

Immunotherapy, Bringing It All Together: The Next Generation of Approaches & Combinations

Moderator: Axel Hoos, MD, Vice President, Oncology Research and Development, GlaxoSmithKline

Panelists:

- Neil Berinstein, MD, Affiliate Scientist, Sunnybrook Research Institute
- Paul Higham, Chief Executive Officer, Immatics
- Sara Zaknoen, MD, CMO, Polynoma, LLC
- Dennis L. Panicali, Ph.D, Vice President, Technical Operations Bavarian Nordic ImmunoTherapeutics
- Charles J. Link, Jr. MD, Chairman, Chief Executive & Scientific Officer at NewLink Genetics Corp

The logo features the words "CANCER" and "PROGRESS" in a bold, black, sans-serif font. "CANCER" is positioned above "PROGRESS". Below "PROGRESS" is the tagline "by Defined Health" in a smaller, italicized, black font. The text is overlaid on a large, light blue, abstract oval shape that is tilted diagonally.

CANCER
PROGRESS
by Defined Health



Cancer Progress

March 2013
Sara Zaknoen, MD, CMO



Polyvalent Shed Antigen Technology

Three unique proprietary human melanoma cancer cell lines* → Rapid release (shedding) of antigens from the surface of cancer cells → Purification and addition of adjuvant → POL-103A Vaccine



SF HM2



SF HM4



SF HM8

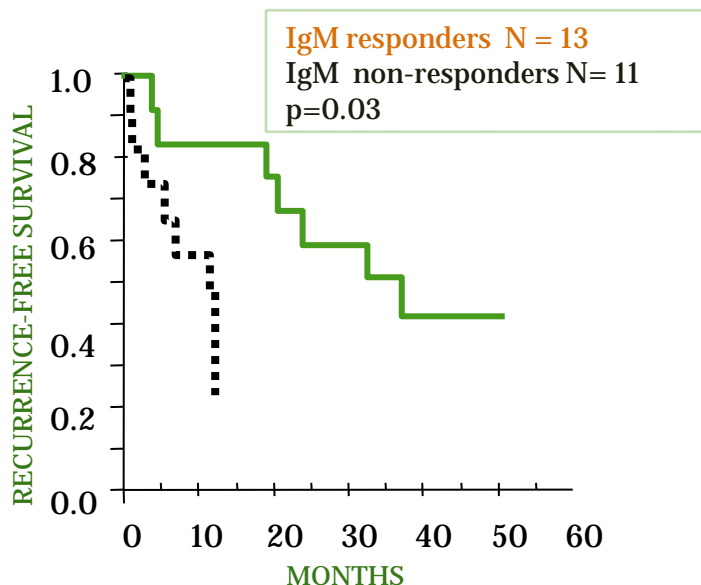


POL-103A Vaccine Overview

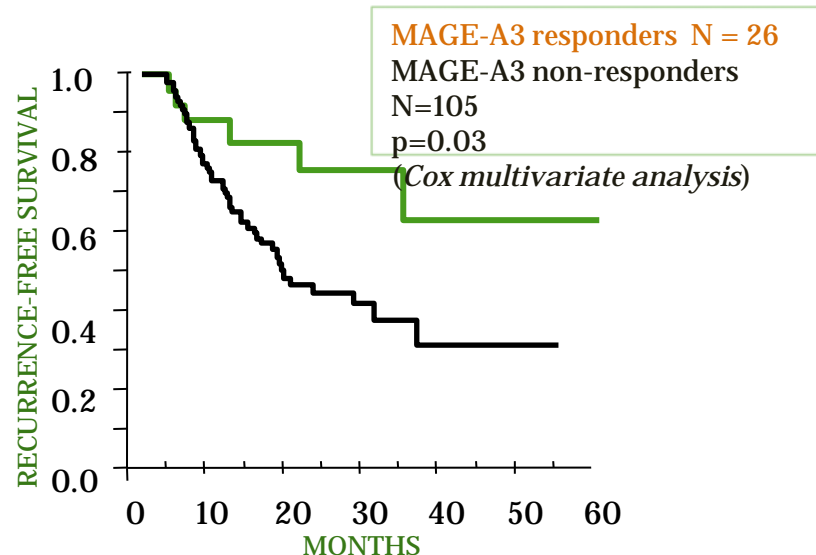
Designed for Improved Immune Response

- Stimulates both antibody and T-cell responses against melanoma antigens in 50% of patients
- Induces antibody and CD8+ T-cell responses, which correlates with improved RFS
- Induces immune infiltration of melanoma lesions in up to 80% of patients
- Clears melanoma cells and antigens from the circulation, this clearance correlates with improved RFS

