

Table 3  
 Study Drug Related Adverse Events  
 Safety Population

System Organ Class Preferred Term	Severity	Denvax N =328	
		n	%
Number of subjects with at least one adverse event	Total	210	( 64.0%)
	Mild	172	( 52.4%)
	Moderate	38	( 11.6%)
	Severe	0	( 0.0%)
Total Adverse Events	Total	358	
	Mild	284	
	Moderate	74	
	Severe	0	
Blood and lymphatic system disorders	Total	2	( 0.6%)
	Mild	1	( 0.3%)
	Moderate	1	( 0.3%)
	Severe	0	( 0.0%)

Subjects are counted once for each preferred term in case of multiple occurrences of the same AE. The AE with the highest intensity is reported.

Table 3  
 Study Drug Related Adverse Events  
 Safety Population

System Organ Class Preferred Term	Severity	Denvax N =328	
		n	%
Anaemia	Total	2	( 0.6%)
	Mild	1	( 0.3%)
	Moderate	1	( 0.3%)
	Severe	0	( 0.0%)
Gastrointestinal disorders	Total	1	( 0.3%)
	Mild	1	( 0.3%)
	Moderate	0	( 0.0%)
	Severe	0	( 0.0%)
Vomiting	Total	1	( 0.3%)
	Mild	1	( 0.3%)
	Moderate	0	( 0.0%)
	Severe	0	( 0.0%)

Subjects are counted once for each preferred term in case of multiple occurrences of the same AE. The AE with the highest intensity is reported.

Table 3  
 Study Drug Related Adverse Events  
 Safety Population

System Organ Class Preferred Term	Severity	Denvax N =328	
		n	%
General disorders and administration site conditions	Total	206	( 62.8%)
	Mild	170	( 51.8%)
	Moderate	36	( 11.0%)
	Severe	0	( 0.0%)
Asthenia	Total	57	( 17.4%)
	Mild	46	( 14.0%)
	Moderate	11	( 3.4%)
	Severe	0	( 0.0%)
Chills	Total	35	( 10.7%)
	Mild	5	( 1.5%)
	Moderate	30	( 9.1%)
	Severe	0	( 0.0%)

Subjects are counted once for each preferred term in case of multiple occurrences of the same AE. The AE with the highest intensity is reported.

Table 3  
 Study Drug Related Adverse Events  
 Safety Population

System Organ Class Preferred Term	Severity	Denvax N =328	
		n	%
Pyrexia	Total	205	( 62.5%)
	Mild	191	( 58.2%)
	Moderate	14	( 4.3%)
	Severe	0	( 0.0%)
Nervous system disorders	Total	35	( 10.7%)
	Mild	28	( 8.5%)
	Moderate	7	( 2.1%)
	Severe	0	( 0.0%)
Lethargy	Total	35	( 10.7%)
	Mild	28	( 8.5%)
	Moderate	7	( 2.1%)
	Severe	0	( 0.0%)

Subjects are counted once for each preferred term in case of multiple occurrences of the same AE. The AE with the highest intensity is reported.

Table 3  
 Study Drug Related Adverse Events  
 Safety Population

System Organ Class Preferred Term	Severity	Denvax N =328	
		n	%
Renal and urinary disorders	Total	2	( 0.6%)
	Mild	0	( 0.0%)
	Moderate	2	( 0.6%)
	Severe	0	( 0.0%)
Haematuria	Total	2	( 0.6%)
	Mild	0	( 0.0%)
	Moderate	2	( 0.6%)
	Severe	0	( 0.0%)
Skin and subcutaneous tissue disorders	Total	2	( 0.6%)
	Mild	2	( 0.6%)
	Moderate	0	( 0.0%)
	Severe	0	( 0.0%)

Subjects are counted once for each preferred term in case of multiple occurrences of the same AE. The AE with the highest intensity is reported.

Table 3  
Study Drug Related Adverse Events  
Safety Population

System Organ Class Preferred Term	Severity	Denvax N =328	
		n	%
Pruritus	Total	2	( 0.6%)
	Mild	2	( 0.6%)
	Moderate	0	( 0.0%)
	Severe	0	( 0.0%)

Subjects are counted once for each preferred term in case of multiple occurrences of the same AE. The AE with the highest intensity is reported.