Disclosure Results

Latuda **European Marketing Authorisation Holder: Sunovion Pharmaceuticals Europe Ltd**

phase	total complete by 31 July 2016	un-evaluable	evaluable	disclosed in 12 month timeframe	disclosed percentage at 12 months	complete by 31 July 2016	disclosed at 31 July 2016	disclosure percentage at 31st July 2016
phase I & II	16	0	16	7	44%	16	13	81%
phase III	30	1	29	20	69%	29	22	76%
phase IV	0	0	0	0		0	0	
other	0	0	0	0		0	0	
total	**46**	**1**	**45**	**27**	**60%**	**45**	**35**	**78%**

Footnote (company communication): Ten trials remained undisclosed at 31 July 2016. Eight of these were carried out in Asia by Sumitomo Dainippon, the parent company of the European MAH; of these, results of three phase III trials are being submitted to ClinicalTrials.Gov and the others were exploratory phase II or II/III, for which disclosure was not mandatory in Japan. The remaining two trials were phase I trials carried out in the US and were out of scope of FDAAA 801.

Key to columns in table above:

total complete by 31 July 2016 = total number of company-sponsored trials identified which were completed by 31 July 2016
unevaluable = trials with completion date within the last 12 months, or key dates missing - excluded from the analysis
evaluable = trials with all criteria present including dates; hence the base number of trials evaluated for the assessment
disclosed in 12 month timeframe = evaluable trials which were disclosed within the target 12 months*
disclosed percentage at 12 months = proportion of evaluable trials which were disclosed within 12 months*
complete before 31 July 2016 = number of evaluable trials completed before 31 July 2016
disclosed at 31 July 2016 = number of evaluable trials with results disclosed by 31 July 2016
disclosure percentage at 31 July 2016 = proportion of evaluable trials which were disclosed by 31 July 2016

[* 12 months measured from the later of: the first date of regulatory approval (in Europe or the US) or the trial completion date]