Antibody Response Correlates with RFS¹



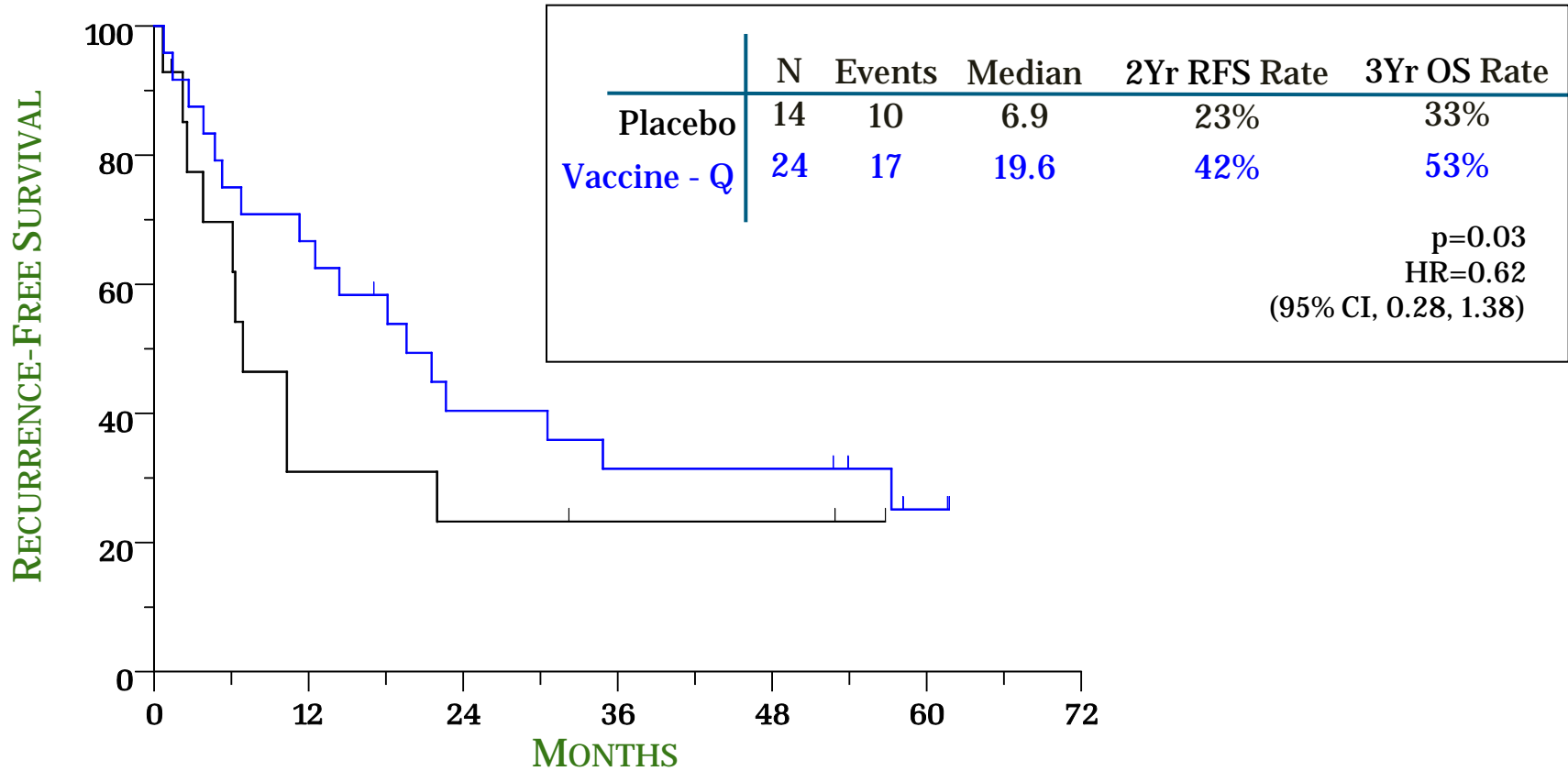
T-Cell response correlates with RFS²



1. Xie et al. ProcASCO 19:2192, 2000.

2. Reynolds et al. CCR 9:1497,2003.

POL-103A Phase II Randomized Trial (91-22)¹



- RFS Statistically Significant in Quadrivalent Vaccine Arm
- Trial Confirmed Safety with No Grade 3 or 4 Toxicities Noted



