

Characterization of CG201, a New More Potent Anti-hCG Cancer Vaccine Formulation

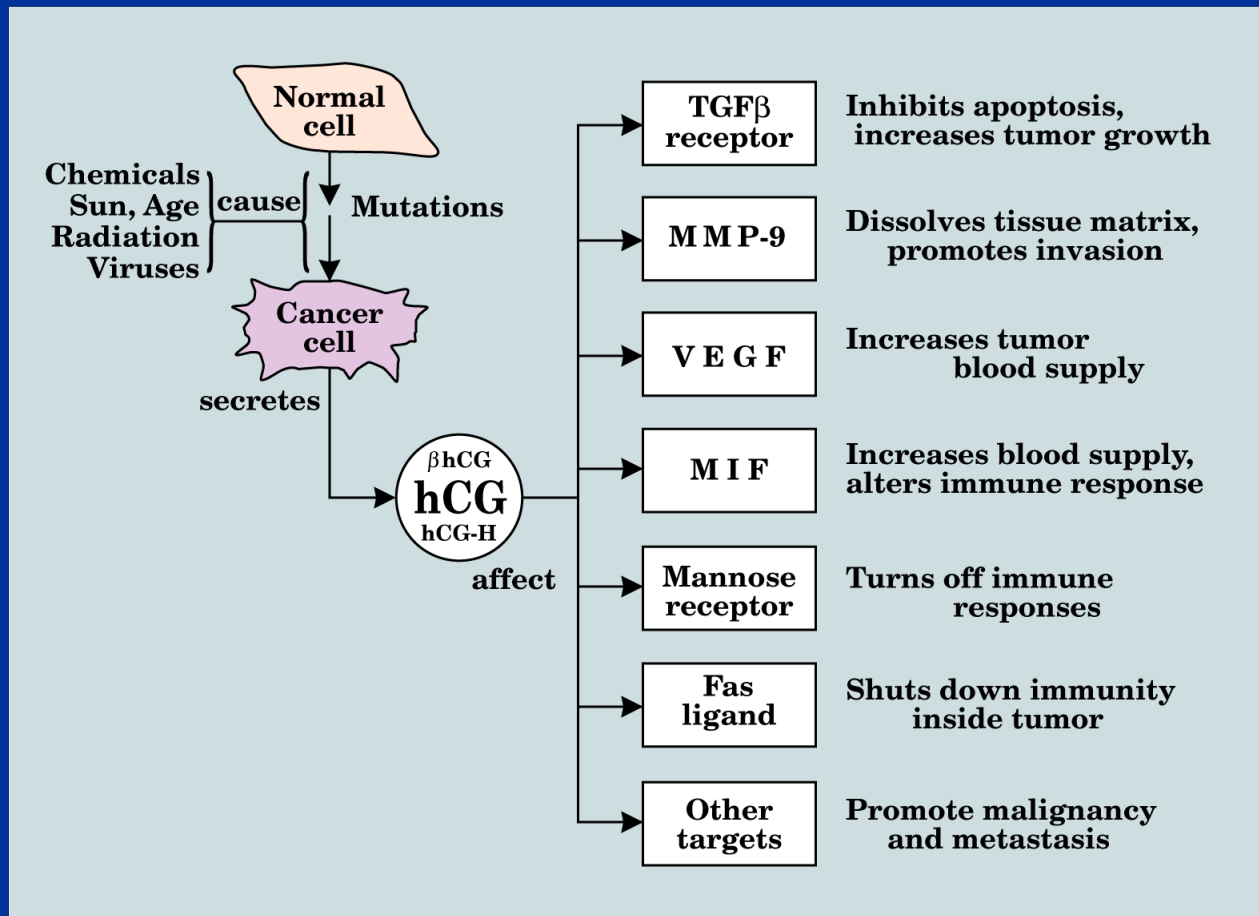
Thomas P Hopp

CGTherapeutics

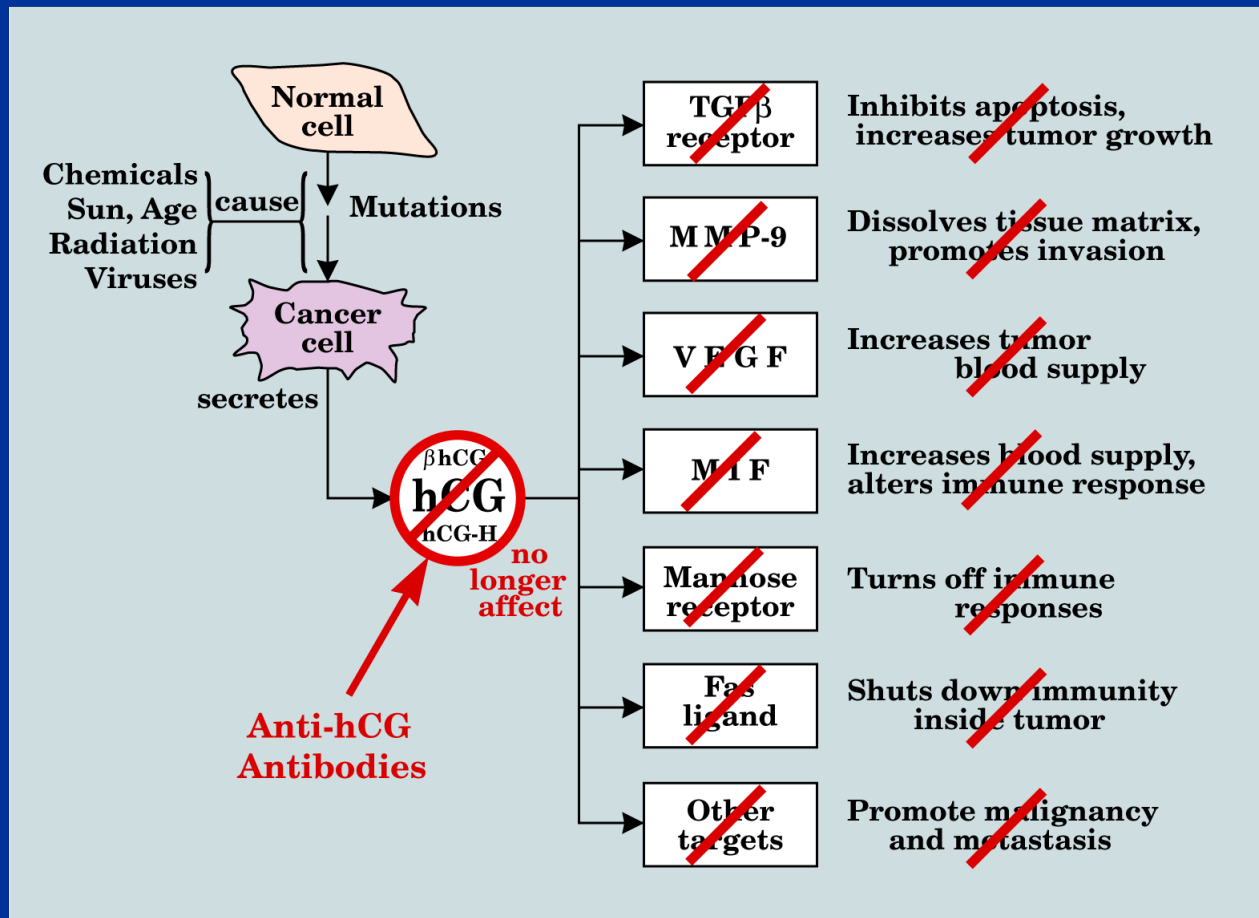
Therapeutic Rationale

- **hCG and its molecular variants promote the