensitivity	1	1	
		Vomiting	1	1	
		Myalgia	1	1	
		Pain in extremity	1	1	
		Headache	1	1	
Overall total, n			Total	10	
Total IRR incidence, %				27	

IRR, infusion-related reaction; PA, pegunigalsidase alfa.