

SUPPLEMENTARY TABLE S2. ACCUMULATED DATA FROM ET-RCL ASSAY TEST RUNS^a

Assay #	Initiated	Type	Purpose	Batch number	PERT endpoint			ET-RCL assay		MLV/HEK293		Comment
					Negative	Positive	Spike	10x Spike	0.1 x Spike	Test	result	
RCL#001	24-May-10	FDP	Pilot	D141/RETI/FCC001	0/1	1/1	1/1	nd	1/5	nd	Pass	na
RCL#002	24-May-10	FDP	Pilot	D141/RETI/FCC001	0/1	1/1	1/1	nd	1/5	nd	Pass	na
RCL-CC#001	16-Jun-10	EOPC	Pilot	140510RT048 (IH48)	0/1	1/1	1/1	nd	na	0/2	Pass	nd
RCL-CC#002	16-Jun-10	EOPC	Pilot	140510RT048 (IH48)	0/1	1/1	1/1	nd	na	0/2	Pass	nd
RCL#003	09-Jul-10	FDP	lot release	G141/RETI/FCC001	0/1	1/1	1/1	nd	na	0/10	Pass	Pass
RCL-CC#003	09-Jul-10	EOPC	lot release	G141/RETI/EPCB001	0/1	1/1	1/1	nd	na	0/10	Pass	Pass
RCL-CC#004	09-Jul-10	EOPC	lot release	G141/RETI/EPCB002	0/1	1/1	1/1	nd	na	0/10	Pass	Pass
RCL-CC#005	19-Jul-10	EOPC	lot release	G141/RETI/EPCB003	0/1	1/1	1/1	nd	na	0/10	Pass	Pass
RCL#004	01-Oct-10	FDP	lot release	G145/STAR/FCC001	0/1	1/1	1/1	nd	na	0/10	Pass	Pass
RCL-CC#006	01-Oct-10	EOPC	lot release	G145/STAR/EPCB001	0/1	1/1	0/1 ^a	nd	na	0/10	Fail	Assay repeated
RCL-CC#007	01-Oct-10	EOPC	lot release	G145/STAR/EPCB002	0/1	1/1	1/1	nd	na	0/10	Pass	Pass
RCL-CC#008	01-Oct-10	EOPC	lot release	G145/STAR/EPCB003	0/1	1/1	1/1	nd	na	0/10	Pass	Pass
RCL-CC#009	07-Jan-11	EOPC	lot release	G145/STAR/EPCB001	0/1	1/1	0/1	nd	na	0/10	Fail	Assay repeated
RCL-CC#014	29-Mar-11	EOPC	lot release	G145/STAR/EPCB001	0/1	1/1	3/3	1/1	na	0/10	Pass	nd
RCL-CC#010	07-Jan-11	EOPC	lot release	G154/USHS/EPCB001	0/1	1/1	1/1	nd	na	0/10	Pass	Pass
RCL-CC#011	07-Jan-11	EOPC	lot release	G154/USHS/EPCB002	0/1	1/1	1/1	nd	na	0/10	Pass	Pass
RCL#005	03-Jun-11	FDP	lot release	G154/USHS/FCC001	0/1	1/1	0/1	nd	na	0/10	Fail	Assay repeated
RCL#007	10-Aug-11	FDP	lot release	G154/USHS/FCC001	0/1	2/2	0/2	1/1	na	0/10	Pass	Pass
RCL#005a	23-Aug-11	FDP	Amendment	EOACs from RCL#005	0/1	1/1	1/1	nd	na	na	Pass	na
RCL-CC#015	14-Jun-11	EOPC	lot release	G154/USHS/EPCB003	0/1	1/1	1/1	nd	na	0/10	Pass	Pass
RCL-CC#016	28-Oct-11	EOPC	lot release	G165/USHS/EPCB001	0/1	1/1	1/1	1/1	na	0/10	Pass	Pass
RCL-CC#017	28-Oct-11	EOPC	lot release	G165/USHS/EPCB002	0/1	0/1	1/1	1/1	na	0/10	Pass*	Pass
Totals					0/22	22/23	20/24[†]	4/4		0/174		
FDP assay					0/7	8/8	5/8	1/1		0/40		
EOPC assay					0/15	14/15	15/16	3/3		0/134		

EOPCs, end-of-production cells; ET-RCL, equine-tropic replication-competent lentivirus; FDP, final drug product; MLV, murine leukemia virus; na, not applicable; nd, not done; PERT, product-enhanced reverse transcriptase.

^aShown are all clinical-lot GMP ET-RCL assay results to date, including those of pilot and troubleshooting runs. No RCL has ever been detected in FDP of EOPCs in either the ET-RCL assay or MLV/HEK293 RCL assays. The observed positive control or spike control failures are summarized and have formed the basis for exploratory studies into EIAVAS2 inhibition.

[†]Spike flask bacterially/fungally contaminated.

^{*}Excluding spike failure of RCL-CC#006.

[‡]Characterization of RT source demonstrated the presence of EIAVAS2.