growth and spread of many types of cancer**
- **CG201 vaccinations stimulate antibodies that neutralize hCG's tumor-promoting activities**

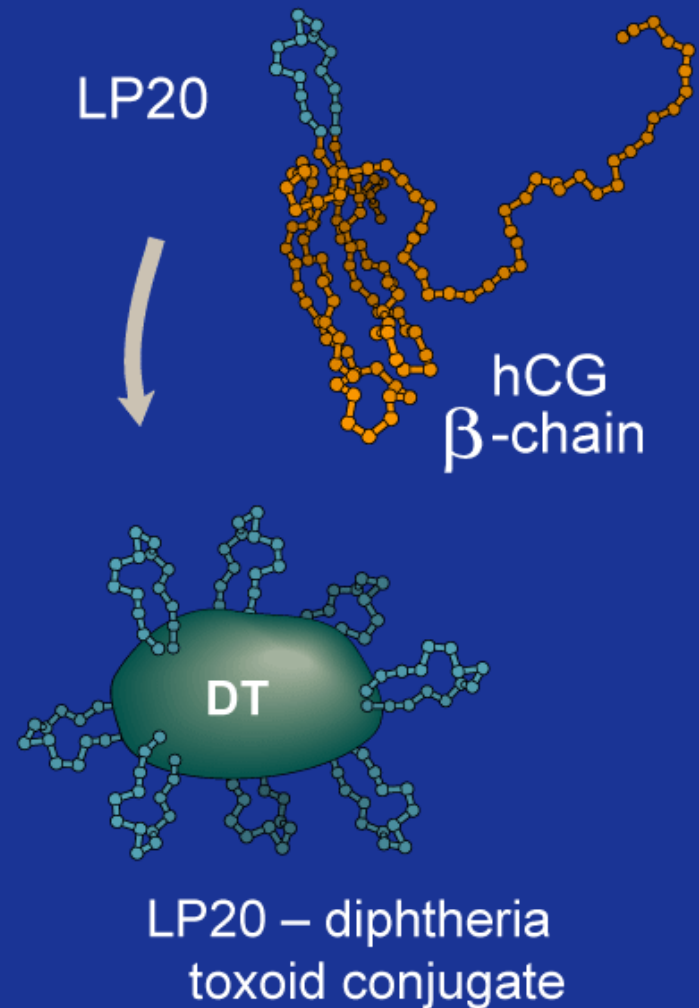
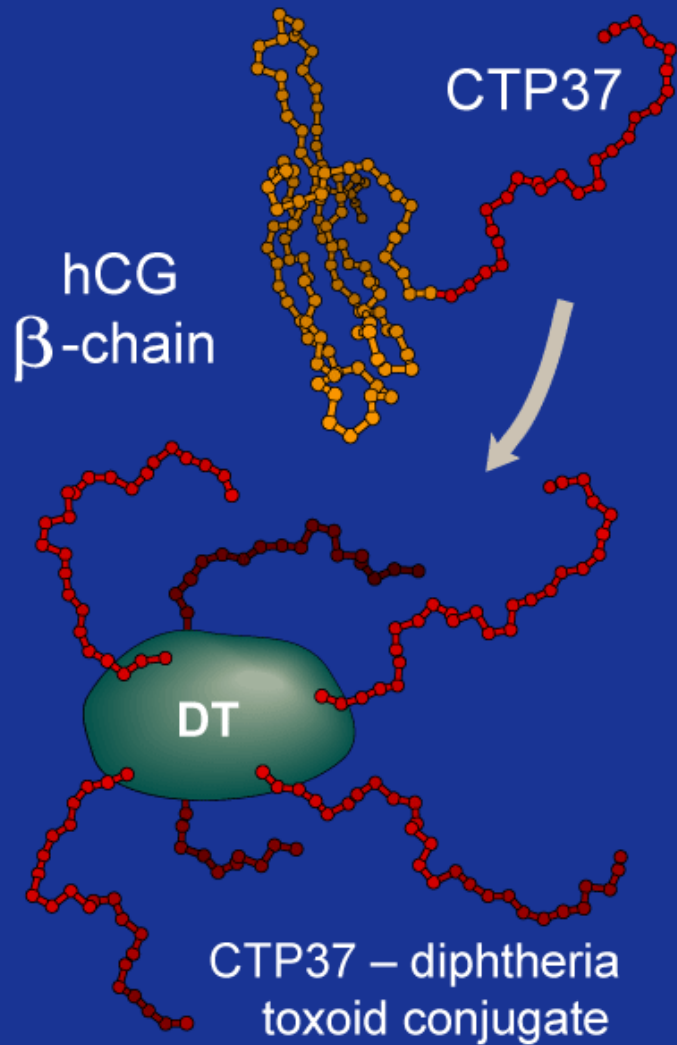
hCG: A Master Control Switch In Cancer



