**Abstract**

SAR3419 is a composed of the humanized anti-CD19 antibody subunit conjugated with the potent cytotoxic maytansinoid, DM4. SAR3419 was shown to exhibit antitumor activity against human B-lineage acute lymphoblastic leukemia (ALL) xenografts generated in nude mice. SAR3419 was tested in the Pediatric Preclinical Testing Program (PPTP). SAR3419 and/or delayed the xenografts, but exerted potent activity within 1-3 weeks of treatment cessation.

**Methods for PPTP In Vivo Testing**

- **SAR3419 In Vivo Activity**
  - **Response Criteria**: Defined by the PPTP. Each individual mouse in the treatment group was assigned a median response score (see Tables above) and a median score for the treatment group was calculated and then each treatment group was assigned an overall response according to the PPTP's standard operating procedures.
  - **Statistical Methods**: Event-free survival (EFS) distributions of each treatment group were compared to the EFS distribution of the respective control groups using the Wilcoxon rank sum test. *P*-values were calculated & not adjusted for multiple comparisons given the exploratory nature of this study. *P*-values ≤ 0.05 were considered to be significant.

**PPTP In Vitro Testing Methods**

- **SAR3419 In Vitro Activity**
  - **Activity vs. B-lineage acute lymphoblastic leukemia (ALL) cell lines**: SAR3419 was provided by Sanofi-Aventis. SAR3419 was tested in a panel of B-lineage ALL cell lines (n=7) and did not induce a significant delay in two ALL T-cell xenografts or two Ewing sarcomas (all CD19 negative). SAR3419 was effective in delaying xenografts in five of seven ALL xenografts of B lineage with high CD19 expression.

**ALL Xenograft Demographics**

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  - **SAR3419 In Vivo Activity**
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**CONCLUSIONS**

- SAR3419 was effective in delaying leukemia in 5 ALL xenografts of B lineage with high CD19 expression and did not induce a significant delay in two ALL T-cell xenografts or two Ewing sarcomas (all CD19 negative). SAR3419 was effective in delaying xenografts in five of seven ALL xenografts of B lineage with high CD19 expression.
- SAR3419 induced objective responses in four out of five B-lineage ALL xenografts (one partial response and did not induce a significant delay in two ALL T-cell xenografts or two Ewing sarcomas (all CD19 negative)).
- SAR3419 was provided by Sanofi-Aventis and testing was supported by NCI N01CM22216, Children's Cancer Institute Australia is affiliated with the University of New South Wales and Sydney Children's Hospital.