

A FIRST-IN-HUMAN PROOF-OF-CONCEPT TRIAL OF INTRAVAGINAL ARTESUNATE TO TREAT CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN2/3)

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On the Horizon: A Glimpse of What's to Come for SGO 2025
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Disclosures

Consultant: Inovio Pharmaceuticals, Merck, GlaxoSmithKline, Vedantra Pharmaceuticals, Janssen

Collaborations: Adaptive Biotechnologies,

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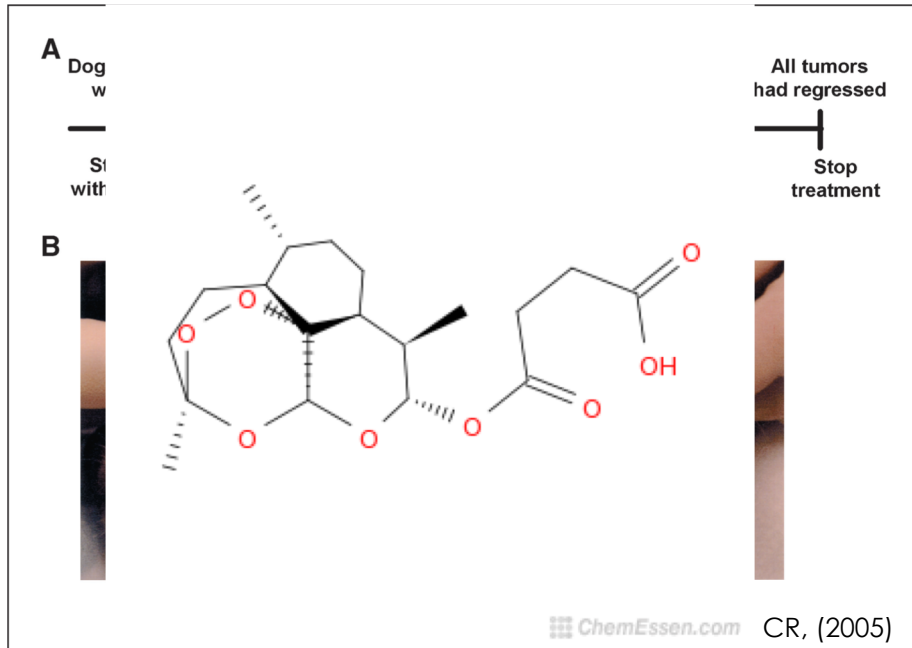
Honoraria from: Merck, Vedantra Pharmaceuticals, Janssen, GlaxoSmithKlein, Roche



ARTESUNATE

WHO-APPROVED FOR FRONT-LINE THERAPY FOR ACUTE MALARIA (PO, IM, IV, PR)