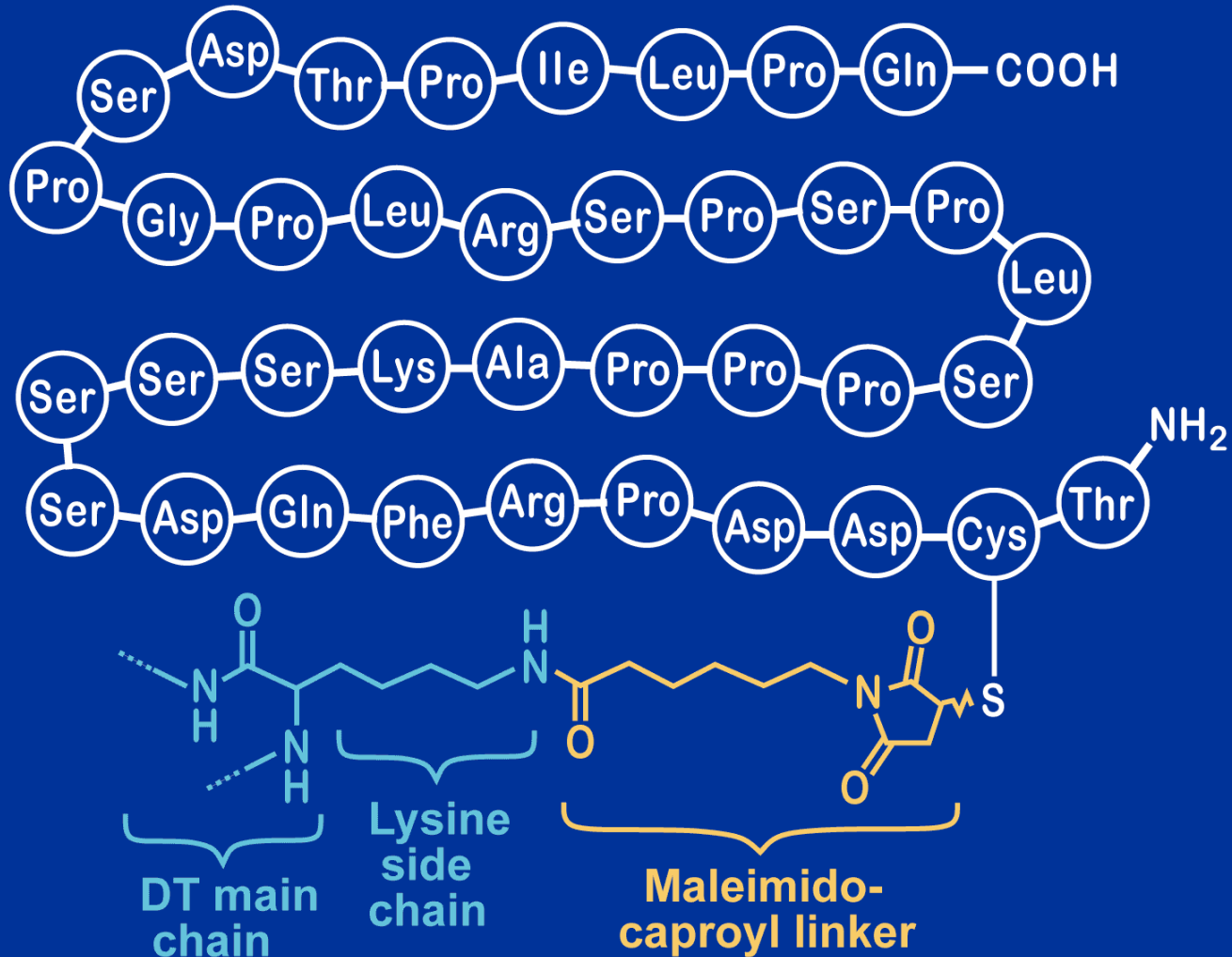
Anti-hCG Antibodies: Turning the Master Control Switch Off



