

Disclosure Results

Deltys

European Marketing Authorisation Holder: Otsuka Novel Products GmbH

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	5	0	5	4	80%	5	4	80%
phase III	1	1	0	0		0	0	
phase IV	0	0	0	0		0	0	
other	0	0	0	0		0	0	
total	6	1	5	4	80%	5	4	80%

Footnote (company communication): One phase II study carried out in Latvia and Lithuania remained undisclosed at 31 July 2016; results have since been posted on EudraCT.

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]