ARTESUNATE IS CYTOTOXIC TO MANY HUMAN SOLID TUMOR CELL LINES, BUT SPARES NORMAL CELLS

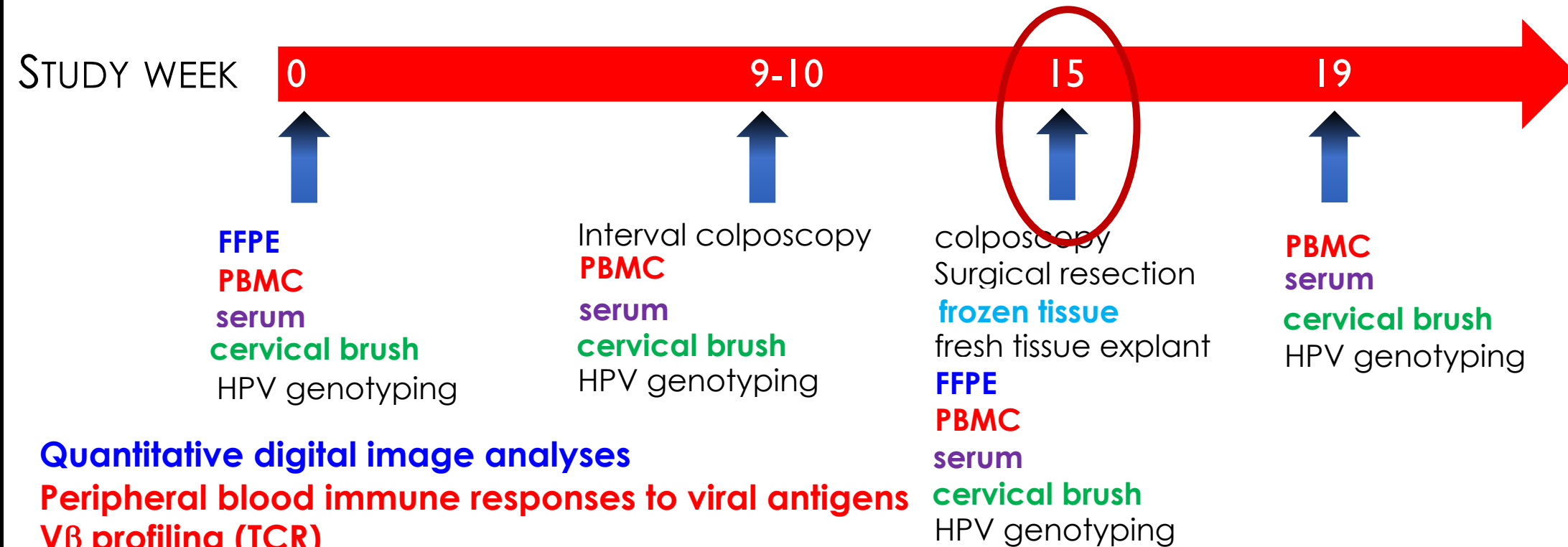


TU YOUYOU: “FOR HER DISCOVERIES CONCERNING A NOVEL THERAPY AGAINST MALARIA”



OBSERVATIONAL STUDY: A PROSPECTIVE 15-WEEK WINDOW OF OBSERVATION OF HPV16+ CIN2/3, BEFORE PLANNED STANDARD THERAPEUTIC RESECTION

20% rate of histologic regression of HPV16+ CIN2/3 in this timeframe



Quantitative digital image analyses

Peripheral blood immune responses to viral antigens

Vβ profiling (TCR)

Cell-free DNA, exosomes

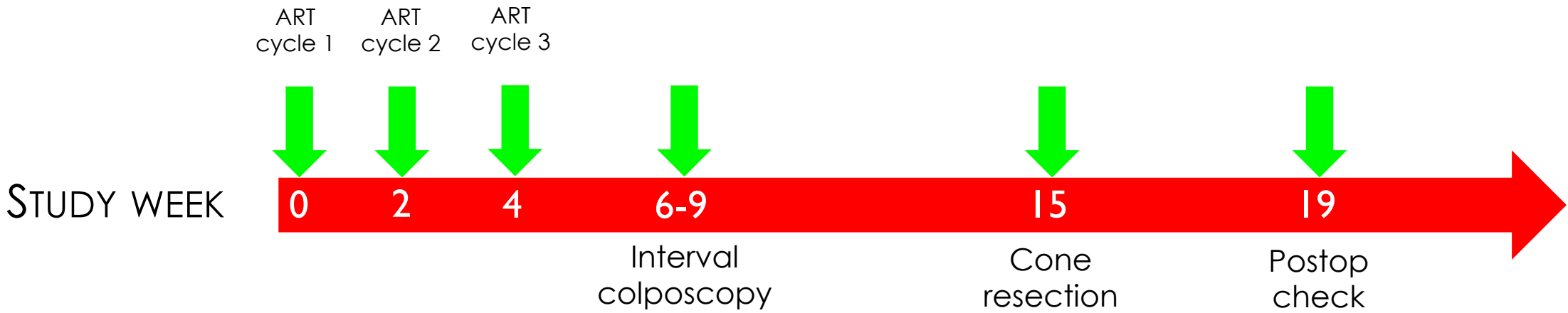
Rapid immuno-laser capture microdissection of cells of interest: transcriptomes, Vβ profiling