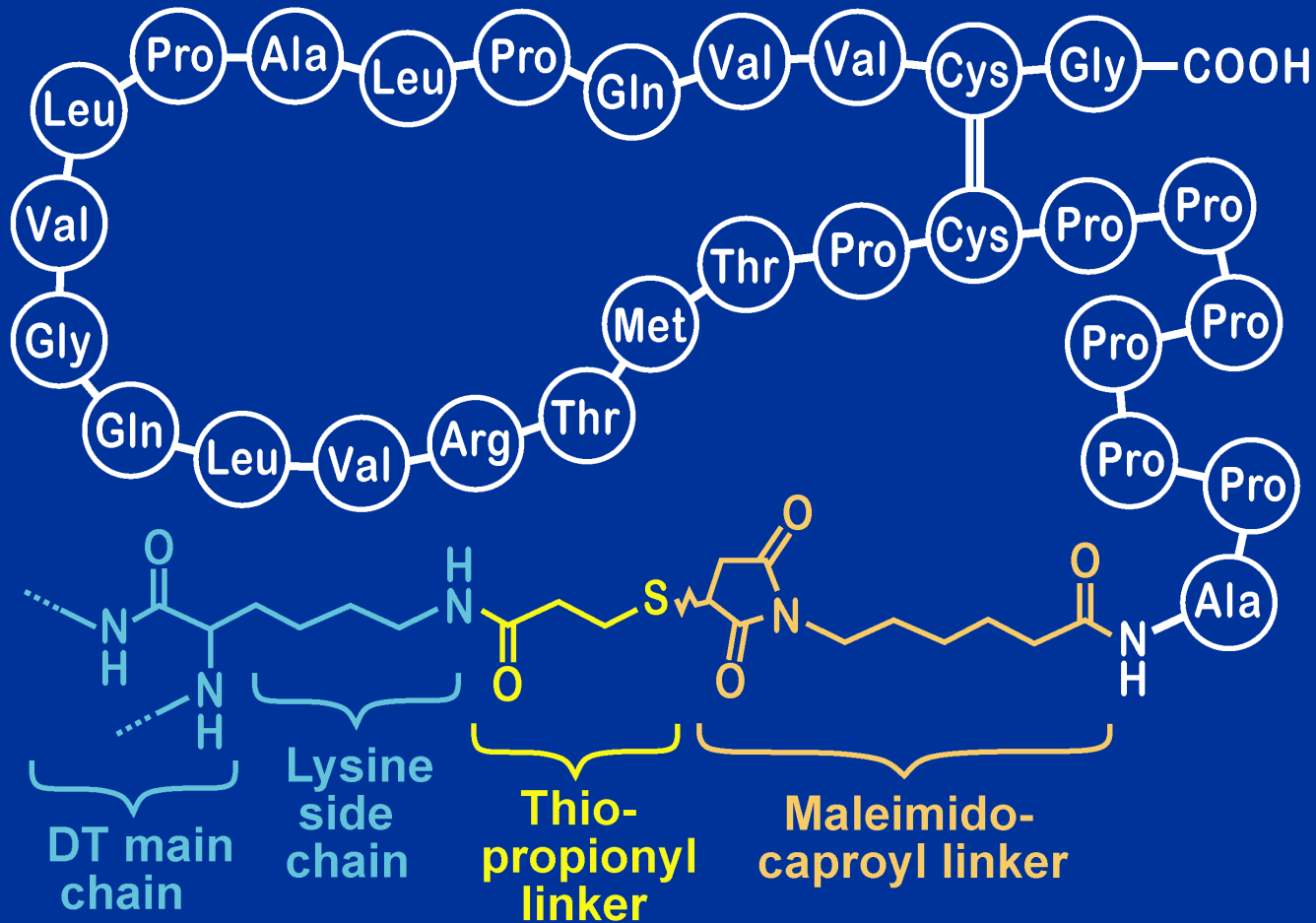
Peptide-DT Immunogens



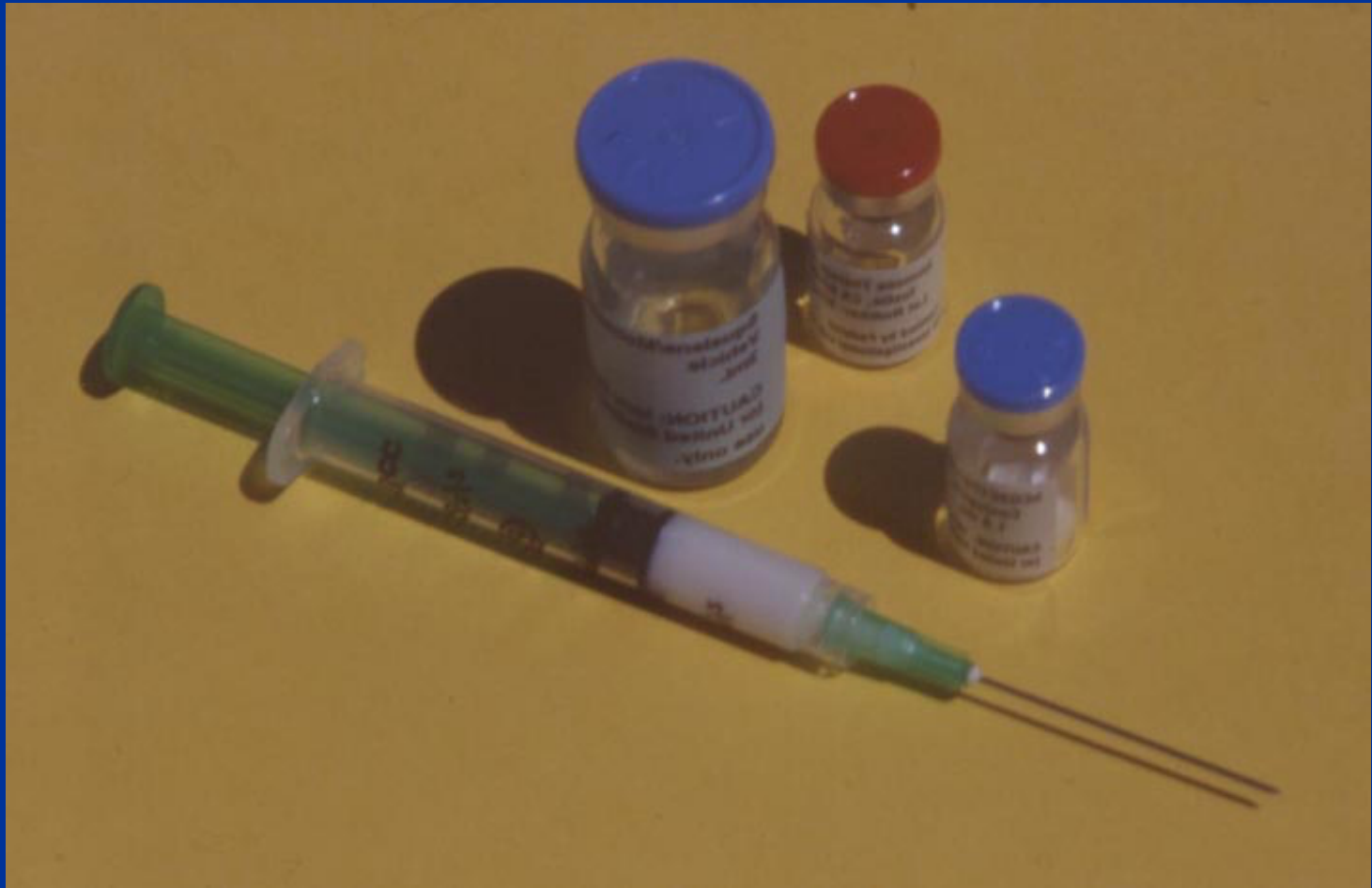
CTP37-DT Conjugate



LP20-DT Conjugate



Early Prototype Vaccines



Clinical Trials with hCG Peptide Vaccines

Study #	Study Description	P.I. / Sponsor	Study Subjects*
Formulation 1, containing CTP37 -DT immunogen			
1	Phase 1 contraceptive study in surgically sterilized women	W. Jones / WHO	n=20/30
2	Phase 2 contraceptive study in fertile women	WHO	n =7/7
3	Phase 1b study in recurrent or metastatic non-trophoblastic cancers	P. Triozzi / ITC	n=23/23
4	Phase 1b study in metastatic non - trophoblastic cancers	P. Triozzi / Vaxcell & ITC	n=21/21
5	Phase 1 -2 study in advanced or recurrent pancreatic cancer	ITC & AVI	n=6/6
6	Phase 2 study in colorectal cancer	AVI & ITC	n=77/77
