CDER Breakthrough Therapy Designation Requests Received by Fiscal Year

Cohort: July 9, 2012* - September 30, 2023

Data as of December 31, 2023

Fiscal Year	Total Requests Received	Granted	Denied	Withdrawn
2023	88	37	44	7
2022	78	26	46	6
2021	103	42	46	15
2020	125	58	53	14
2019	156	67	68	21
2018	136	59	60	17
2017	111	50	49	12
2016	106	46	48	12
2015	93	32	43	18
2014	96	31	51	14
2013	92	31	52	9
2012	2	1	1	0
Total	**1186**	**480**	**561**	**145**

* Breakthrough therapy designation was enacted in the Food and Drug Administration Safety and Innovation Act on July 9, 2012.

MERCK EX1128
Merck Sharp & Dohme LLC v. The Johns Hopkins University
IPR2024-00625