POL-103A Phase II Randomized Trial (89-38)¹



	N	Events	Median
Vaccine - T	42	24	36.5
Vaccine - Q	45	29	13.2

	N	Events	Median
Null	29	25	11.0
Vaccine - T	42	24	36.5
Vaccine - Q	45	29	13.2

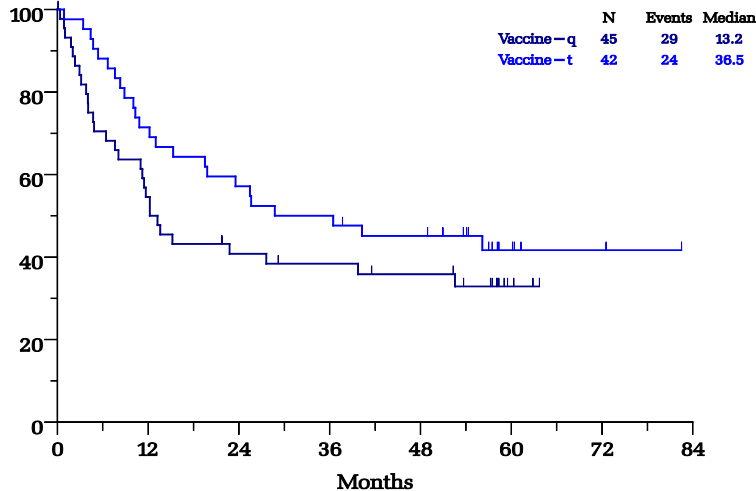
p=0.1701
HR=0.648
(95% CI, 0.398 to 1.176)

Null vs. Vaccine - T
p=0.0018
HR=0.407
(95% CI, 0.231 to 0.717)

Null vs. Vaccine - Q
p=0.095
HR=0.632
(95% CI, 0.369 to 1.083)

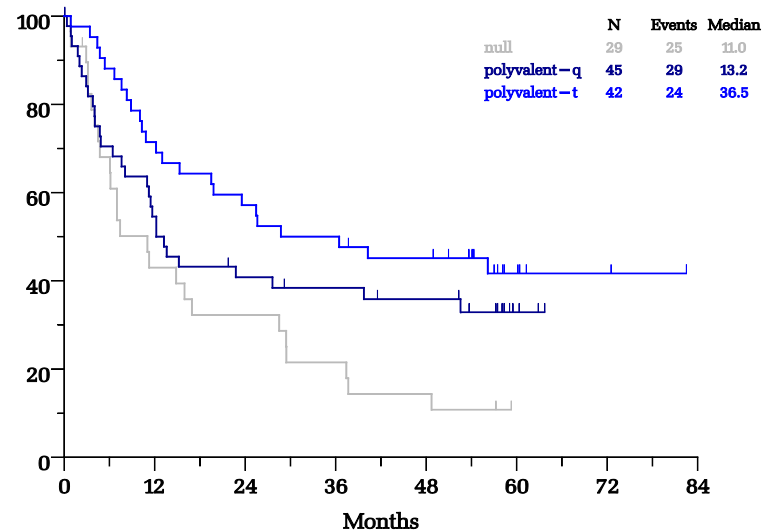
RECURRENCE-FREE SURVIVAL

89 - 38 Recurrence-Free Survival
HR = 0.648 (0.398 to 1.176), P = 0.1701



RECURRENCE-FREE SURVIVAL

89 - 38 Recurrence-Free Survival



- Immune Response Similar Between Tri and Quad Vaccine Arms
- RFS Significantly Better in Trivalent Vaccine Arm vs. Null Vaccine

POL-103A Phase III Clinical Trial

Melanoma Antigen Vaccine Immunotherapy Study (MAVIS)



Lead-in Phase

Part A N=99

- **Purpose:** To confirm safety and bioactivity/immune response of vaccine and select dosing
- **Protocol:** Three arms of 33 patients each including placebo (40µg, 100µg, placebo)
- **Endpoint Assessment:** Immune response at week 10

Pivotal Phase

Part B N=960

- **Purpose:** To demonstrate vaccine efficacy
- **Primary Endpoints:** RFS at 362 events or OS at 472 events
- **Hazard Ratio:** 0.755 (37.5% improvement vs. control arm)
- **Power:** 87% with type I error at 0.01
- **Randomized:** 2:1
- **Logistics:** Approximately 150 sites in 14 countries



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