Formulation 2, containing CTP37 -DT+LP20h -DT dual immunogen			
7	Phase 2 study in pancreatic cancer	AVI	n = 55/55

*n = subjects receiving vaccine /total subjects receiving Formulation 1 or 2 was 209. . The overall total number of subjects

Trial 6: Phase 2 Study in Advanced Colorectal Cancer

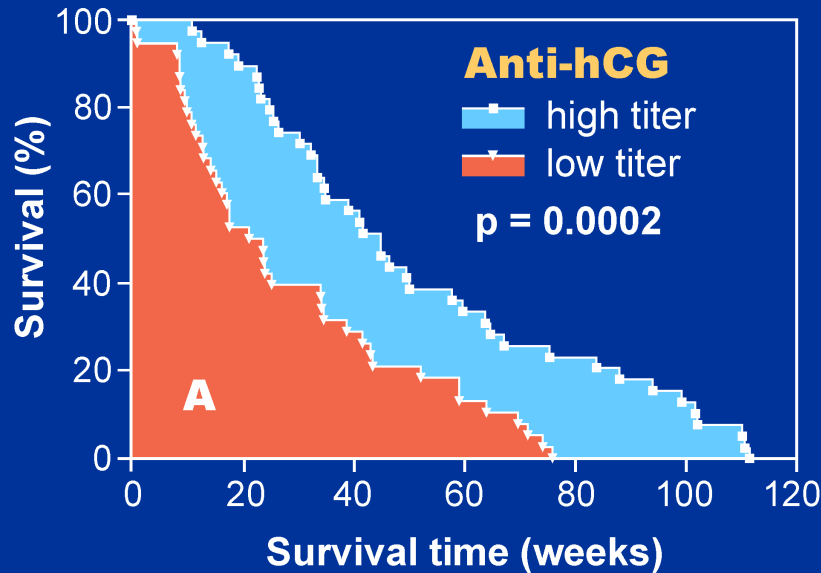
77 colorectal cancer patients

- **Measurable metastatic cancer**
- **Failure of conventional chemotherapy**

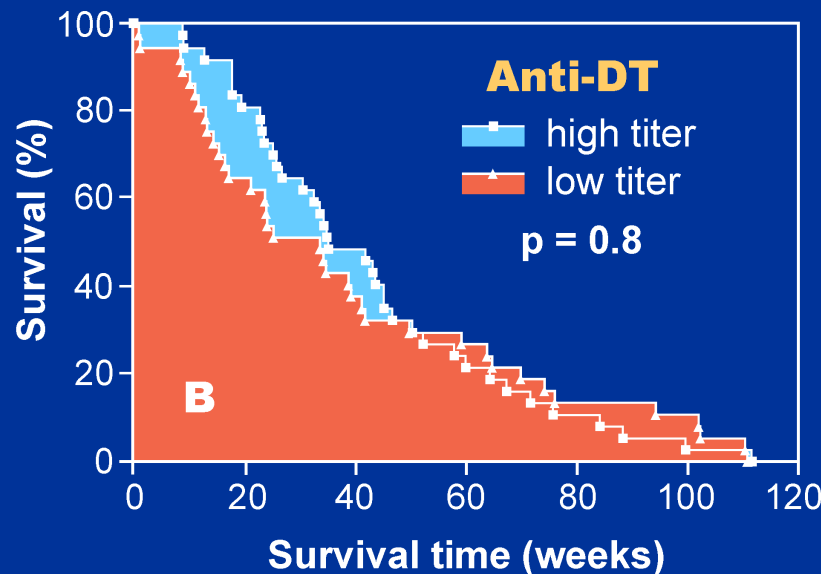
Vaccinations

- **CTP37 vaccine at 0, 4 and 10 weeks**
- **Followed for immune response,
survival**

Antibody Responses and Survival



Patients responding with above-median anti-hCG antibody titers survived significantly longer than those with titers below the median.



