



# SZABO SCANDIC

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## Simlukafusp alfa

Cat. No.:	HY-P99902
CAS No.:	1776942-10-9
Target:	Interleukin Related
Pathway:	Immunology/Inflammation
Storage:	Please store the product under the recommended conditions in the Certificate of Analysis.

### BIOLOGICAL ACTIVITY

<b>Description</b>	Simlukafusp alfa (FAP-IL2v) is an immunocytokine comprising an antibody against fibroblast activation protein $\alpha$ (FAP $\alpha$ ) and an IL-2 variant that only binds IL-2R $\beta\gamma$ . Isotype: human IgG1 <sup>[1]</sup> .								
<b>In Vitro</b>	<p>Simlukafusp alfa (FAP-IL2v) shows binding affinity constants of 43<math>\pm</math>9 pM, 80<math>\pm</math>20 pM, 660<math>\pm</math>80 pM, 0.3 nM, 0.23 nM and 0.5 nM with huIL-2R<math>\beta\gamma</math>, cyIL-2R<math>\beta\gamma</math>, muIL-2R<math>\beta\gamma</math>, huFAP, cyFAP and muFAP, respectively<sup>[1]</sup>.</p> <p>Simlukafusp alfa (0-100 nM; 5 days) activates CD4+/CD8+ T cells and NK cells in vitro, but not preferentially Tregs<sup>[1]</sup>.</p> <p>Simlukafusp alfa (0-100 nM) enhances Cetuximab (HY-P9905)-mediated antibody-dependent cellular cytotoxicity (ADCC) and Cibisatamab (HY-P99011)-mediated T-cell-dependent cellular cytotoxicity (TDCC) in vitro<sup>[1]</sup>.</p> <p>MCE has not independently confirmed the accuracy of these methods. They are for reference only.</p> <p>Cell Proliferation Assay<sup>[1]</sup></p> <table border="1"> <tr> <td>Cell Line:</td> <td>NK cells, CD4+ and CD8+ T cells</td> </tr> <tr> <td>Concentration:</td> <td>0-100 nM</td> </tr> <tr> <td>Incubation Time:</td> <td>5 days</td> </tr> <tr> <td>Result:</td> <td>Induced a dose-dependent proliferation of resting NK cells and resting and activated CD4+ and CD8+ T cells within peripheral blood mononuclear cells (PBMCs).</td> </tr> </table>	Cell Line:	NK cells, CD4+ and CD8+ T cells	Concentration:	0-100 nM	Incubation Time:	5 days	Result:	Induced a dose-dependent proliferation of resting NK cells and resting and activated CD4+ and CD8+ T cells within peripheral blood mononuclear cells (PBMCs).
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<b>In Vivo</b>	<p>Simlukafusp alfa (FAP-IL2v) (1 mg/kg; i.v.; weekly for 4 weeks) is efficacious in combination with therapeutic antibodies in murine models of human cancer<sup>[1]</sup>.</p> <p>MCE has not independently confirmed the accuracy of these methods. They are for reference only.</p> <table border="1"> <tr> <td>Animal Model:</td> <td>huCD16-transgenic SCID mice, lung orthotopic xenograft A549 model<sup>[1]</sup></td> </tr> <tr> <td>Dosage:</td> <td>1 mg/kg in combination with 25 mg/kg Cetuximab (HY-P9905) as single agents</td> </tr> <tr> <td>Administration:</td> <td>IV, weekly starting at Day 14 for 4 weeks</td> </tr> <tr> <td>Result:</td> <td>Achieved greater tumor control than either agent given as monotherapy. Reduced tumor volume and tumor growth.</td> </tr> </table>	Animal Model:	huCD16-transgenic SCID mice, lung orthotopic xenograft A549 model <sup>[1]</sup>	Dosage:	1 mg/kg in combination with 25 mg/kg Cetuximab (HY-P9905) as single agents	Administration:	IV, weekly starting at Day 14 for 4 weeks	Result:	Achieved greater tumor control than either agent given as monotherapy. Reduced tumor volume and tumor growth.
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Animal Model:	CD-1 mice <sup>[1]</sup>																
Dosage:	1, 2 or 4 mg/kg																
Administration:	IV (Pharmacokinetic Analysis)																
Result:	<p>Pharmacokinetic parameters after first dose of human FAP-IL2v (huFAP-IL2v) in CD-1 mice CD-1 mice (n=10 per group) were given 1, 2, and 4 mg/kg huFAP-IL2v by IV administration once weekly. Multiple IV doses at 1 and 2 mg/kg were administered QW for up to a maximum of three doses, at which point toxicity was observed. Only a single dose was administered to the 4-mg/kg IV treatment group because of toxicity in these treatment groups. Blood was sampled at 0.5, 6, 24, 48, 72, and 168 h.</p> <table border="1"> <thead> <tr> <th>huFAP-IL2v dose (mg/kg)</th> <th>C<sub>max</sub> (µg/mL)</th> <th>AUC<sub>0-168h</sub> (µg·h/mL per mg/kg)</th> <th>CL (mL/d/kg)</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>19.0</td> <td>557</td> <td>40.0</td> </tr> <tr> <td>2</td> <td>36.3</td> <td>479</td> <td>46.8</td> </tr> <tr> <td>4</td> <td>78.7</td> <td>541</td> <td>38.7</td> </tr> </tbody> </table> <p>AUC<sub>0-168h</sub>, area under the concentration-time curve from 0 to 168 hours; C<sub>max</sub>, maximum serum concentration observed; CL, total clearance; FAP-IL2v, fibroblast activation protein-α-targeted interleukin 2 variant (IL2v) immunocytokine; hu, humanized; IV, intravenous.</p>	huFAP-IL2v dose (mg/kg)	C <sub>max</sub> (µg/mL)	AUC <sub>0-168h</sub> (µg·h/mL per mg/kg)	CL (mL/d/kg)	1	19.0	557	40.0	2	36.3	479	46.8	4	78.7	541	38.7
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## REFERENCES

[1]. Waldhauer I, et al. Simlukafusp alfa (FAP-IL2v) immunocytokine is a versatile combination partner for cancer immunotherapy. *MAbs*. 2021 Jan-Dec;13(1):1913791.

**Caution: Product has not been fully validated for medical applications. For research use only.**

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