Microbiota, virome, fungome



FIRST-IN-(Wo)MAN CLINICAL TRIAL TESTING SAFETY, TOLERABILITY, AND EFFICACY OF SELF-ADMINISTERED ARTESUNATE VAGINAL SUPPOSITORIES TO TREAT CIN2/3*

* Each treatment cycle consists of 5 consecutive nights of dosing

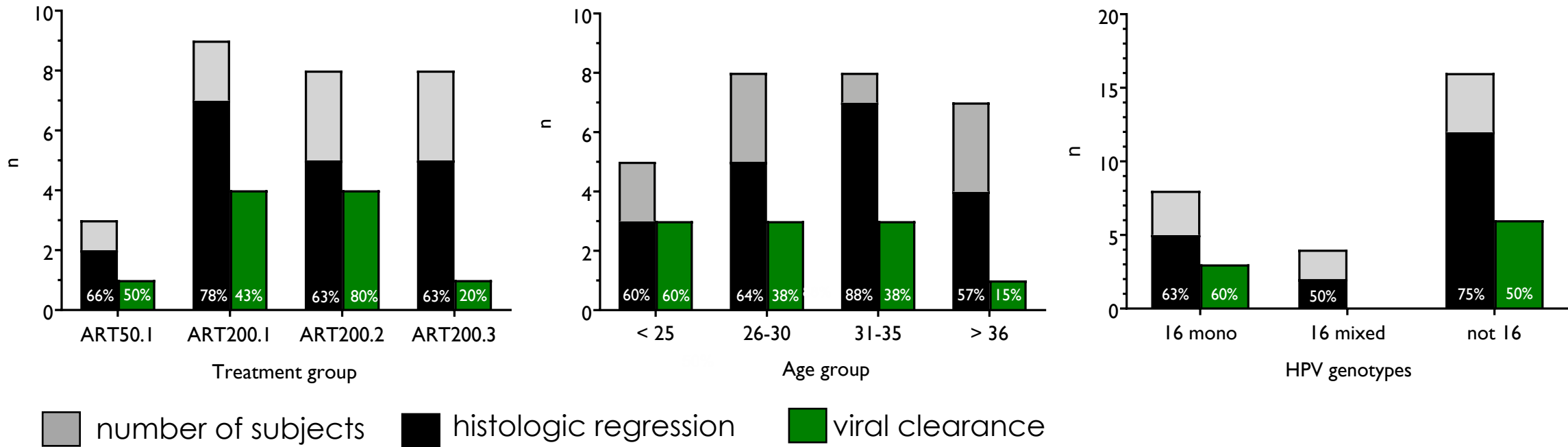


Treatment group	dose	cycles
1	50 mg	1
2	200 mg	1
3	200 mg	2
4	200 mg	3

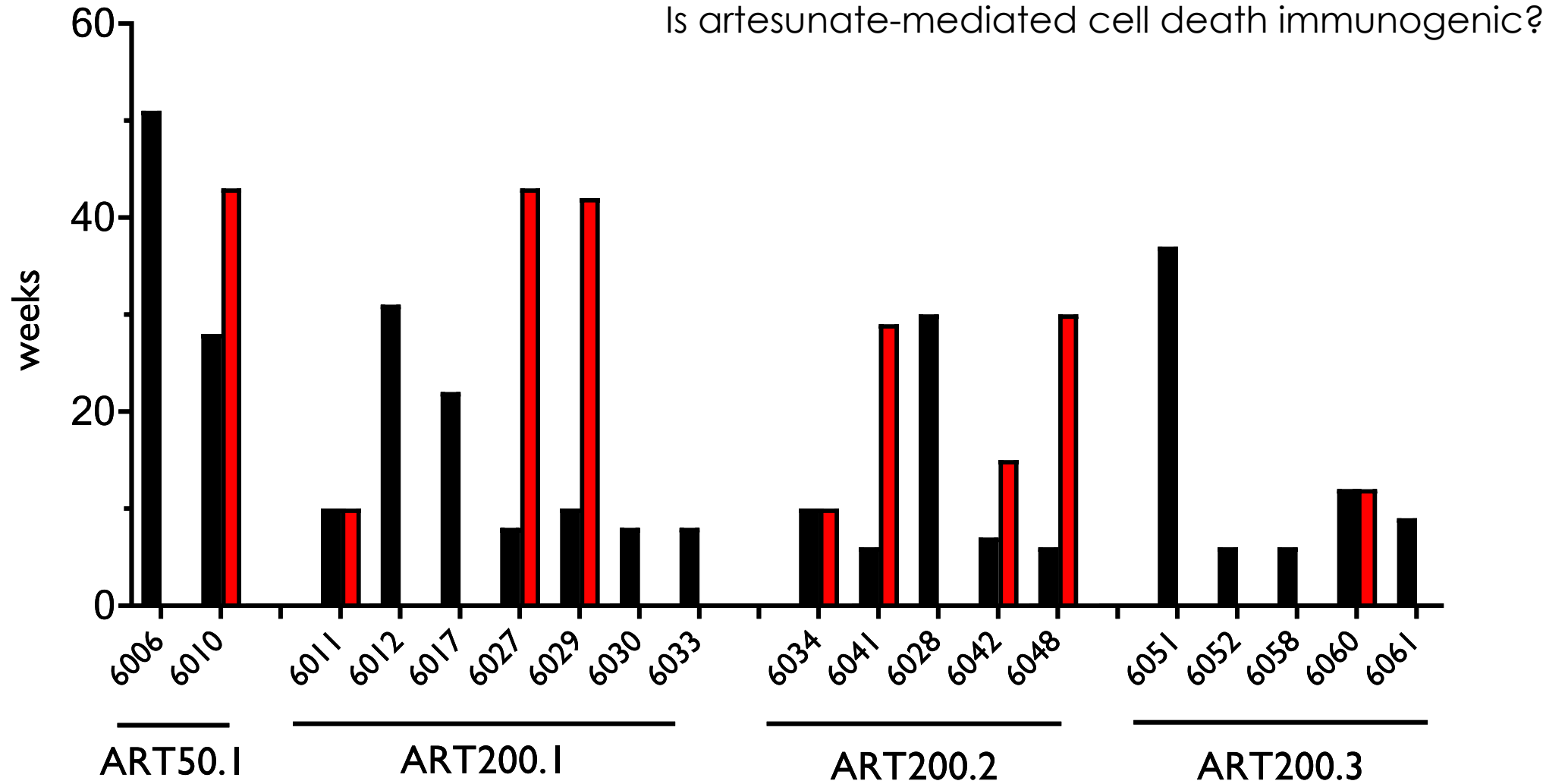
SELF-ADMINISTERED VAGINAL ARTESUNATE INSERTS CAN ELIMINATE CIN2/3 AS WELL AS HPV

Histologic regression in 19/28 (67.9 %) of subjects

Viral clearance in 9/19 (47.4 %) of histologic regressors



HISTOLOGIC REGRESSION OFTEN PRECEDES LOSS OF DETECTABLE HPV



PRE-INVASIVE, INTRAEPITHELIAL HPV LESIONS: AN OPPORTUNITY TO IDENTIFY STRATEGIES TO 'INTERCEPT' THE DEVELOPMENT OF CANCER.

WHAT'S NEXT?

Phase I: CIN (NCT_02354534) *manuscript in press*

Phase IIb: CIN (NCT_04098744)

Phase I: AIN (NCT_03100045)

Phase I: VIN (NCT_03792516)

Compassionate use: (NCT_02354534)

GOING GLOBAL:

- SAFE
- SELF-ADMINISTERED
- MINIMAL COLD CHAIN REQUIREMENTS



Pre-clinical development

Dick Schlegel lab

Hang Yuan

Xuefeng Liu

Clinical translation

Trimble group:

Mihaela Plesa

Kim Levinson

Katharine Clark

Betty Sauter

Maria Shay

Jie Fu

Stephanie Sanders

OUR PATIENTS AND THEIR FAMILIES

Drug formulation and oversight

Mark Frantz, Frantz Viral Therapeutics, LLC

Peter S. Frantz, Amarex Clinical Research, LLC

Study pathologists:

Leo Maldonado

Michael Donovan