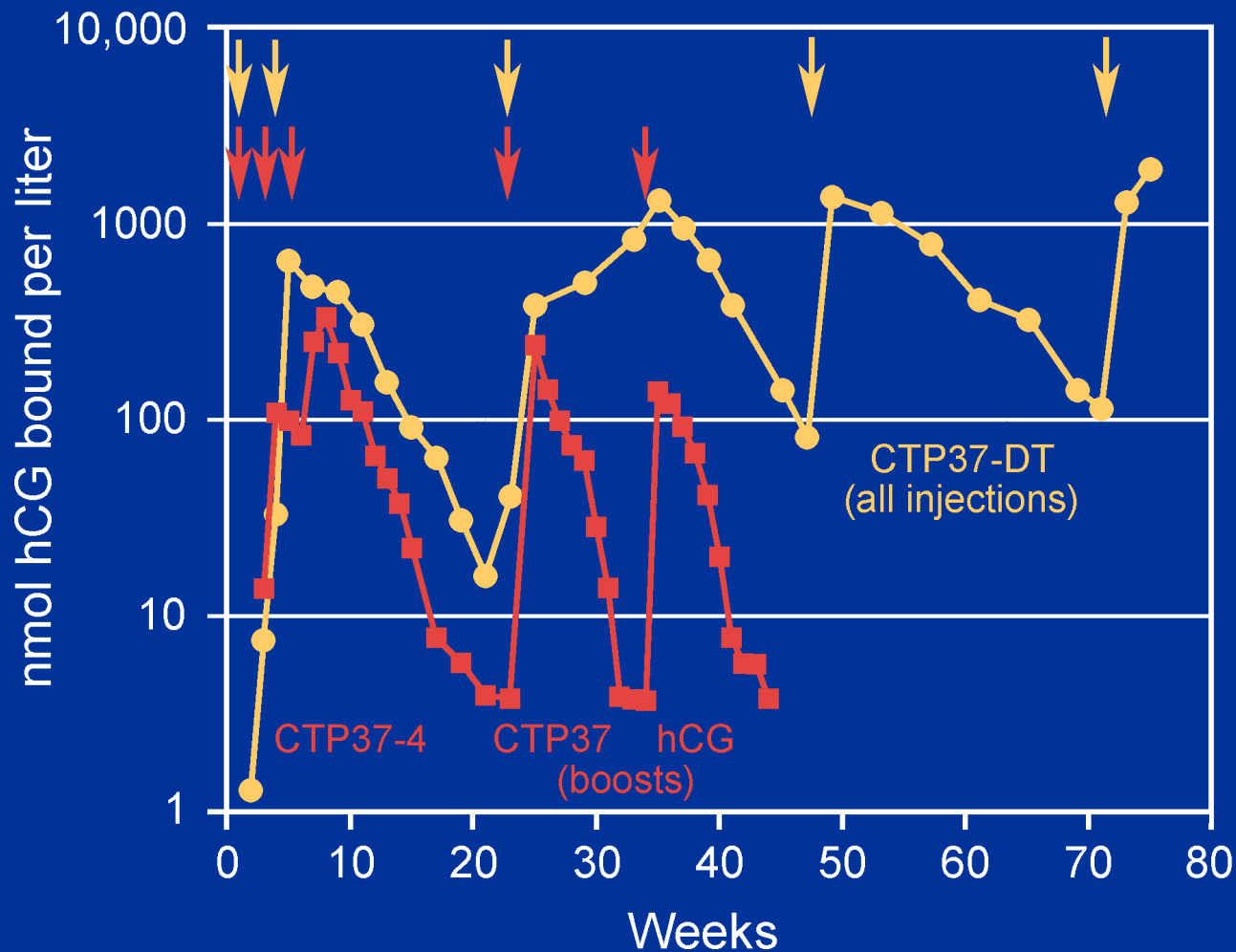
Patients responding with above-median anti-DT titers did not survive significantly longer than those with titers below the median.

Trial 7: Phase 2 Study in Pancreatic Cancer

**55 pancreatic cancer patients, two arms,
measuring immune response and one year
survival**

	1 yr. survival
5FU (Historical)	4-8%
Gemcitabine only (Historical)	16%
Arm 1 - Vaccine alone	15%
Arm 2 - Vaccine + gemcitabine	30%

Antibody Titers Increase on Repeated Boosting



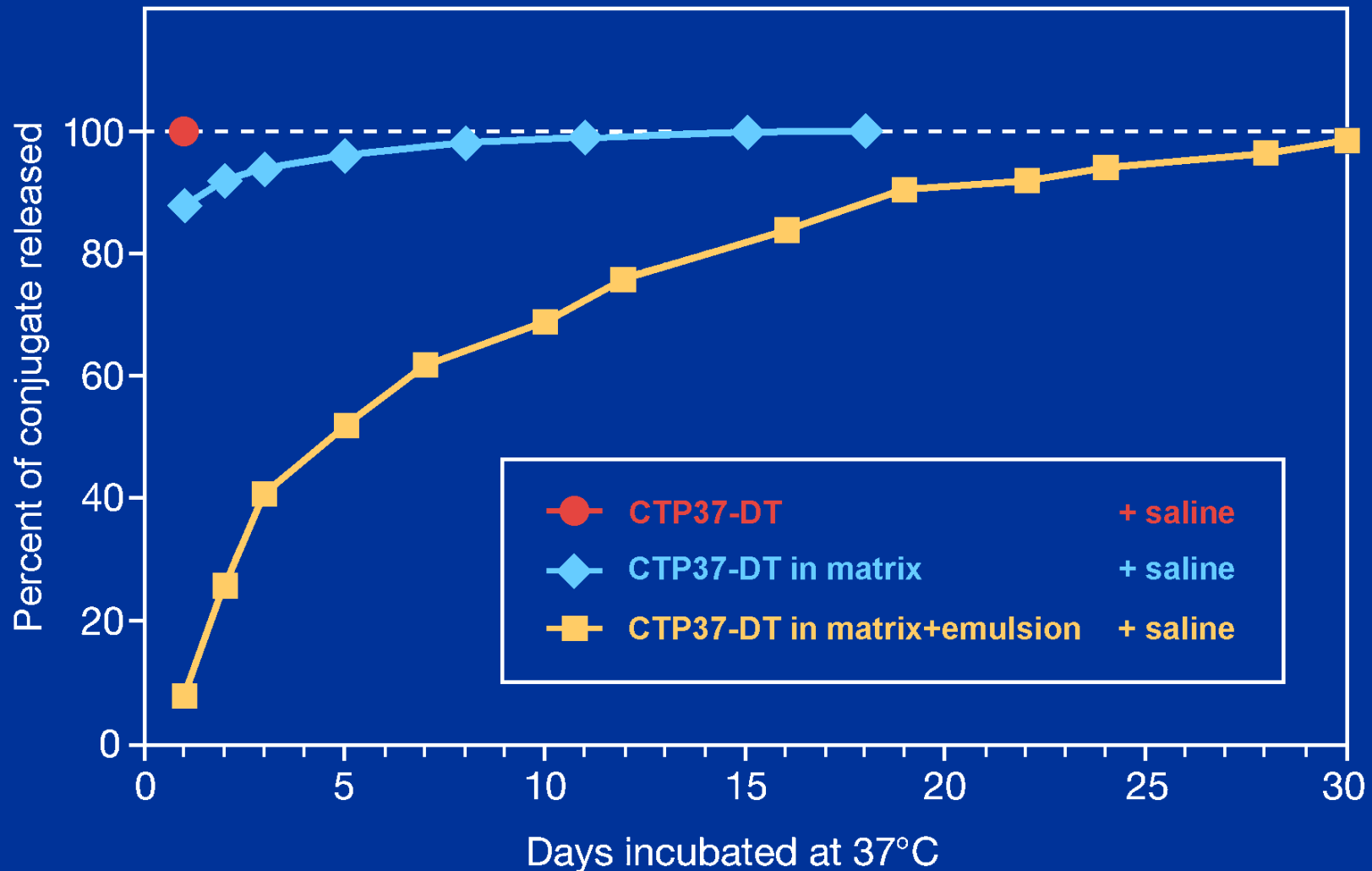
Old Formulations

- CTP37-DT
- LP20-DT
- --
- MDP
- Squalene/MMO
- Saline

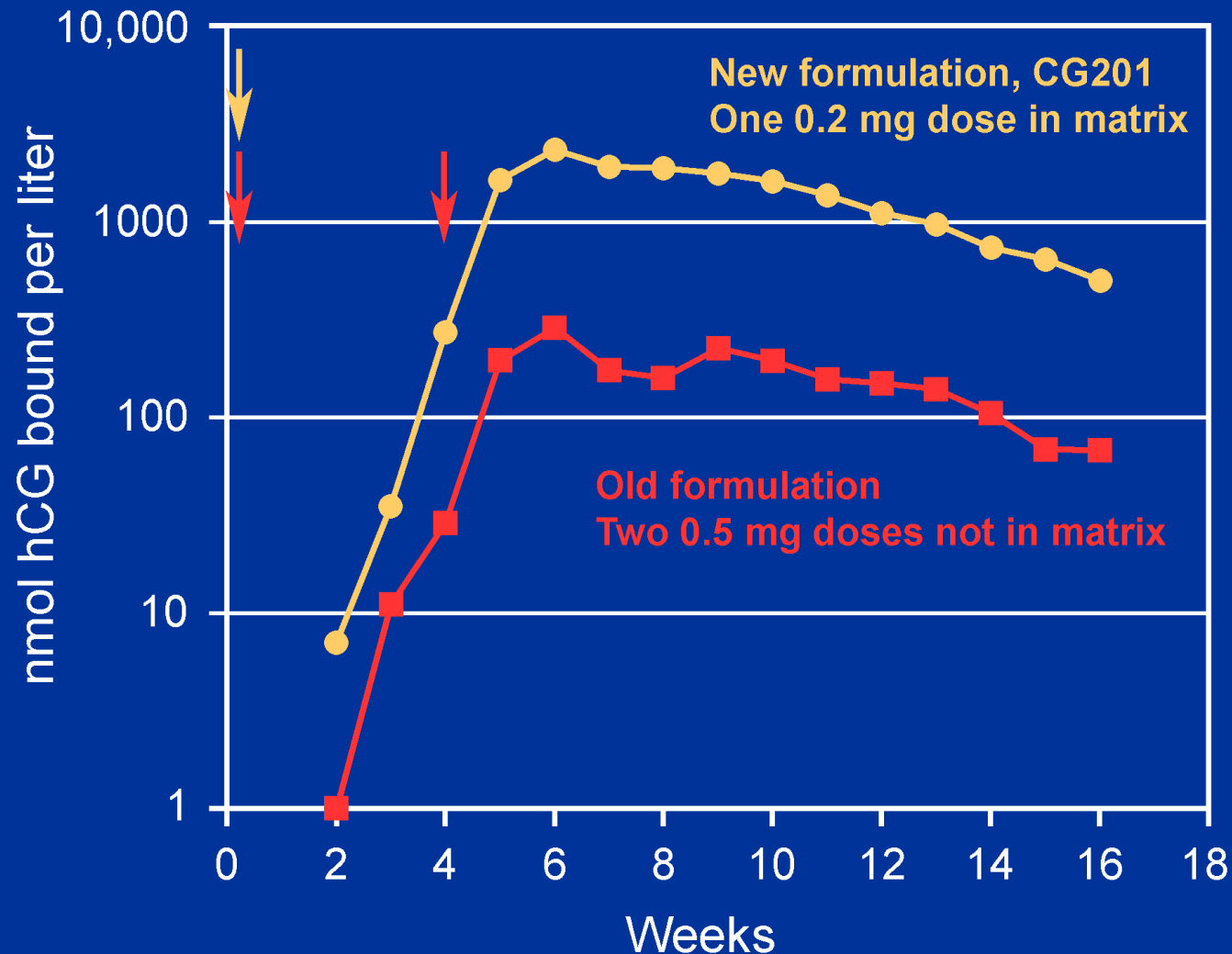
CG201

- CTP37-DT
- LP20-DT
- M_{III} matrix
- MDP
- Squalene/MMO
- Saline

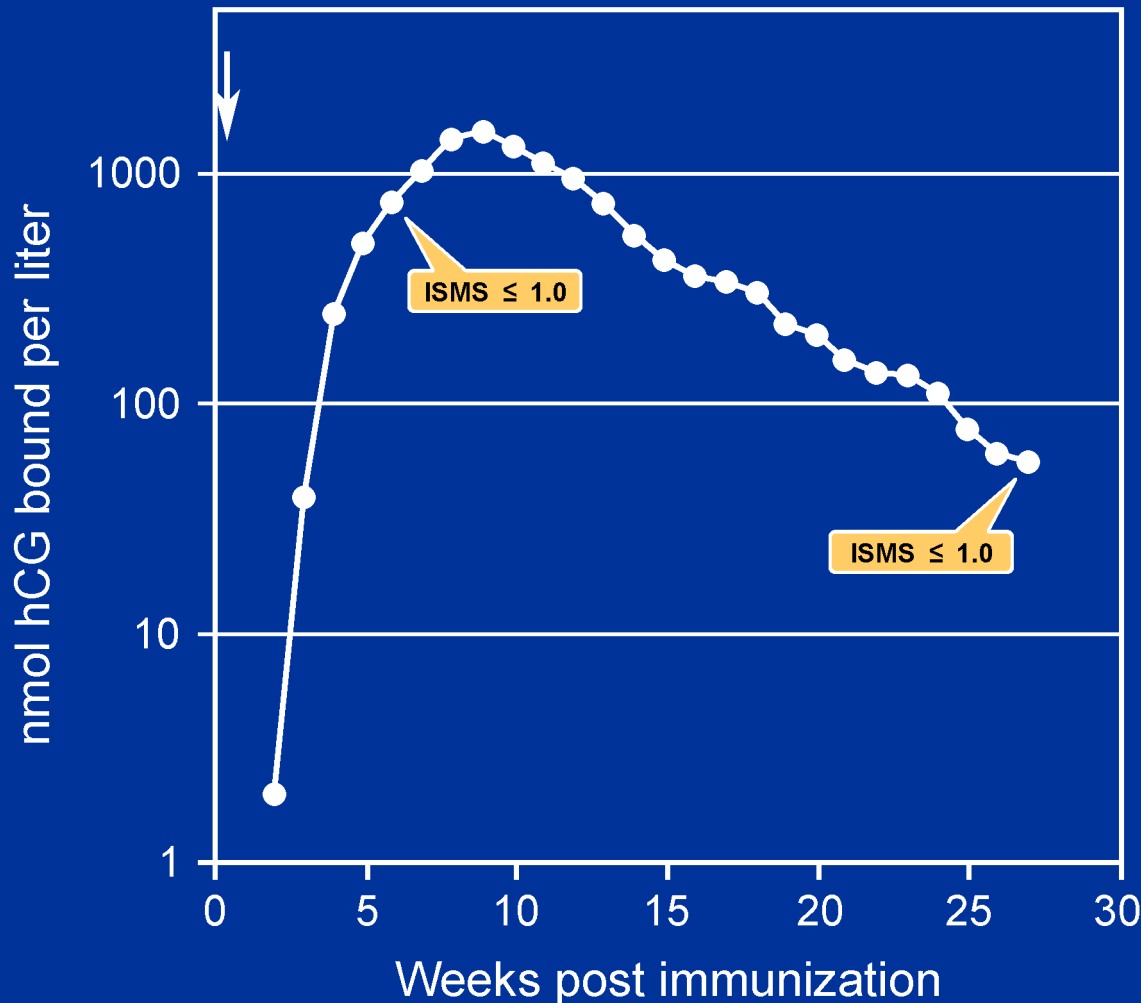
Vaccine Slow-Release Kinetics



CG201: More Potent Than Earlier Formulations



CG201 Shows Minimal Pathology at the Injection Site



Pathology
Scores:

- 0 Normal
- 1 Minimal Pathology
- 2 Moderate Pathology
- 3 Severe Pathology

Planned Phase 2 Clinical Trial

- **Colorectal cancer, third-line therapy, primary end point: survival**
- **Seeking venture funding**